

## Disclaimer

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

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

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

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

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**Overview**

**Request Description**

FDA requested use of Modular Program #3 (MP3) to investigate gastrointestinal hemorrhage (GIH) or intracerebral hemorrhage (ICH) events following new use of dabigatran or warfarin among all patients as well as those with a pre-existing condition of atrial fibrillation. This is a re-run of MSY3\_MPR41. This required one run of MP3. The time window for the request was October 19, 2010 to June 30, 2013. The package was distributed to 15 Data Partners on June 26, 2014. Please see the Specifications tab for more details on each scenario.

This report contains results for patients with a pre-existing condition of atrial fibrillation only. A second report (to09y05\_mpr\_wp37\_v01 - report 2 of 2) contains results for all patients.

**Request ID**

to09y05\_mpr\_wp37\_v01 - report 1 of 2

**Specifications**

Program parameter inputs and scenarios

**Glossary**

List of Terms found in this Report and their Definitions

**Table 1**

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, and Outcome.

**Table 2**

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group.

**Table 3**

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, Outcome, and Sex.

**Table 4**

Table displaying the Number of New Users, New Episodes, Dispensings, Total Days Supplied, Amount Supplied, New Episodes with Events, Years at Risk, Days Supplied per User, Dispensings per User, Days Supplied per Dispensing, and New Episodes with Events per 10,000 Years at Risk by Drug, Incidence Criteria, Washout Period, Outcome, and Year.

**Appendix A**

List of event diagnosis codes

**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 for to09y05\_mpr\_wp37\_v01**

Modular Program 3, version 7.2, was used to investigate gastrointestinal hemorrhage (GIH) or intracerebral hemorrhage (ICH) events (see Appendix B) following new use of dabigatran or warfarin among all patients and among patients with a pre-existing condition of atrial fibrillation (ICD-9-CM 427.31). In total, 48 scenarios were examined in this report with differing exposures of interest, incidence criteria, pre-existing condition criteria, and event/outcome. See below for a description of each of these scenarios. **This report contains results for patients with a pre-existing condition of atrial fibrillation (scenarios 1-24) only.** A second report contains results for all patients (scenarios 25-48).

Enrollment Gap 45 days  
 Age Groups 00-40, 41-54, 55-64, 65-74, 75-84, 85+  
 Query Period October 19, 2010 - June 30, 2013  
 Coverage Requirement Medical and Drug Coverage  
 Enrollment Requirement 183-Days

Scenario	Drug/Exposure		Pre-Existing Condition										Event/Outcome							
	Incident exposure	Incident w/ respect to:	Washout (days)	Cohort Definition	Episode Gap	Exposure Extension Period	Min Duration	Min Days Supplied	Episode Truncation by Incident Exposure	Pre-Existing Condition	Include or Exclude	Lookback Start	Lookback End	Care Setting/PDX	Event/Outcome	Care Setting/PDX	Incident w/ respect to:	Washout (days)	Event De-duplication	Blackout Period
1	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
2	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
3	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
4	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
5	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
6	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
7	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
8	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
9	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
10	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
11	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
12	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
13	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
14	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
15	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
16	Warfarin	Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
17	Warfarin	Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
18	Warfarin	Warfarin	183	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
19	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
20	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
21	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
22	Warfarin	Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH	ED*, IP*	ICH	183	0	0
23	Warfarin	Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	GIH	ED*, IP*	GIH	183	0	0
24	Warfarin	Warfarin	365	01	10	10	1	1	Yes	Atrial fibrillation	Include	-183	-1	Any	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
25	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
26	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
27	Dabigatran	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
28	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
29	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
30	Warfarin	Dabigatran, Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
31	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
32	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
33	Dabigatran	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
34	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0

35	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
36	Warfarin	Dabigatran, Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
37	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
38	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
39	Dabigatran	Dabigatran	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
40	Warfarin	Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
41	Warfarin	Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
42	Warfarin	Warfarin	183	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
43	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
44	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
45	Dabigatran	Dabigatran	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	0
46	Warfarin	Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH	ED*, IP*	ICH	183	0	0
47	Warfarin	Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	GIH	ED*, IP*	GIH	183	0	0
48	Warfarin	Warfarin	365	01	10	10	1	1	Yes	N/A	N/A	N/A	N/A	N/A	ICH or GIH	ED*, IP*	ICH or GIH	183	0	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

### Glossary of Terms in Modular Program 3\*

- Amount Supplied** - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing. This is equivalent to the "RxAmt" value in the
- 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). Along with the Principal Diagnosis Indicator, forms the Caresetting/PDX parameter.
- Principal Diagnosis (PDX)** - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.
- Cohort Definition (drug/exposure)**- Indicates how the cohort will be defined: (1) 01: Cohort includes only the first valid incident treatment episode during the query period; (2) 02: Cohort includes all valid incident treatment episodes during the query period; (3) 03: Cohort includes all valid incident treatment episodes during the query period until an event occurs
- Days Supplied** - number of days supplied for all dispensings in qualifying treatment episodes.
- Years at Risk** - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.23.
- 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
- Event De-duplication** - specifies how events are counted by the MP algorithm. '0' counts all occurrences of an event group code of interest. '1' de-duplicates occurrences of the same event code on the same day (i.e., de-duplicates at the exact match code level), '2' de-duplicates occurrences of the same event group code on the same day (e.g., de-duplicates at the GROUP level).
- Exposure Extension Period** - number of days post treatment period in which the outcomes/events are counted for a treatment 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-Years** - sum of all days of enrollment with medical and drug coverage\*\* in the query period preceded by an exposure washout period all divided by 365.23
- 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 consecutive dispensings bridged by the
- 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.
- Query Period** - period in which the modular program looks for exposures and outcomes of interest.
- Treatment Episode Truncation Indicator** - indicates whether observation of the incident query code during follow-up requires truncation of valid treatment episodes. A value of Y indicates that the treatment episodes should be truncated at the first occurrence of an incident query code. A value of N indicates that the treatment episodes should not be truncated at the occurrence of the incident query code.
- 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 1. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, and Outcome**

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Days Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Dabigatran (Incident with respect to Dabigatran)</b>														
<i>GIH</i>														
183-Day Washout Period	56,134	56,134	276,670	10,326,682	20,610,963	30,088.1	84	1,158,945	1,138,634.1	48.44	183.96	4.93	37.32	0.76
365 Day Washout Period	51,220	51,220	255,486	9,577,741	19,117,220	27,884.0	79	1,078,118	1,058,075.8	47.51	186.99	4.99	37.49	0.78
<i>ICH</i>														
183-Day Washout Period	56,038	56,038	275,841	10,296,779	20,550,979	30,000.7	86	1,158,222	1,138,100.1	48.38	183.75	4.92	37.33	0.78
365 Day Washout Period	51,135	51,135	254,731	9,550,043	19,061,646	27,805.0	78	1,077,440	1,057,570.6	47.46	186.76	4.98	37.49	0.77
<i>GIH or ICH</i>														
183-Day Washout Period	55,959	55,959	275,473	10,285,043	20,527,875	29,955.2	168	1,156,632	1,135,231.5	48.38	183.80	4.92	37.34	1.54
365 Day Washout Period	51,055	51,055	254,357	9,538,124	19,038,176	27,759.8	155	1,075,930	1,054,900.9	47.45	186.82	4.98	37.50	1.53
<b>Dabigatran (Incident with respect to Dabigatran and Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period	32,801	32,801	140,095	5,007,787	9,995,663	14,696.2	40	858,585	590,359.6	38.20	152.67	4.27	35.75	0.75
365 Day Washout Period	27,948	27,948	121,140	4,345,573	8,675,445	12,738.0	36	754,492	515,284.5	37.04	155.49	4.33	35.87	0.77
<i>ICH</i>														
183-Day Washout Period	32,750	32,750	139,676	4,992,854	9,965,410	14,652.3	43	857,833	590,192.3	38.18	152.45	4.26	35.75	0.80
365 Day Washout Period	27,900	27,900	120,766	4,331,979	8,647,870	12,699.9	35	753,841	515,169.0	37.01	155.27	4.33	35.87	0.75
<i>GIH or ICH</i>														
183-Day Washout Period	32,715	32,715	139,536	4,988,278	9,956,468	14,634.2	82	856,239	588,400.6	38.21	152.48	4.27	35.75	1.53
365 Day Washout Period	27,870	27,870	120,640	4,327,883	8,639,888	12,683.5	70	752,374	513,574.4	37.04	155.29	4.33	35.87	1.51
<b>Warfarin (Incident with respect to Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period	126,769	126,769	487,979	19,514,104	25,660,055	56,526.6	357	879,609	630,882.2	144.12	153.93	3.85	39.99	1.73
365 Day Washout Period	100,721	100,721	404,817	15,794,698	20,815,081	45,685.5	304	776,219	555,516.2	129.76	156.82	4.02	39.02	1.82
<i>ICH</i>														
183-Day Washout Period	126,421	126,421	485,628	19,433,852	25,556,857	56,319.9	522	878,883	630,734.4	143.84	153.72	3.84	40.02	2.54
365 Day Washout Period	100,409	100,409	402,820	15,727,996	20,729,848	45,524.8	419	775,594	555,403.1	129.46	156.64	4.01	39.04	2.52
<i>GIH or ICH</i>														
183-Day Washout Period	126,028	126,028	483,742	19,373,003	25,482,914	56,045.7	861	877,289	628,918.1	143.66	153.72	3.84	40.05	4.21
365 Day Washout Period	100,077	100,077	401,141	15,673,864	20,663,594	45,280.2	710	774,128	553,765.4	129.28	156.62	4.01	39.07	4.29

**Table 1. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, and Outcome**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Warfarin (Incident with respect to Dabigatran and Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period	121,585	121,585	465,286	18,582,954	24,510,956	53,783.9	347	858,585	583,696.5	141.61	152.84	3.83	39.94	1.77
365 Day Washout Period	96,250	96,250	385,366	15,008,845	19,839,722	43,372.4	295	754,492	512,940.1	127.57	155.94	4.00	38.95	1.86
<i>ICH</i>														
183-Day Washout Period	121,238	121,238	462,968	18,505,418	24,411,987	53,588.7	500	857,833	583,552.6	141.33	152.64	3.82	39.97	2.55
365 Day Washout Period	95,941	95,941	383,376	14,943,817	19,756,669	43,218.5	404	753,841	512,833.3	127.27	155.76	4.00	38.98	2.56
<i>GIH or ICH</i>														
183-Day Washout Period	120,868	120,868	461,233	18,448,566	24,341,847	53,329.3	829	856,239	581,789.7	141.16	152.63	3.82	40.00	4.26
365 Day Washout Period	95,625	95,625	381,825	14,892,796	19,693,558	42,986.0	686	752,374	511,245.6	127.10	155.74	3.99	39.00	4.37

**Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Dabigatran (Incident with respect to Dabigatran)</b>														
<i>GIH</i>														
183-Day Washout Period														
00 to 40 Years	782	782	2,117	66,783	133,568	207.3	0	35,462	18,592.6	22.05	85.40	2.71	31.55	0.00
41 to 54 Years	5,916	5,916	24,271	800,612	1,600,827	2,392.0	3	117,593	78,375.1	50.31	135.33	4.10	32.99	0.34
55 to 64 Years	14,503	14,503	73,811	2,608,553	5,213,614	7,614.4	18	228,921	178,222.9	63.35	179.86	5.09	35.34	0.65
65 to 74 Years	15,958	15,958	80,494	3,138,767	6,267,626	9,101.8	16	318,983	291,136.3	50.03	196.69	5.04	38.99	0.48
75 to 84 Years	14,162	14,162	71,929	2,826,034	5,636,570	8,195.7	33	354,261	360,976.6	39.98	199.55	5.08	39.29	1.10
85+ Years	4,813	4,813	24,048	885,933	1,758,757	2,576.8	14	216,527	211,330.5	22.23	184.07	5.00	36.84	1.49
365 Day Washout Period														
00 to 40 Years	656	656	1,747	55,675	111,352	173.1	0	29,891	15,769.3	21.95	84.87	2.66	31.87	0.00
41 to 54 Years	5,181	5,181	21,777	719,970	1,439,876	2,148.1	2	103,799	69,592.0	49.91	138.96	4.20	33.06	0.25
55 to 64 Years	13,042	13,042	67,093	2,376,464	4,750,392	6,933.3	17	207,458	161,733.7	62.87	182.22	5.14	35.42	0.67
65 to 74 Years	14,422	14,422	73,852	2,893,364	5,778,127	8,382.6	15	295,020	266,721.0	48.88	200.62	5.12	39.18	0.49
75 to 84 Years	13,352	13,352	68,161	2,687,277	5,359,725	7,789.3	32	338,482	341,900.3	39.45	201.26	5.10	39.43	1.12
85+ Years	4,567	4,567	22,856	844,991	1,677,748	2,457.7	13	208,890	202,359.5	21.86	185.02	5.00	36.97	1.45
<i>ICH</i>														
183-Day Washout Period														
00 to 40 Years	782	782	2,117	66,783	133,568	207.3	0	35,447	18,597.6	22.06	85.40	2.71	31.55	0.00
41 to 54 Years	5,912	5,912	24,177	797,573	1,594,619	2,383.6	2	117,563	78,372.0	50.29	134.91	4.09	32.99	0.23
55 to 64 Years	14,482	14,482	73,660	2,602,891	5,202,188	7,596.9	18	228,823	178,188.9	63.29	179.73	5.09	35.34	0.65
65 to 74 Years	15,926	15,926	80,193	3,126,926	6,244,077	9,066.9	22	318,768	291,009.4	49.96	196.34	5.04	38.99	0.66
75 to 84 Years	14,129	14,129	71,653	2,818,002	5,620,575	8,171.7	34	353,976	360,667.3	39.92	199.45	5.07	39.33	1.14
85+ Years	4,807	4,807	24,041	884,604	1,755,951	2,574.2	10	216,428	211,264.8	22.21	184.02	5.00	36.80	1.06
365 Day Washout Period														
00 to 40 Years	656	656	1,747	55,675	111,352	173.1	0	29,879	15,776.7	21.96	84.87	2.66	31.87	0.00
41 to 54 Years	5,177	5,177	21,683	716,931	1,433,668	2,139.7	1	103,768	69,587.5	49.89	138.48	4.19	33.06	0.13
55 to 64 Years	13,024	13,024	66,963	2,371,507	4,740,376	6,920.0	16	207,357	161,701.4	62.81	182.09	5.14	35.42	0.63
65 to 74 Years	14,395	14,395	73,607	2,883,132	5,757,796	8,352.4	20	294,836	266,603.3	48.82	200.29	5.11	39.17	0.66
75 to 84 Years	13,320	13,320	67,890	2,679,376	5,343,992	7,765.9	32	338,193	341,606.7	39.39	201.15	5.10	39.47	1.13
85+ Years	4,563	4,563	22,841	843,422	1,674,462	2,453.8	9	208,802	202,295.0	21.85	184.84	5.01	36.93	1.00



**Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>GIH or ICH</b>														
183-Day Washout Period														
00 to 40 Years	782	782	2,117	66,783	133,568	207.3	0	35,422	18,556.7	22.08	85.40	2.71	31.55	0.00
41 to 54 Years	5,905	5,905	24,165	797,173	1,593,829	2,382.1	5	117,426	78,224.4	50.29	135.00	4.09	32.99	0.57
55 to 64 Years	14,465	14,465	73,582	2,600,491	5,197,568	7,586.8	34	228,560	177,801.8	63.29	179.78	5.09	35.34	1.23
65 to 74 Years	15,911	15,911	80,144	3,125,471	6,241,197	9,060.9	38	318,369	290,334.9	49.98	196.43	5.04	39.00	1.15
75 to 84 Years	14,107	14,107	71,544	2,814,000	5,612,571	8,156.1	67	353,470	359,732.2	39.91	199.48	5.07	39.33	2.25
85+ Years	4,789	4,789	23,921	881,125	1,749,141	2,562.0	24	216,012	210,581.4	22.17	183.99	4.99	36.83	2.56
365 Day Washout Period														
00 to 40 Years	656	656	1,747	55,675	111,352	173.1	0	29,860	15,740.2	21.97	84.87	2.66	31.87	0.00
41 to 54 Years	5,170	5,170	21,671	716,531	1,432,878	2,138.2	3	103,645	69,459.7	49.88	138.59	4.19	33.06	0.38
55 to 64 Years	13,007	13,007	66,885	2,369,107	4,735,756	6,910.0	31	207,122	161,351.3	62.80	182.14	5.14	35.42	1.23
65 to 74 Years	14,380	14,380	73,558	2,881,677	5,754,916	8,346.4	35	294,450	265,982.2	48.84	200.39	5.12	39.18	1.15
75 to 84 Years	13,298	13,298	67,781	2,675,371	5,335,982	7,750.3	64	337,709	340,725.1	39.38	201.19	5.10	39.47	2.26
85+ Years	4,544	4,544	22,715	839,763	1,667,292	2,441.8	22	208,392	201,642.4	21.81	184.81	5.00	36.97	2.47
<b>Dabigatran (Incident with respect to Dabigatran and Warfarin)</b>														
<b>GIH</b>														
183-Day Washout Period														
00 to 40 Years	627	627	1,454	44,128	88,230	139.6	0	32,182	15,511.3	19.48	70.38	2.32	30.35	0.00
41 to 54 Years	4,163	4,163	14,271	455,172	910,451	1,377.6	1	96,958	53,611.4	42.94	109.34	3.43	31.89	0.20
55 to 64 Years	8,998	8,998	38,760	1,327,515	2,652,878	3,907.0	9	172,893	102,297.2	52.04	147.53	4.31	34.25	0.63
65 to 74 Years	9,183	9,183	40,466	1,497,669	2,992,474	4,371.0	11	221,883	140,732.4	41.39	163.09	4.41	37.01	0.69
75 to 84 Years	7,404	7,404	34,084	1,289,298	2,569,530	3,751.1	15	236,755	161,405.5	31.27	174.14	4.60	37.83	1.09
85+ Years	2,426	2,426	11,060	394,005	782,099	1,149.9	4	158,522	116,801.8	15.30	162.41	4.56	35.62	0.95
365 Day Washout Period														
00 to 40 Years	502	502	1,120	34,072	68,083	108.3	0	26,565	12,836.2	18.90	67.87	2.23	30.42	0.00
41 to 54 Years	3,459	3,459	12,158	387,863	775,811	1,171.3	0	82,179	45,210.3	42.09	112.13	3.51	31.90	0.00
55 to 64 Years	7,504	7,504	32,595	1,117,749	2,233,665	3,287.5	7	148,198	86,787.3	50.63	148.95	4.34	34.29	0.58
65 to 74 Years	7,755	7,755	34,872	1,294,091	2,586,819	3,772.2	10	192,512	120,592.5	40.28	166.87	4.50	37.11	0.73
75 to 84 Years	6,559	6,559	30,507	1,156,635	2,305,560	3,363.1	15	212,123	143,413.7	30.92	176.34	4.65	37.91	1.22
85+ Years	2,169	2,169	9,888	355,163	705,507	1,035.6	4	145,292	106,444.6	14.93	163.75	4.56	35.92	1.06

**Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>ICH</b>														
183-Day Washout Period														
00 to 40 Years	627	627	1,454	44,128	88,230	139.6	0	32,166	15,513.5	19.49	70.38	2.32	30.35	0.00
41 to 54 Years	4,163	4,163	14,238	453,987	907,961	1,374.4	1	96,926	53,616.2	42.95	109.05	3.42	31.89	0.20
55 to 64 Years	8,987	8,987	38,682	1,324,340	2,646,291	3,896.0	10	172,778	102,295.9	52.01	147.36	4.30	34.24	0.70
65 to 74 Years	9,162	9,162	40,308	1,491,516	2,980,138	4,354.3	9	221,668	140,685.2	41.33	162.79	4.40	37.00	0.57
75 to 84 Years	7,391	7,391	33,965	1,286,459	2,563,852	3,742.9	18	236,460	161,280.5	31.26	174.06	4.60	37.88	1.32
85+ Years	2,420	2,420	11,029	392,424	778,937	1,145.1	5	158,437	116,801.1	15.27	162.16	4.56	35.58	1.20
365 Day Washout Period														
00 to 40 Years	502	502	1,120	34,072	68,083	108.3	0	26,556	12,840.3	18.90	67.87	2.23	30.42	0.00
41 to 54 Years	3,458	3,458	12,121	386,558	773,081	1,167.8	0	82,161	45,214.0	42.09	111.79	3.51	31.89	0.00
55 to 64 Years	7,493	7,493	32,512	1,114,523	2,226,976	3,278.1	9	148,078	86,786.0	50.60	148.74	4.34	34.28	0.75
65 to 74 Years	7,737	7,737	34,754	1,289,113	2,576,833	3,758.8	6	192,337	120,559.4	40.23	166.62	4.49	37.09	0.44
75 to 84 Years	6,546	6,546	30,416	1,154,551	2,301,392	3,357.2	15	211,843	143,314.0	30.90	176.38	4.65	37.96	1.22
85+ Years	2,164	2,164	9,843	353,162	701,505	1,029.7	5	145,233	106,455.3	14.90	163.20	4.55	35.88	1.33
<b>GIH or ICH</b>														
183-Day Washout Period														
00 to 40 Years	627	627	1,454	44,128	88,230	139.6	0	32,142	15,485.8	19.51	70.38	2.32	30.35	0.00
41 to 54 Years	4,158	4,158	14,228	453,712	907,411	1,373.5	2	96,790	53,515.6	42.96	109.12	3.42	31.89	0.40
55 to 64 Years	8,977	8,977	38,625	1,322,690	2,643,171	3,889.7	18	172,516	102,049.0	52.04	147.34	4.30	34.24	1.27
65 to 74 Years	9,158	9,158	40,291	1,491,030	2,979,196	4,351.8	20	221,283	140,287.6	41.39	162.81	4.40	37.01	1.26
75 to 84 Years	7,382	7,382	33,926	1,284,739	2,560,412	3,736.1	33	235,957	160,730.0	31.29	174.04	4.60	37.87	2.42
85+ Years	2,413	2,413	11,012	391,979	778,047	1,143.5	9	158,035	116,332.6	15.27	162.44	4.56	35.60	2.15
365 Day Washout Period														
00 to 40 Years	502	502	1,120	34,072	68,083	108.3	0	26,536	12,815.6	18.92	67.87	2.23	30.42	0.00
41 to 54 Years	3,454	3,454	12,115	386,403	772,771	1,167.3	0	82,038	45,130.2	42.10	111.87	3.51	31.89	0.00
55 to 64 Years	7,484	7,484	32,462	1,113,083	2,224,276	3,272.5	15	147,854	86,574.4	50.62	148.73	4.34	34.29	1.25
65 to 74 Years	7,734	7,734	34,738	1,288,657	2,575,951	3,756.4	16	191,979	120,211.0	40.29	166.62	4.49	37.10	1.17
75 to 84 Years	6,539	6,539	30,379	1,152,951	2,298,192	3,350.8	30	211,383	142,820.7	30.93	176.32	4.65	37.95	2.45
85+ Years	2,157	2,157	9,826	352,717	700,615	1,028.1	9	144,847	106,022.4	14.89	163.52	4.56	35.90	2.40

**Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Warfarin (Incident with respect to Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period														
00 to 40 Years	1,245	1,245	4,338	149,235	223,772	440.8	2	32,403	16,008.3	38.42	119.87	3.48	34.40	1.24
41 to 54 Years	8,757	8,757	31,884	1,101,491	1,564,096	3,250.1	19	98,878	57,787.0	88.56	125.78	3.64	34.55	1.60
55 to 64 Years	22,688	22,688	81,061	3,024,657	4,218,053	8,863.0	46	179,018	113,410.3	126.74	133.32	3.57	37.31	1.42
65 to 74 Years	36,488	36,488	136,982	5,842,189	7,721,147	16,881.0	93	228,997	152,642.5	159.34	160.11	3.75	42.65	1.51
75 to 84 Years	41,008	41,008	162,954	6,779,133	8,673,275	19,541.1	138	242,568	171,197.1	169.06	165.31	3.97	41.60	1.93
85+ Years	16,583	16,583	70,760	2,617,399	3,259,711	7,550.5	59	160,381	119,837.0	103.40	157.84	4.27	36.99	2.14
365 Day Washout Period														
00 to 40 Years	933	933	3,394	116,649	175,399	343.3	2	26,832	13,321.5	34.77	125.03	3.64	34.37	1.59
41 to 54 Years	6,811	6,811	25,523	872,883	1,245,112	2,571.3	15	84,208	49,277.2	80.88	128.16	3.75	34.20	1.60
55 to 64 Years	17,650	17,650	65,217	2,395,762	3,365,753	7,009.2	39	154,507	97,361.8	114.23	135.74	3.70	36.74	1.52
65 to 74 Years	28,698	28,698	111,844	4,652,472	6,180,938	13,432.0	83	199,900	132,132.2	143.56	162.12	3.90	41.60	1.69
75 to 84 Years	33,167	33,167	138,264	5,585,658	7,149,635	16,077.0	116	218,379	153,477.2	151.88	168.41	4.17	40.40	1.98
85+ Years	13,462	13,462	60,575	2,171,274	2,698,245	6,252.6	49	147,646	109,946.3	91.18	161.29	4.50	35.84	2.15
<i>ICH</i>														
183-Day Washout Period														
00 to 40 Years	1,238	1,238	4,291	147,351	220,830	434.7	6	32,387	16,009.6	38.23	119.02	3.47	34.34	3.78
41 to 54 Years	8,732	8,732	31,711	1,096,103	1,555,683	3,235.4	20	98,844	57,795.4	88.34	125.53	3.63	34.57	1.69
55 to 64 Years	22,622	22,622	80,556	3,009,496	4,197,498	8,819.6	55	178,917	113,408.8	126.44	133.03	3.56	37.36	1.71
65 to 74 Years	36,402	36,402	136,384	5,823,516	7,697,491	16,834.8	131	228,789	152,595.8	159.11	159.98	3.75	42.70	2.13
75 to 84 Years	40,869	40,869	162,084	6,745,998	8,634,169	19,458.5	212	242,277	171,083.4	168.69	165.06	3.97	41.62	2.98
85+ Years	16,558	16,558	70,602	2,611,388	3,251,185	7,536.9	98	160,299	119,841.4	103.29	157.71	4.26	36.99	3.56
365 Day Washout Period														
00 to 40 Years	930	930	3,369	115,600	173,947	339.6	5	26,823	13,325.2	34.67	124.30	3.62	34.31	4.03
41 to 54 Years	6,794	6,794	25,386	868,612	1,239,288	2,559.6	16	84,189	49,282.7	80.70	127.85	3.74	34.22	1.71
55 to 64 Years	17,593	17,593	64,793	2,382,464	3,348,368	6,973.7	44	154,397	97,360.3	113.95	135.42	3.68	36.77	1.73
65 to 74 Years	28,616	28,616	111,297	4,636,617	6,161,448	13,394.2	105	199,731	132,096.3	143.27	162.03	3.89	41.66	2.15
75 to 84 Years	33,038	33,038	137,546	5,557,759	7,115,962	16,014.1	166	218,106	153,382.3	151.48	168.22	4.16	40.41	2.84
85+ Years	13,438	13,438	60,429	2,166,944	2,690,836	6,243.5	83	147,594	109,956.2	91.05	161.25	4.50	35.86	3.64

**Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>GIH or ICH</b>														
183-Day Washout Period														
00 to 40 Years	1,231	1,231	4,265	146,611	219,975	432.3	8	32,363	15,982.9	38.04	119.10	3.46	34.38	5.07
41 to 54 Years	8,699	8,699	31,569	1,091,311	1,549,680	3,217.8	35	98,711	57,692.4	88.13	125.45	3.63	34.57	2.98
55 to 64 Years	22,551	22,551	80,317	3,000,531	4,185,965	8,781.3	98	178,655	113,156.1	126.23	133.06	3.56	37.36	3.06
65 to 74 Years	36,287	36,287	135,887	5,805,339	7,674,840	16,756.8	220	228,405	152,198.1	158.87	159.98	3.74	42.72	3.59
75 to 84 Years	40,758	40,758	161,437	6,728,114	8,611,882	19,363.9	346	241,774	170,521.0	168.58	165.07	3.96	41.68	4.89
85+ Years	16,502	16,502	70,267	2,601,097	3,240,573	7,493.6	154	159,897	119,367.6	103.20	157.62	4.26	37.02	5.63
365 Day Washout Period														
00 to 40 Years	924	924	3,345	114,918	173,164	337.4	7	26,803	13,300.9	34.47	124.37	3.62	34.36	5.68
41 to 54 Years	6,765	6,765	25,258	864,370	1,233,864	2,544.8	27	84,069	49,196.6	80.47	127.77	3.73	34.22	2.90
55 to 64 Years	17,536	17,536	64,593	2,375,524	3,338,990	6,941.5	82	154,172	97,139.0	113.74	135.47	3.68	36.78	3.23
65 to 74 Years	28,518	28,518	110,847	4,619,799	6,140,312	13,324.2	185	199,374	131,739.6	143.04	162.00	3.89	41.68	3.80
75 to 84 Years	32,944	32,944	136,960	5,541,584	7,095,346	15,927.9	279	217,645	152,872.5	151.37	168.21	4.16	40.46	4.80
85+ Years	13,390	13,390	60,138	2,157,669	2,681,919	6,204.5	130	147,206	109,516.6	90.96	161.14	4.49	35.88	5.74
<b>Warfarin (Incident with respect to Dabigatran and Warfarin)</b>														
<b>GIH</b>														
183-Day Washout Period														
00 to 40 Years	1,202	1,202	4,163	143,179	214,496	422.2	2	32,182	15,491.2	37.35	119.12	3.46	34.39	1.30
41 to 54 Years	8,366	8,366	30,136	1,039,991	1,482,867	3,064.0	19	96,944	53,397.2	86.30	124.31	3.60	34.51	1.70
55 to 64 Years	21,587	21,587	76,608	2,857,412	4,002,005	8,361.5	42	172,726	101,329.3	124.98	132.37	3.55	37.30	1.38
65 to 74 Years	34,955	34,955	130,395	5,557,362	7,367,914	16,045.2	89	221,524	138,970.2	157.79	158.99	3.73	42.62	1.52
75 to 84 Years	39,389	39,389	155,558	6,462,124	8,292,906	18,616.0	136	236,075	159,013.3	166.85	164.06	3.95	41.54	2.00
85+ Years	16,086	16,086	68,426	2,522,886	3,150,768	7,274.8	59	157,829	115,495.3	101.92	156.84	4.25	36.87	2.22
365 Day Washout Period														
00 to 40 Years	894	894	3,240	111,347	167,008	327.1	2	26,565	12,823.9	33.65	124.55	3.62	34.37	1.67
41 to 54 Years	6,451	6,451	23,916	818,087	1,174,140	2,406.1	15	82,172	45,143.5	78.51	126.82	3.71	34.21	1.71
55 to 64 Years	16,699	16,699	61,407	2,252,781	3,181,734	6,581.6	35	148,142	86,445.8	112.72	134.91	3.68	36.69	1.46
65 to 74 Years	27,387	27,387	106,165	4,410,223	5,878,821	12,722.9	79	192,352	119,990.0	142.38	161.03	3.88	41.54	1.70
75 to 84 Years	31,784	31,784	132,129	5,326,450	6,837,092	15,318.8	115	211,819	142,573.5	150.05	167.58	4.16	40.31	2.06
85+ Years	13,035	13,035	58,509	2,089,957	2,600,928	6,015.9	49	144,984	105,963.3	89.91	160.33	4.49	35.72	2.23

**Table 2. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Age Group**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>ICH</b>														
183-Day Washout Period														
00 to 40 Years	1,195	1,195	4,116	141,295	211,554	416.1	6	32,166	15,492.5	37.15	118.24	3.44	34.33	3.95
41 to 54 Years	8,339	8,339	29,960	1,034,435	1,474,182	3,048.8	20	96,912	53,405.3	86.05	124.05	3.59	34.53	1.80
55 to 64 Years	21,520	21,520	76,141	2,843,656	3,983,386	8,320.7	54	172,612	101,331.1	124.67	132.14	3.54	37.35	1.78
65 to 74 Years	34,870	34,870	129,806	5,539,204	7,345,071	16,003.2	121	221,307	138,927.3	157.56	158.85	3.72	42.67	2.07
75 to 84 Years	39,253	39,253	154,673	6,429,897	8,255,493	18,538.4	202	235,778	158,896.6	166.48	163.81	3.94	41.57	2.98
85+ Years	16,061	16,061	68,272	2,516,931	3,142,300	7,261.5	97	157,747	115,499.7	101.81	156.71	4.25	36.87	3.66
365 Day Washout Period														
00 to 40 Years	891	891	3,215	110,298	165,556	323.4	5	26,556	12,827.6	33.55	123.79	3.61	34.31	4.23
41 to 54 Years	6,432	6,432	23,777	813,693	1,168,088	2,394.1	16	82,154	45,148.3	78.29	126.51	3.70	34.22	1.83
55 to 64 Years	16,641	16,641	61,007	2,240,438	3,165,325	6,547.3	41	148,022	86,445.8	112.42	134.63	3.67	36.72	1.71
65 to 74 Years	27,305	27,305	105,638	4,395,108	5,860,043	12,688.3	99	192,178	119,960.9	142.08	160.96	3.87	41.61	2.14
75 to 84 Years	31,660	31,660	131,368	5,298,499	6,803,981	15,258.0	161	211,539	142,476.5	149.67	167.36	4.15	40.33	2.89
85+ Years	13,012	13,012	58,371	2,085,781	2,593,675	6,007.4	82	144,928	105,974.1	89.78	160.30	4.49	35.73	3.74
<b>GIH or ICH</b>														
183-Day Washout Period														
00 to 40 Years	1,188	1,188	4,090	140,555	210,699	413.8	8	32,142	15,465.8	36.96	118.31	3.44	34.37	5.29
41 to 54 Years	8,309	8,309	29,824	1,029,881	1,468,586	3,031.9	35	96,776	53,305.1	85.86	123.95	3.59	34.53	3.16
55 to 64 Years	21,453	21,453	75,910	2,835,021	3,972,244	8,285.2	93	172,350	101,088.4	124.47	132.15	3.54	37.35	3.07
65 to 74 Years	34,760	34,760	129,334	5,522,126	7,323,559	15,929.2	206	220,924	138,538.8	157.34	158.86	3.72	42.70	3.54
75 to 84 Years	39,149	39,149	154,115	6,413,679	8,234,417	18,449.0	334	235,280	158,356.3	166.39	163.83	3.94	41.62	4.96
85+ Years	16,009	16,009	67,960	2,507,304	3,132,342	7,220.1	153	157,344	115,035.2	101.75	156.62	4.25	36.89	5.80
365 Day Washout Period														
00 to 40 Years	885	885	3,191	109,616	164,773	321.2	7	26,536	12,803.4	33.35	123.86	3.61	34.35	5.97
41 to 54 Years	6,405	6,405	23,652	809,607	1,162,991	2,379.8	27	82,031	45,064.5	78.08	126.40	3.69	34.23	3.11
55 to 64 Years	16,587	16,587	60,813	2,233,678	3,156,187	6,517.4	75	147,798	86,235.4	112.23	134.66	3.67	36.73	3.15
65 to 74 Years	27,212	27,212	105,212	4,379,236	5,840,002	12,622.0	175	191,819	119,612.7	141.86	160.93	3.87	41.62	3.80
75 to 84 Years	31,568	31,568	130,854	5,283,489	6,784,192	15,175.3	273	211,081	141,986.3	149.55	167.37	4.15	40.38	4.93
85+ Years	12,968	12,968	58,103	2,077,170	2,585,412	5,970.3	129	144,542	105,543.3	89.72	160.18	4.48	35.75	5.92

**Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Dabigatran (Incident with respect to Dabigatran)</b>														
<i>GIH</i>														
183-Day Washout Period														
Female	20,507	20,507	103,412	3,814,146	7,607,564	11,102.2	36	503,861	497,579.5	40.70	185.99	5.04	36.88	0.89
Male	35,609	35,609	173,189	6,510,386	12,999,099	18,979.6	48	654,712	640,774.9	54.39	182.83	4.86	37.59	0.69
Unknown	18	18	69	2,150	4,300	6.3	0	372	279.7	48.39	119.44	3.83	31.16	0.00
365 Day Washout Period														
Female	18,840	18,840	96,125	3,556,221	7,093,823	10,343.6	33	471,502	465,257.9	39.96	188.76	5.10	37.00	0.87
Male	32,362	32,362	159,292	6,019,370	12,019,097	17,534.1	46	606,276	592,608.8	53.38	186.00	4.92	37.79	0.72
Unknown	18	18	69	2,150	4,300	6.3	0	340	209.0	52.94	119.44	3.83	31.16	0.00
<i>ICH</i>														
183-Day Washout Period														
Female	20,472	20,472	103,226	3,806,626	7,592,634	11,079.1	33	503,528	497,250.6	40.66	185.94	5.04	36.88	0.82
Male	35,548	35,548	172,546	6,488,003	12,954,045	18,915.3	53	654,322	640,570.2	54.33	182.51	4.85	37.60	0.77
Unknown	18	18	69	2,150	4,300	6.3	0	372	279.3	48.39	119.44	3.83	31.16	0.00
365 Day Washout Period														
Female	18,809	18,809	95,961	3,549,312	7,080,115	10,321.7	30	471,176	464,954.2	39.92	188.70	5.10	36.99	0.80
Male	32,308	32,308	158,701	5,998,581	11,977,231	17,476.9	48	605,924	592,407.8	53.32	185.67	4.91	37.80	0.75
Unknown	18	18	69	2,150	4,300	6.3	0	340	208.6	52.94	119.44	3.83	31.16	0.00
<i>GIH or ICH</i>														
183-Day Washout Period														
Female	20,438	20,438	103,013	3,800,182	7,579,774	11,055.5	68	502,832	496,003.1	40.65	185.94	5.04	36.89	1.68
Male	35,503	35,503	172,391	6,482,711	12,943,801	18,893.4	100	653,428	638,949.2	54.33	182.60	4.86	37.60	1.45
Unknown	18	18	69	2,150	4,300	6.3	0	372	279.2	48.39	119.44	3.83	31.16	0.00
365 Day Washout Period														
Female	18,774	18,774	95,747	3,542,861	7,067,241	10,298.9	62	470,520	463,786.6	39.90	188.71	5.10	37.00	1.65
Male	32,263	32,263	158,541	5,993,113	11,966,635	17,454.6	93	605,070	590,905.7	53.32	185.76	4.91	37.80	1.46
Unknown	18	18	69	2,150	4,300	6.3	0	340	208.5	52.94	119.44	3.83	31.16	0.00

**Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Dabigatran (Incident with respect to Dabigatran and Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period														
Female	11,570	11,570	51,908	1,838,989	3,669,841	5,376.5	18	378,757	262,980.0	30.55	158.94	4.49	35.43	0.92
Male	21,218	21,218	88,154	3,167,705	6,323,636	9,316.5	22	479,480	327,149.2	44.25	149.29	4.15	35.93	0.65
Unknown	13	13	33	1,093	2,186	3.2	0	348	230.4	37.36	84.08	2.54	33.12	0.00
365 Day Washout Period														
Female	9,973	9,973	45,634	1,618,583	3,231,041	4,725.6	16	336,898	232,813.9	29.60	162.30	4.58	35.47	0.93
Male	17,962	17,962	75,473	2,725,897	5,442,219	8,009.2	20	417,283	282,312.3	43.05	151.76	4.20	36.12	0.68
Unknown	13	13	33	1,093	2,186	3.2	0	311	158.4	41.80	84.08	2.54	33.12	0.00
<i>ICH</i>														
183-Day Washout Period														
Female	11,552	11,552	51,791	1,834,939	3,661,714	5,365.8	12	378,395	262,846.9	30.53	158.84	4.48	35.43	0.61
Male	21,185	21,185	87,852	3,156,822	6,301,510	9,283.3	31	479,090	327,115.4	44.22	149.01	4.15	35.93	0.91
Unknown	13	13	33	1,093	2,186	3.2	0	348	230.0	37.36	84.08	2.54	33.12	0.00
365 Day Washout Period														
Female	9,956	9,956	45,529	1,614,808	3,223,464	4,715.6	10	336,573	232,718.4	29.58	162.19	4.57	35.47	0.58
Male	17,931	17,931	75,204	2,716,078	5,422,221	7,981.1	25	416,957	282,292.6	43.00	151.47	4.19	36.12	0.86
Unknown	13	13	33	1,093	2,186	3.2	0	311	157.9	41.80	84.08	2.54	33.12	0.00
<i>GIH or ICH</i>														
183-Day Washout Period														
Female	11,536	11,536	51,731	1,833,074	3,658,014	5,358.2	30	377,715	262,072.3	30.54	158.90	4.48	35.43	1.53
Male	21,166	21,166	87,772	3,154,111	6,296,268	9,272.8	52	478,176	326,098.4	44.26	149.02	4.15	35.94	1.54
Unknown	13	13	33	1,093	2,186	3.2	0	348	229.9	37.36	84.08	2.54	33.12	0.00
365 Day Washout Period														
Female	9,941	9,941	45,470	1,613,033	3,219,944	4,708.4	26	335,942	232,020.4	29.59	162.26	4.57	35.47	1.51
Male	17,916	17,916	75,137	2,713,757	5,417,759	7,971.9	44	416,121	281,396.1	43.05	151.47	4.19	36.12	1.51
Unknown	13	13	33	1,093	2,186	3.2	0	311	157.9	41.80	84.08	2.54	33.12	0.00

**Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Warfarin (Incident with respect to Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period														
Female	53,939	53,939	217,437	8,514,171	10,995,831	24,603.8	167	386,029	276,638.5	139.73	157.85	4.03	39.16	1.86
Male	72,743	72,743	270,385	10,994,828	14,657,146	31,908.0	190	493,227	354,005.8	147.48	151.15	3.72	40.66	1.63
Unknown	87	87	157	5,105	7,079	14.8	0	353	237.9	246.46	58.68	1.80	32.52	0.00
365 Day Washout Period														
Female	43,550	43,550	183,332	7,014,094	9,058,770	20,236.3	141	344,356	246,729.7	126.47	161.06	4.21	38.26	1.91
Male	57,086	57,086	221,331	8,775,622	11,749,418	25,434.8	163	431,550	308,621.7	132.28	153.73	3.88	39.65	1.75
Unknown	85	85	154	4,982	6,893	14.4	0	313	164.8	271.57	58.61	1.81	32.35	0.00
<i>ICH</i>														
183-Day Washout Period														
Female	53,777	53,777	216,353	8,478,718	10,954,346	24,516.3	249	385,673	276,523.2	139.44	157.66	4.02	39.19	2.78
Male	72,557	72,557	269,118	10,950,029	14,595,431	31,788.8	273	492,857	353,973.8	147.22	150.92	3.71	40.69	2.35
Unknown	87	87	157	5,105	7,079	14.8	0	353	237.5	246.46	58.68	1.80	32.52	0.00
365 Day Washout Period														
Female	43,399	43,399	182,326	6,982,504	9,021,034	20,163.7	202	344,041	246,639.5	126.14	160.89	4.20	38.30	2.74
Male	56,925	56,925	220,340	8,740,510	11,701,922	25,346.6	217	431,240	308,599.2	132.00	153.54	3.87	39.67	2.34
Unknown	85	85	154	4,982	6,893	14.4	0	313	164.4	271.57	58.61	1.81	32.35	0.00
<i>GIH or ICH</i>														
183-Day Washout Period														
Female	53,609	53,609	215,492	8,452,645	10,922,948	24,391.6	406	384,995	275,738.6	139.25	157.67	4.02	39.22	4.56
Male	72,332	72,332	268,093	10,915,253	14,552,888	31,639.3	455	491,941	352,942.0	147.03	150.90	3.71	40.71	3.94
Unknown	87	87	157	5,105	7,079	14.8	0	353	237.4	246.46	58.68	1.80	32.52	0.00
365 Day Washout Period														
Female	43,257	43,257	181,556	6,958,882	8,992,356	20,049.5	336	343,412	245,925.2	125.96	160.87	4.20	38.33	4.59
Male	56,735	56,735	219,431	8,710,000	11,664,346	25,216.3	374	430,403	307,675.8	131.82	153.52	3.87	39.69	4.06
Unknown	85	85	154	4,982	6,893	14.4	0	313	164.3	271.57	58.61	1.81	32.35	0.00



**Table 3. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Sex**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Warfarin (Incident with respect to Dabigatran and Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period														
Female	51,822	51,822	207,645	8,109,668	10,511,020	23,417.4	162	378,757	259,973.9	136.82	156.49	4.01	39.06	1.89
Male	69,676	69,676	257,484	10,468,181	13,992,857	30,351.7	185	479,480	323,491.5	145.32	150.24	3.70	40.66	1.67
Unknown	87	87	157	5,105	7,079	14.8	0	348	231.1	250.00	58.68	1.80	32.52	0.00
365 Day Washout Period														
Female	41,726	41,726	174,885	6,672,639	8,646,723	19,234.4	137	336,898	231,735.7	123.85	159.92	4.19	38.15	1.95
Male	54,439	54,439	210,327	8,331,224	11,186,106	24,123.5	158	417,283	281,045.6	130.46	153.04	3.86	39.61	1.79
Unknown	85	85	154	4,982	6,893	14.4	0	311	158.8	273.31	58.61	1.81	32.35	0.00
<i>ICH</i>														
183-Day Washout Period														
Female	51,662	51,662	206,541	8,075,021	10,470,834	23,333.9	237	378,395	259,858.9	136.53	156.30	4.00	39.10	2.78
Male	69,489	69,489	256,270	10,425,292	13,934,074	30,239.9	263	479,090	323,463.0	145.04	150.03	3.69	40.68	2.38
Unknown	87	87	157	5,105	7,079	14.8	0	348	230.6	250.00	58.68	1.80	32.52	0.00
365 Day Washout Period														
Female	41,577	41,577	173,862	6,641,696	8,609,948	19,164.5	197	336,573	231,647.0	123.53	159.74	4.18	38.20	2.81
Male	54,279	54,279	209,360	8,297,139	11,139,828	24,039.6	207	416,957	281,027.9	130.18	152.86	3.86	39.63	2.36
Unknown	85	85	154	4,982	6,893	14.4	0	311	158.4	273.31	58.61	1.81	32.35	0.00
<i>GIH or ICH</i>														
183-Day Washout Period														
Female	51,504	51,504	205,789	8,051,387	10,441,474	23,216.8	389	377,715	259,096.9	136.36	156.33	4.00	39.12	4.59
Male	69,277	69,277	255,287	10,392,074	13,893,294	30,097.7	440	478,176	322,462.2	144.88	150.01	3.69	40.71	4.00
Unknown	87	87	157	5,105	7,079	14.8	0	348	230.6	250.00	58.68	1.80	32.52	0.00
365 Day Washout Period														
Female	41,443	41,443	173,184	6,619,988	8,582,825	19,056.2	327	335,942	230,953.3	123.36	159.74	4.18	38.23	4.70
Male	54,097	54,097	208,487	8,267,826	11,103,840	23,915.4	359	416,121	280,133.9	130.00	152.83	3.85	39.66	4.11
Unknown	85	85	154	4,982	6,893	14.4	0	311	158.3	273.31	58.61	1.81	32.35	0.00

**Table 4. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Dabigatran (Incident with respect to Dabigatran)</b>														
<i>GIH</i>														
183-Day Washout Period														
2010	3,651	3,651	23,712	901,487	1,798,842	2,592.3	9	513,290	88,472.1	7.11	246.92	6.49	38.02	0.95
2011	32,725	32,725	181,177	6,865,894	13,708,580	19,928.5	50	722,241	417,765.8	45.31	209.81	5.54	37.90	0.69
2012	15,330	15,330	60,312	2,175,844	4,340,093	6,422.1	23	725,295	425,357.3	21.14	141.93	3.93	36.08	0.98
2013	4,428	4,428	11,469	383,457	763,447	1,145.1	2	566,338	207,039.0	7.82	86.60	2.59	33.43	0.48
365 Day Washout Period														
2010	3,251	3,251	21,201	811,437	1,618,833	2,332.3	7	448,244	78,116.7	7.25	249.60	6.52	38.27	0.82
2011	29,977	29,977	167,827	6,389,817	12,757,603	18,534.2	48	645,741	386,791.1	46.42	213.16	5.60	38.07	0.71
2012	13,910	13,910	55,809	2,020,600	4,032,019	5,955.6	22	685,317	393,377.2	20.30	145.26	4.01	36.21	1.01
2013	4,082	4,082	10,649	355,887	708,765	1,061.9	2	544,618	199,790.7	7.50	87.18	2.61	33.42	0.52
<i>ICH</i>														
183-Day Washout Period														
2010	3,636	3,636	23,569	896,823	1,789,543	2,578.6	7	513,028	88,428.5	7.09	246.65	6.48	38.05	0.74
2011	32,682	32,682	180,592	6,845,137	13,666,756	19,866.8	56	721,859	417,564.6	45.27	209.45	5.53	37.90	0.77
2012	15,302	15,302	60,247	2,172,685	4,333,878	6,413.7	21	724,938	425,145.1	21.11	141.99	3.94	36.06	0.90
2013	4,418	4,418	11,433	382,134	760,801	1,141.6	2	566,159	206,961.9	7.80	86.49	2.59	33.42	0.48
365 Day Washout Period														
2010	3,237	3,237	21,059	806,785	1,609,558	2,319.8	6	448,007	78,077.7	7.23	249.24	6.51	38.31	0.71
2011	29,939	29,939	167,320	6,371,376	12,720,411	18,479.8	50	645,403	386,606.2	46.39	212.81	5.59	38.08	0.74
2012	13,887	13,887	55,739	2,017,318	4,025,558	5,946.9	20	684,967	393,172.0	20.27	145.27	4.01	36.19	0.92
2013	4,072	4,072	10,613	354,564	706,119	1,058.4	2	544,428	199,714.6	7.48	87.07	2.61	33.41	0.52
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	3,633	3,633	23,546	896,075	1,788,047	2,574.0	15	512,077	88,213.0	7.09	246.65	6.48	38.06	1.60
2011	32,634	32,634	180,371	6,837,965	13,652,780	19,840.6	105	721,014	416,533.4	45.26	209.53	5.53	37.91	1.45
2012	15,279	15,279	60,129	2,169,073	4,326,654	6,400.4	44	724,072	424,072.4	21.10	141.96	3.94	36.07	1.88
2013	4,413	4,413	11,427	381,930	760,393	1,140.3	4	565,401	206,412.7	7.81	86.55	2.59	33.42	0.96
365 Day Washout Period														
2010	3,234	3,234	21,036	806,037	1,608,062	2,315.9	12	447,190	77,890.0	7.23	249.24	6.50	38.32	1.42
2011	29,891	29,891	167,094	6,364,028	12,706,083	18,453.2	97	644,646	385,648.5	46.37	212.91	5.59	38.09	1.44
2012	13,863	13,863	55,620	2,013,699	4,018,320	5,933.6	42	684,076	392,182.6	20.27	145.26	4.01	36.20	1.94
2013	4,067	4,067	10,607	354,360	705,711	1,057.1	4	543,702	199,179.7	7.48	87.13	2.61	33.41	1.04

**Table 4. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Dabigatran (Incident with respect to Dabigatran and Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period														
2010	1,124	1,124	6,603	236,648	472,372	684.7	3	278,501	43,517.2	4.04	210.54	5.87	35.84	1.20
2011	16,482	16,482	80,332	2,922,282	5,835,011	8,538.5	18	474,126	210,759.4	34.76	177.30	4.87	36.38	0.58
2012	11,563	11,563	43,816	1,539,525	3,072,870	4,549.9	18	491,314	223,548.8	23.53	133.14	3.79	35.14	1.08
2013	3,632	3,632	9,344	309,332	615,410	923.1	1	362,211	112,534.2	10.03	85.17	2.57	33.10	0.30
365 Day Washout Period														
2010	900	900	5,213	186,108	371,347	539.0	2	223,473	35,352.4	4.03	206.79	5.79	35.70	1.02
2011	13,962	13,962	68,984	2,523,419	5,038,847	7,366.9	17	398,384	182,633.3	35.05	180.73	4.94	36.58	0.63
2012	9,920	9,920	38,658	1,362,441	2,720,402	4,017.5	16	434,130	194,472.6	22.85	137.34	3.90	35.24	1.09
2013	3,166	3,166	8,285	273,605	544,849	814.6	1	328,910	102,826.2	9.63	86.42	2.62	33.02	0.34
<i>ICH</i>														
183-Day Washout Period														
2010	1,117	1,117	6,538	234,752	468,580	677.0	2	278,338	43,499.5	4.01	210.16	5.85	35.91	0.81
2011	16,459	16,459	80,052	2,912,360	5,814,900	8,510.1	24	473,781	210,678.0	34.74	176.95	4.86	36.38	0.77
2012	11,547	11,547	43,770	1,537,396	3,068,492	4,544.3	16	490,963	223,492.3	23.52	133.14	3.79	35.12	0.96
2013	3,627	3,627	9,316	308,346	613,438	920.9	1	362,040	112,522.5	10.02	85.01	2.57	33.10	0.30
365 Day Washout Period														
2010	894	894	5,149	184,224	367,579	533.2	1	223,365	35,342.5	4.00	206.07	5.76	35.78	0.51
2011	13,939	13,939	68,758	2,515,025	5,021,792	7,342.9	19	398,075	182,574.5	35.02	180.43	4.93	36.58	0.71
2012	9,906	9,906	38,602	1,360,111	2,715,622	4,011.4	14	433,832	194,430.3	22.83	137.30	3.90	35.23	0.96
2013	3,161	3,161	8,257	272,619	542,877	812.4	1	328,763	102,821.6	9.61	86.24	2.61	33.02	0.34
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	1,117	1,117	6,538	234,752	468,580	676.4	4	277,686	43,371.4	4.02	210.16	5.85	35.91	1.62
2011	16,443	16,443	79,975	2,909,635	5,809,660	8,500.9	42	472,970	210,040.3	34.77	176.95	4.86	36.38	1.35
2012	11,533	11,533	43,713	1,535,638	3,064,976	4,536.9	34	490,114	222,808.5	23.53	133.15	3.79	35.13	2.05
2013	3,622	3,622	9,310	308,253	613,252	920.0	2	361,359	112,180.4	10.02	85.11	2.57	33.11	0.60
365 Day Washout Period														
2010	894	894	5,149	184,224	367,579	532.7	2	222,828	35,236.8	4.01	206.07	5.76	35.78	1.03
2011	13,927	13,927	68,694	2,512,750	5,017,452	7,335.1	36	397,377	182,009.9	35.05	180.42	4.93	36.58	1.34
2012	9,893	9,893	38,546	1,358,383	2,712,166	4,004.2	30	433,030	193,824.7	22.85	137.31	3.90	35.24	2.05
2013	3,156	3,156	8,251	272,526	542,691	811.4	2	328,129	102,503.0	9.62	86.35	2.61	33.03	0.67

**Table 4. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Warfarin (Incident with respect to Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period														
2010	11,209	11,209	48,630	1,974,435	2,627,805	5,695.0	37	278,648	43,594.6	40.23	176.15	4.34	40.60	1.78
2011	47,640	47,640	206,913	8,543,326	11,255,323	24,673.3	155	484,422	220,999.4	98.34	179.33	4.34	41.29	1.72
2012	46,819	46,819	176,869	7,025,749	9,199,798	20,381.9	115	510,402	245,057.6	91.73	150.06	3.78	39.72	1.54
2013	21,101	21,101	55,567	1,970,594	2,577,129	5,776.4	50	377,006	121,230.7	55.97	93.39	2.63	35.46	2.37
365 Day Washout Period														
2010	8,240	8,240	38,243	1,508,478	2,021,128	4,342.4	28	223,584	35,414.0	36.85	183.07	4.64	39.44	1.77
2011	36,453	36,453	168,134	6,785,347	8,972,019	19,555.3	133	403,950	190,646.2	90.24	186.14	4.61	40.36	1.86
2012	37,763	37,763	148,984	5,791,946	7,597,876	16,781.3	99	459,914	215,699.9	82.11	153.38	3.95	38.88	1.62
2013	18,265	18,265	49,456	1,708,927	2,224,058	5,006.5	44	352,151	113,756.2	51.87	93.56	2.71	34.55	2.41
<i>ICH</i>														
183-Day Washout Period														
2010	11,168	11,168	48,336	1,962,965	2,613,048	5,673.8	48	278,484	43,576.4	40.10	175.77	4.33	40.61	2.32
2011	47,533	47,533	205,942	8,508,685	11,209,441	24,584.2	242	484,086	220,912.1	98.19	179.01	4.33	41.32	2.70
2012	46,683	46,683	176,002	6,999,003	9,166,018	20,307.2	184	510,082	245,009.5	91.52	149.93	3.77	39.77	2.48
2013	21,037	21,037	55,348	1,963,199	2,568,350	5,754.7	48	376,873	121,236.4	55.82	93.32	2.63	35.47	2.28
365 Day Washout Period														
2010	8,206	8,206	38,018	1,500,044	2,009,746	4,327.9	33	223,476	35,403.8	36.72	182.80	4.63	39.46	2.09
2011	36,352	36,352	167,352	6,758,199	8,937,052	19,491.4	192	403,649	190,579.2	90.06	185.91	4.60	40.38	2.70
2012	37,645	37,645	148,207	5,768,005	7,568,280	16,718.7	155	459,633	215,658.9	81.90	153.22	3.94	38.92	2.54
2013	18,206	18,206	49,243	1,701,748	2,214,771	4,986.9	39	352,030	113,761.3	51.72	93.47	2.70	34.56	2.14
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	11,148	11,148	48,205	1,958,926	2,608,229	5,644.3	84	277,832	43,448.3	40.12	175.72	4.32	40.64	4.07
2011	47,374	47,374	205,098	8,480,079	11,176,142	24,454.6	386	483,280	220,264.9	98.03	179.00	4.33	41.35	4.32
2012	46,551	46,551	175,363	6,978,498	9,140,423	20,219.5	295	509,270	244,311.7	91.41	149.91	3.77	39.79	3.99
2013	20,955	20,955	55,076	1,955,500	2,558,120	5,727.3	96	376,226	120,893.2	55.70	93.32	2.63	35.51	4.59
365 Day Washout Period														
2010	8,191	8,191	37,920	1,496,994	2,005,919	4,304.8	61	222,939	35,298.0	36.74	182.76	4.63	39.48	3.88
2011	36,226	36,226	166,592	6,732,638	8,907,001	19,375.1	318	402,955	190,006.1	89.90	185.85	4.60	40.41	4.49
2012	37,525	37,525	147,617	5,748,922	7,544,122	16,637.3	250	458,832	215,029.8	81.78	153.20	3.93	38.94	4.11
2013	18,135	18,135	49,012	1,695,310	2,206,552	4,963.0	81	351,409	113,431.5	51.61	93.48	2.70	34.59	4.47

**Table 4. Summary of Incident Dabigatran and Warfarin Use among Patients with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to June 30, 2013, by Drug, Incidence Criteria, Washout Period, Outcome, and Year**

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	Years at Risk	New Episodes w/ Events	Eligible Members	Member-Years	New Users / 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	New Episodes w/ Events / 100K Days at Risk
<b>Warfarin (Incident with respect to Dabigatran and Warfarin)</b>														
<i>GIH</i>														
183-Day Washout Period														
2010	11,185	11,185	48,232	1,948,610	2,597,065	5,612.2	37	278,501	43,517.2	40.16	174.22	4.31	40.40	1.81
2011	46,060	46,060	198,774	8,186,542	10,814,046	23,614.9	151	472,174	209,998.4	97.55	177.74	4.32	41.19	1.75
2012	44,075	44,075	165,070	6,561,505	8,628,010	19,029.5	110	483,325	220,029.9	91.19	148.87	3.75	39.75	1.58
2013	20,265	20,265	53,210	1,886,297	2,471,836	5,527.3	49	353,672	110,150.9	57.30	93.08	2.63	35.45	2.43
365 Day Washout Period														
2010	8,218	8,218	37,916	1,487,961	1,996,835	4,276.3	28	223,473	35,352.4	36.77	181.06	4.61	39.24	1.79
2011	35,306	35,306	161,921	6,514,319	8,635,362	18,750.5	130	398,114	182,616.6	88.68	184.51	4.59	40.23	1.90
2012	35,406	35,406	138,667	5,390,041	7,099,258	15,612.4	94	430,875	193,246.1	82.17	152.24	3.92	38.87	1.65
2013	17,320	17,320	46,862	1,616,524	2,108,266	4,733.1	43	325,287	101,725.0	53.25	93.33	2.71	34.50	2.49
<i>ICH</i>														
183-Day Washout Period														
2010	11,144	11,144	47,955	1,937,916	2,583,116	5,593.4	47	278,338	43,499.5	40.04	173.90	4.30	40.41	2.30
2011	45,953	45,953	197,794	8,152,525	10,770,301	23,528.6	233	471,833	209,917.8	97.39	177.41	4.30	41.22	2.71
2012	43,940	43,940	164,230	6,536,038	8,595,611	18,960.7	173	482,989	219,983.1	90.98	148.75	3.74	39.80	2.50
2013	20,201	20,201	52,989	1,878,939	2,462,959	5,505.9	47	353,535	110,152.1	57.14	93.01	2.62	35.46	2.34
365 Day Washout Period														
2010	8,184	8,184	37,708	1,480,303	1,986,261	4,264.4	32	223,365	35,342.5	36.64	180.88	4.61	39.26	2.05
2011	35,209	35,209	161,100	6,486,999	8,600,869	18,686.3	188	397,806	182,557.8	88.51	184.24	4.58	40.27	2.75
2012	35,290	35,290	137,925	5,367,291	7,070,921	15,554.1	147	430,584	193,206.9	81.96	152.09	3.91	38.91	2.59
2013	17,258	17,258	46,643	1,609,224	2,098,618	4,713.7	37	325,160	101,726.0	53.08	93.25	2.70	34.50	2.15
<i>GIH or ICH</i>														
183-Day Washout Period														
2010	11,124	11,124	47,825	1,933,955	2,578,453	5,564.2	83	277,686	43,371.4	40.06	173.85	4.30	40.44	4.08
2011	45,805	45,805	197,035	8,125,947	10,738,615	23,405.5	373	471,026	209,283.5	97.25	177.40	4.30	41.24	4.36
2012	43,815	43,815	163,642	6,516,992	8,571,488	18,879.7	279	482,173	219,312.6	90.87	148.74	3.73	39.82	4.05
2013	20,124	20,124	52,731	1,871,672	2,453,291	5,479.8	94	352,884	109,822.1	57.03	93.01	2.62	35.49	4.70
365 Day Washout Period														
2010	8,169	8,169	37,611	1,477,331	1,982,590	4,241.5	60	222,828	35,236.8	36.66	180.85	4.60	39.28	3.87
2011	35,087	35,087	160,415	6,462,889	8,571,853	18,574.6	311	397,108	181,993.3	88.36	184.20	4.57	40.29	4.58
2012	35,174	35,174	137,367	5,349,159	7,047,849	15,478.1	237	429,792	192,603.8	81.84	152.08	3.91	38.94	4.19
2013	17,195	17,195	46,432	1,603,417	2,091,265	4,691.9	78	324,540	101,411.7	52.98	93.25	2.70	34.53	4.55

**Appendix A: Codes Used to Define Exposures in this Report**

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<b>Event</b>	<b>Description</b>	<b>Code</b>
ICH	Intracerebral hemorrhage	431*
GIH	Acute gastric ulcer with hemorrhage	531.0
GIH	Acute gastric ulcer with hemorrhage and perforation	531.2
GIH	Chronic or unspecified gastric ulcer with hemorrhage	531.4
GIH	Chronic or unspecified gastric ulcer with hemorrhage and perforation	531.6
GIH	Acute duodenal ulcer with hemorrhage	532.0
GIH	Acute duodenal ulcer with hemorrhage and perforation	532.2
GIH	Chronic or unspecified duodenal ulcer with hemorrhage	532.4
GIH	Chronic or unspecified duodenal ulcer with hemorrhage and perforation	532.6
GIH	Acute peptic ulcer of unspecified site with hemorrhage	533.0
GIH	Acute peptic ulcer of unspecified site with hemorrhage and perforation	533.2
GIH	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage	533.4
GIH	Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation	533.6
GIH	Acute gastrojejunal ulcer with hemorrhage	534.0
GIH	Acute gastrojejunal ulcer with hemorrhage and perforation	534.2
GIH	Chronic or unspecified gastrojejunal ulcer with hemorrhage	534.4
GIH	Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation	534.6
GIH	Hematemesis	578.0
Afib	Atrial Fibrillation	427.31