



Modular Program Report

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

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

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

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

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| Overview | |
|-----------------------------------|--|
| <u>Request Description</u> | FDA requested use MP #3 (version 2.3) to investigate gastrointestinal (GIH) and/or intracerebral hemorrhage (ICH) events following new use of dabigatran or warfarin among patients with a pre-existing condition of atrial fibrillation. The query was run against the Mini-Sentinel Distributed Database for the time period 10/19/2010 to 12/31/2011 (query period). The package was distributed to Data Partners on June 5, 2012. |
| | Results provide counts of new users of dabigatran and warfarin, dispensings, total days supplied, treatment episodes, eligible members (denominator), and member days. Total days supplied are from the MSCDM outpatient pharmacy table for records identified using valid NDC codes (for any form, e.g., tablet, vial, topical). Users were considered new to the drug of interest if they had no prior use of either dabigatran or warfarin in the prior 183 days. Counts of new gastrointestinal (GIH) or intracerebral hemorrhage (ICH) events and days at risk following exposure to dabigatran and warfarin are also presented. Events were considered new if the user had no event in the prior 183 days. Events found in the inpatient (IP) and emergent (ED) care settings were included. |
| <u>Request ID</u> | MSY3_MPR31 - Dabigatran/Warfarin |
| <u>Requester</u> | FDA/CDER |

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| 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 Query ID MPR31 Part 2

FDA requested use MP #3 (version 2.3) to investigate gastrointestinal (GIH) or intracerebral hemorrhage (ICH) events following new use of dabigatran or warfarin among patients with a pre-existing condition of atrial fibrillation. The query was run against the Mini-Sentinel Distributed Database for the time period 10/19/2010 to 12/31/2011. For drug and exposure the episode gap was set to 10 days; the extension period was set to 10 days, and both minimum episode duration and minimum days supplied were set to 1 day. Age groups were split as follows: 0-40, 41-54, 55-64, 65-74, 75-84, and 85+ years. In total, 12 different scenarios were examined in this report with differing exposures of interest, incidence type, and event/outcome. See below for a description of each of these scenarios.

| Scenario | Drug/Exposure | | | | Pre-Existing Condition | | | | | | Event/Outcome | | | | | |
|----------|-------------------|-------------------------|----------------|---------------|------------------------|-----------|-----------------|---------------|--------------|--------------|---------------|----------------|----------------|--------------|--------------|-----------------|
| | Incident exposure | Incident w/ respect to: | Washout (days) | Washout Type* | Pre-Existing Condition | Code Type | Lookback Period | Lookback Type | Care Setting | Principal Dx | Event/Outcome | Washout (days) | Washout Type** | Care Setting | Principal Dx | Blackout Period |
| 1 | Dabigatran | Dabigatran, Warfarin | 183 | Single | Atrial fibrillation | DX | 183 | F | All | NO | ICH | 183 | Mult | ED, IP | NO | 0 |
| 2 | Dabigatran | Dabigatran, Warfarin | 183 | Single | Atrial fibrillation | DX | 183 | F | All | NO | GIH | 183 | Mult | ED, IP | NO | 0 |
| 3 | Dabigatran | Dabigatran, Warfarin | 183 | Single | Atrial fibrillation | DX | 183 | F | All | NO | ICH or GIH | 183 | Mult | ED, IP | NO | 0 |
| 4 | Warfarin | Dabigatran, Warfarin | 183 | Single | Atrial fibrillation | DX | 183 | F | All | NO | ICH | 183 | Mult | ED, IP | NO | 0 |
| 5 | Warfarin | Dabigatran, Warfarin | 183 | Single | Atrial fibrillation | DX | 183 | F | All | NO | GIH | 183 | Mult | ED, IP | NO | 0 |
| 6 | Warfarin | Dabigatran, Warfarin | 183 | Single | Atrial fibrillation | DX | 183 | F | All | NO | ICH or GIH | 183 | Mult | ED, IP | NO | 0 |
| 7 | Dabigatran | Dabigatran, Warfarin | 183 | Mult | Atrial fibrillation | DX | 183 | F | All | NO | ICH | 183 | Mult | ED, IP | NO | 0 |
| 8 | Dabigatran | Dabigatran, Warfarin | 183 | Mult | Atrial fibrillation | DX | 183 | F | All | NO | GIH | 183 | Mult | ED, IP | NO | 0 |
| 9 | Dabigatran | Dabigatran, Warfarin | 183 | Mult | Atrial fibrillation | DX | 183 | F | All | NO | ICH or GIH | 183 | Mult | ED, IP | NO | 0 |
| 10 | Warfarin | Dabigatran, Warfarin | 183 | Mult | Atrial fibrillation | DX | 183 | F | All | NO | ICH | 183 | Mult | ED, IP | NO | 0 |
| 11 | Warfarin | Dabigatran, Warfarin | 183 | Mult | Atrial fibrillation | DX | 183 | F | All | NO | GIH | 183 | Mult | ED, IP | NO | 0 |
| 12 | Warfarin | Dabigatran, Warfarin | 183 | Mult | Atrial fibrillation | DX | 183 | F | All | NO | ICH or GIH | 183 | Mult | ED, IP | NO | 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

*Single washout type for the exposure will only consider the first incident episode for each user during the query period that satisfies the Washout Period criteria (183 or 365 days). There can be at most one episode per user. A Multiple washout type for the exposure will consider all episodes for each member that meet the 183 washout period. There can be more than one incident episode per member.

**Multiple washout type for the event will only consider all valid incident events during the query period that satisfy the Washout Period criteria of 183 days. One individual can contribute more than one event.

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.

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 consecutive dispensings bridged by the episode gap).

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. YES will only consider diagnoses flagged as Principal

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.

Washout Type (drug/exposure)- *Minimum washout 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 washout 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.

Washout Type (event/outcome)- *Minimum washout 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 washout 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 washout type* will consider more than one event per user if a user has more than one incident 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 Dabigatran and Warfarin Use and GIH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug and Incidence Type

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New GIH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|-------------------------------------|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | 10,460 | 27,483 | 994,006 | 980,839 | 16 | 405,361 | 70,008,962 | 25.8 | 2.6 | 95.0 | 36.2 | 1.6 |
| Multiple Incidence Type | 10,460 | 27,514 | 994,996 | 981,846 | 16 | 405,397 | 70,044,136 | 25.8 | 2.6 | 95.1 | 36.2 | 1.6 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | 43,836 | 113,622 | 4,676,460 | 4,581,179 | 153 | 405,036 | 69,827,243 | 108.2 | 2.6 | 106.7 | 41.2 | 3.3 |
| Multiple Incidence Type | 43,836 | 113,890 | 4,688,618 | 4,590,980 | 153 | 405,397 | 70,044,136 | 108.1 | 2.6 | 107.0 | 41.2 | 3.3 |

Figure 1a. New Events of GIH per 100k Days at Risk for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 and December 31, 2011, by Drug and Incidence Type

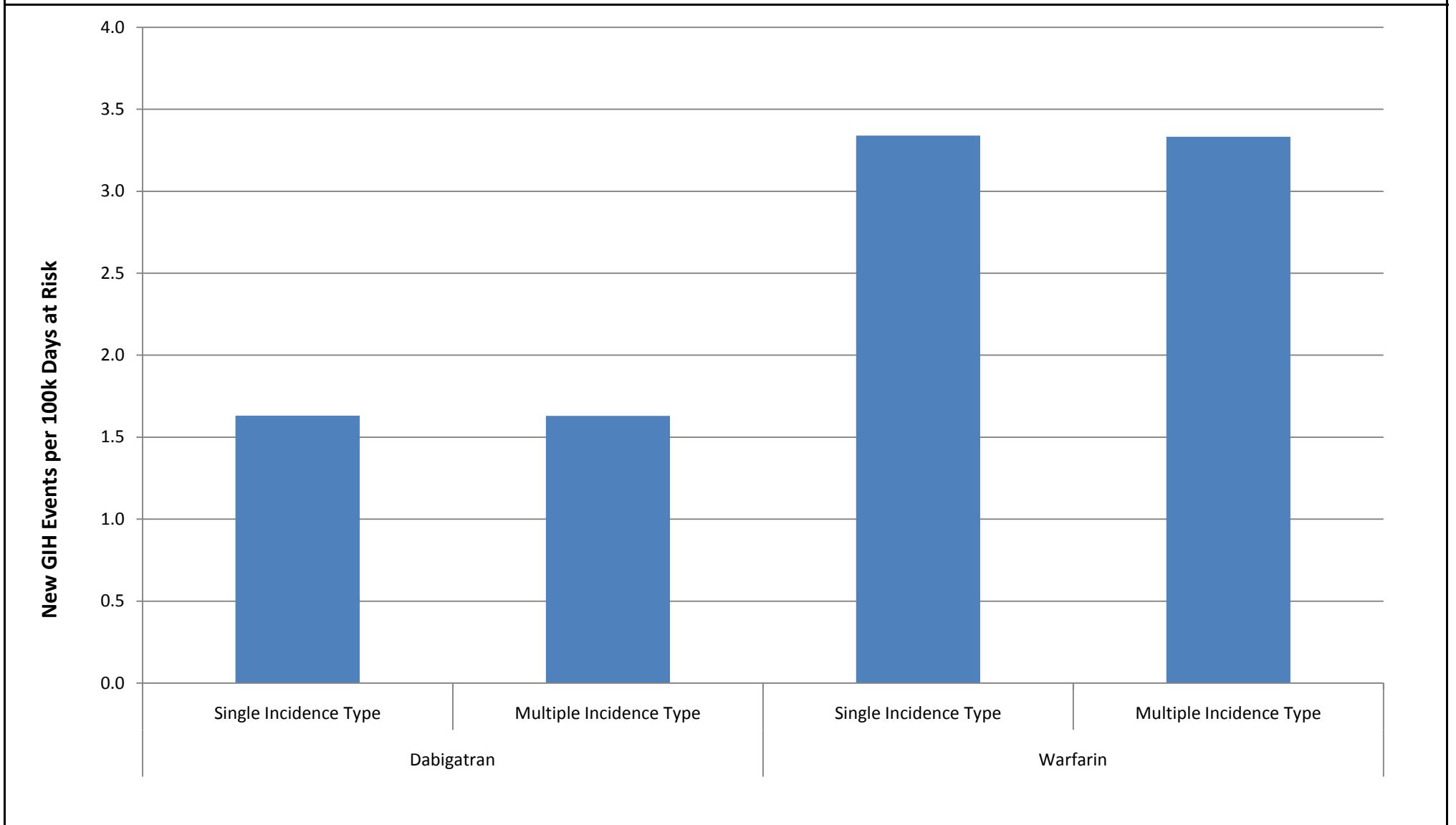


Table 1b. Summary of Incident Dabigatran and Warfarin Use and ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug and Incidence Type

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New ICH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New ICH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|--|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | 10,449 | 27,416 | 991,751 | 979,274 | 6 | 405,363 | 70,010,613 | 25.8 | 2.6 | 94.9 | 36.2 | 0.6 |
| Multiple Incidence Type | 10,449 | 27,447 | 992,741 | 980,281 | 6 | 405,399 | 70,045,806 | 25.8 | 2.6 | 95.0 | 36.2 | 0.6 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | 43,904 | 113,629 | 4,681,004 | 4,589,974 | 105 | 403,993 | 69,603,392 | 108.7 | 2.6 | 106.6 | 41.2 | 2.3 |
| Multiple Incidence Type | 43,904 | 113,899 | 4,693,272 | 4,599,931 | 105 | 405,399 | 70,045,806 | 108.3 | 2.6 | 106.9 | 41.2 | 2.3 |

Figure 1b. New Events of ICH per 100k Days at Risk for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 and December 31, 2011, by Drug and Incidence Type

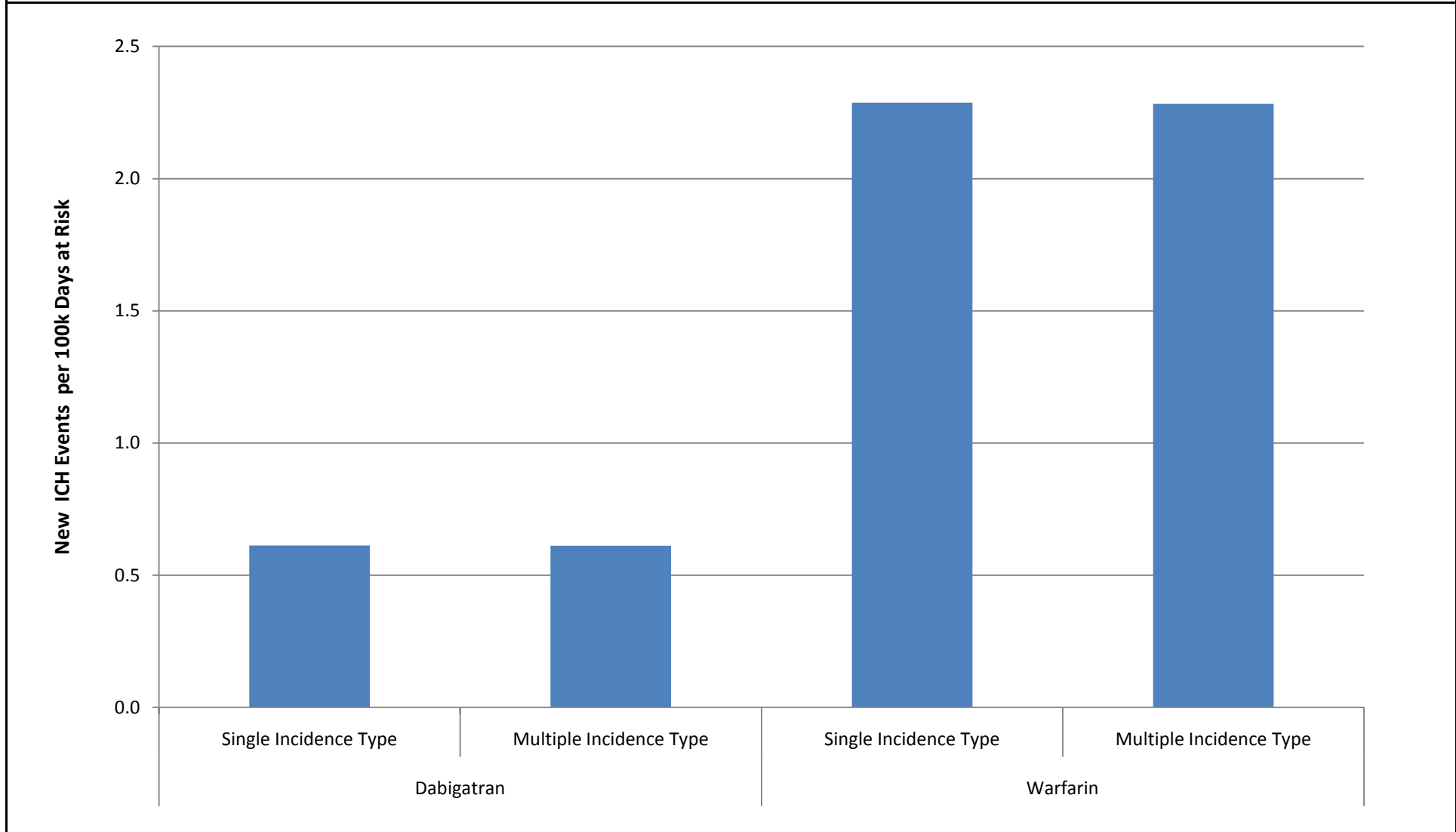


Table 1c. Summary of Incident Dabigatran and Warfarin Use and GIH or ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug and Incidence Type

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH or ICH Events | Eligible Members | Member-Days | New Users/1K Eligible Members | Dispensings/User | Days Supplied/User | Days Supplied/Dispensing | New GIH or ICH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|-----------------------|------------------|-------------|-------------------------------|------------------|--------------------|--------------------------|---|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | 10,431 | 27,370 | 989,951 | 976,897 | 21 | 405,359 | 70,007,963 | 25.7 | 2.6 | 94.9 | 36.2 | 2.1 |
| Multiple Incidence Type | 10,431 | 27,401 | 990,941 | 977,904 | 21 | 405,395 | 70,043,137 | 25.7 | 2.6 | 95.0 | 36.2 | 2.1 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | 43,656 | 112,943 | 4,655,148 | 4,556,940 | 256 | 405,034 | 69,826,518 | 107.8 | 2.6 | 106.6 | 41.2 | 5.6 |
| Multiple Incidence Type | 43,656 | 113,210 | 4,667,276 | 4,566,727 | 256 | 405,395 | 70,043,137 | 107.7 | 2.6 | 106.9 | 41.2 | 5.6 |

Figure 1c. New Events of GIH or ICH per 100k Days at Risk for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 and December 31, 2011, by Drug and Incidence Type

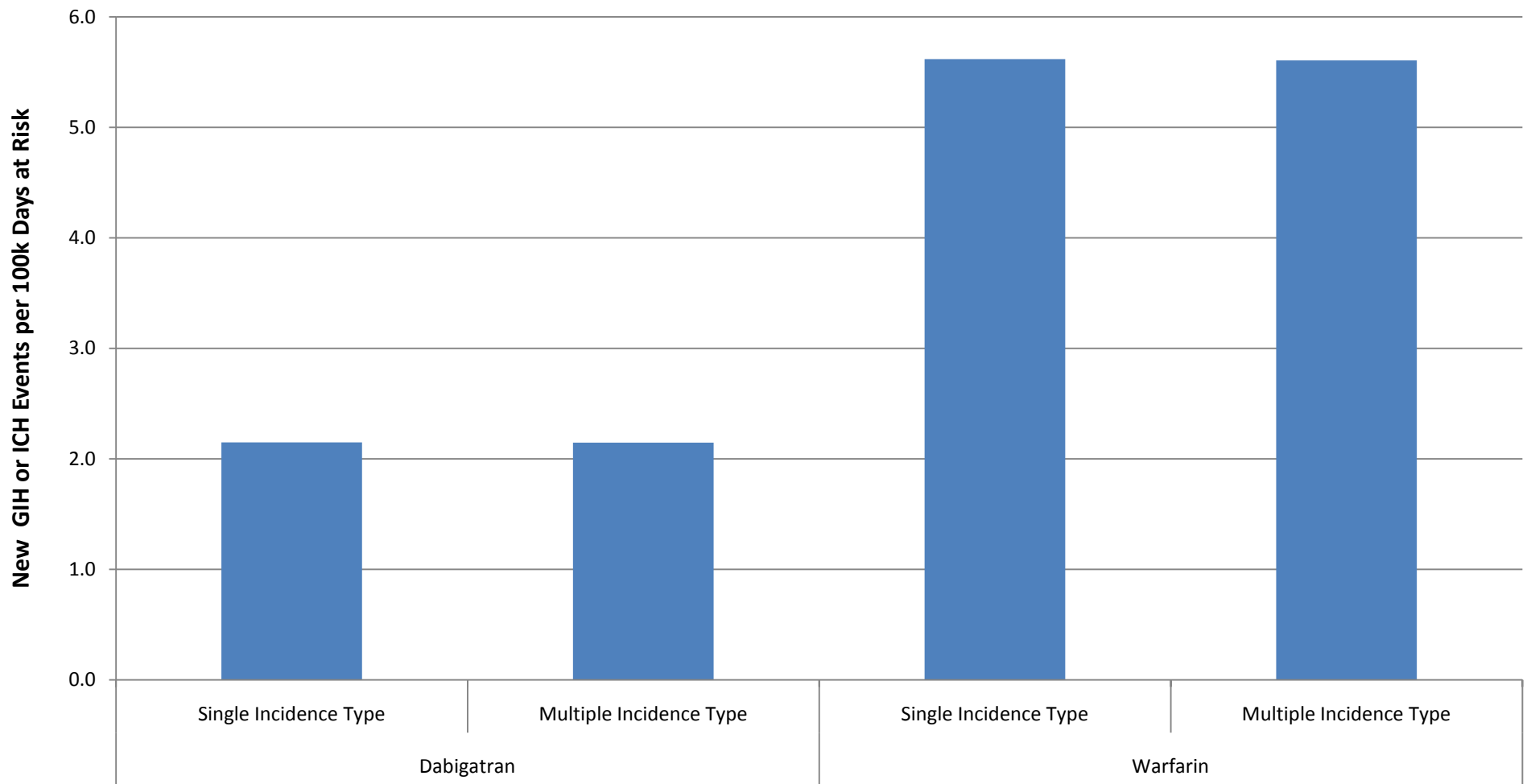


Table 2a. Summary of Incident Dabigatran and Warfarin Use and GIH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Age Group

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New GIH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|--------------------------------------|----------------------|---------------------------|---------------------------------|--|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 155 | 328 | 10,460 | 11,481 | 0 | 11,732 | 1,602,731 | 13.2 | 2.1 | 67.5 | 31.9 | 0.0 |
| 41 to 54 years | 1,085 | 2,545 | 82,822 | 86,947 | 1 | 37,769 | 5,539,874 | 28.7 | 2.3 | 76.3 | 32.5 | 1.2 |
| 55 to 64 years | 2,530 | 6,882 | 239,092 | 240,192 | 1 | 70,883 | 10,918,180 | 35.7 | 2.7 | 94.5 | 34.7 | 0.4 |
| 65 to 74 years | 3,114 | 8,113 | 302,349 | 295,324 | 5 | 103,993 | 16,846,210 | 29.9 | 2.6 | 97.1 | 37.3 | 1.7 |
| 75 to 84 years | 2,653 | 7,168 | 272,609 | 261,728 | 8 | 118,851 | 20,602,806 | 22.3 | 2.7 | 102.8 | 38.0 | 3.1 |
| 85+ years | 923 | 2,447 | 86,674 | 85,167 | 1 | 79,041 | 14,500,787 | 11.7 | 2.7 | 93.9 | 35.4 | 1.2 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 155 | 328 | 10,460 | 11,481 | 0 | 11,732 | 1,603,505 | 13.2 | 2.1 | 67.5 | 31.9 | 0.0 |
| 41 to 54 years | 1,085 | 2,549 | 83,002 | 87,167 | 1 | 37,778 | 5,545,344 | 28.7 | 2.3 | 76.5 | 32.6 | 1.1 |
| 55 to 64 years | 2,531 | 6,888 | 239,272 | 240,361 | 1 | 70,899 | 10,927,818 | 35.7 | 2.7 | 94.5 | 34.7 | 0.4 |
| 65 to 74 years | 3,115 | 8,128 | 302,799 | 295,729 | 5 | 104,011 | 16,853,885 | 29.9 | 2.6 | 97.2 | 37.3 | 1.7 |
| 75 to 84 years | 2,653 | 7,172 | 272,729 | 261,861 | 8 | 118,870 | 20,610,380 | 22.3 | 2.7 | 102.8 | 38.0 | 3.1 |
| 85+ years | 923 | 2,449 | 86,734 | 85,247 | 1 | 79,051 | 14,504,830 | 11.7 | 2.7 | 94.0 | 35.4 | 1.2 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 403 | 1,019 | 35,128 | 35,951 | 2 | 11,728 | 1,600,766 | 34.4 | 2.5 | 87.2 | 34.5 | 5.6 |
| 41 to 54 years | 2,910 | 7,414 | 263,166 | 268,627 | 4 | 37,724 | 5,524,034 | 77.1 | 2.5 | 90.4 | 35.5 | 1.5 |
| 55 to 64 years | 7,449 | 19,056 | 734,612 | 736,004 | 17 | 70,781 | 10,881,878 | 105.2 | 2.6 | 98.6 | 38.6 | 2.3 |
| 65 to 74 years | 12,779 | 32,678 | 1,403,008 | 1,365,507 | 33 | 103,829 | 16,795,841 | 123.1 | 2.6 | 109.8 | 42.9 | 2.4 |
| 75 to 84 years | 14,669 | 38,156 | 1,637,567 | 1,588,782 | 72 | 118,733 | 20,551,087 | 123.5 | 2.6 | 111.6 | 42.9 | 4.5 |
| 85+ years | 5,626 | 15,299 | 602,979 | 586,308 | 25 | 78,936 | 14,475,265 | 71.3 | 2.7 | 107.2 | 39.4 | 4.3 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 403 | 1,022 | 35,218 | 36,047 | 2 | 11,732 | 1,603,505 | 34.4 | 2.5 | 87.4 | 34.5 | 5.5 |
| 41 to 54 years | 2,910 | 7,427 | 263,686 | 269,118 | 4 | 37,778 | 5,545,344 | 77.0 | 2.6 | 90.6 | 35.5 | 1.5 |
| 55 to 64 years | 7,452 | 19,088 | 735,751 | 737,088 | 17 | 70,899 | 10,927,818 | 105.1 | 2.6 | 98.7 | 38.5 | 2.3 |
| 65 to 74 years | 12,783 | 32,767 | 1,407,373 | 1,368,965 | 33 | 104,011 | 16,853,885 | 122.9 | 2.6 | 110.1 | 43.0 | 2.4 |
| 75 to 84 years | 14,675 | 38,239 | 1,641,955 | 1,591,992 | 72 | 118,870 | 20,610,380 | 123.5 | 2.6 | 111.9 | 42.9 | 4.5 |
| 85+ years | 5,630 | 15,347 | 604,635 | 587,770 | 25 | 79,051 | 14,504,830 | 71.2 | 2.7 | 107.4 | 39.4 | 4.3 |

Table 2b. Summary of Incident Dabigatran and Warfarin Use and ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Age Group

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New ICH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New ICH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|----------------------------------|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 155 | 328 | 10,460 | 11,481 | 0 | 11,732 | 1,602,741 | 13.2 | 2.1 | 67.5 | 31.9 | 0.0 |
| 41 to 54 years | 1,085 | 2,541 | 82,582 | 86,788 | 0 | 37,769 | 5,539,923 | 28.7 | 2.3 | 76.1 | 32.5 | 0.0 |
| 55 to 64 years | 2,525 | 6,846 | 237,727 | 238,839 | 0 | 70,881 | 10,918,470 | 35.6 | 2.7 | 94.1 | 34.7 | 0.0 |
| 65 to 74 years | 3,111 | 8,104 | 301,839 | 295,164 | 1 | 103,992 | 16,846,059 | 29.9 | 2.6 | 97.0 | 37.2 | 0.3 |
| 75 to 84 years | 2,651 | 7,158 | 272,729 | 262,057 | 3 | 118,857 | 20,603,993 | 22.3 | 2.7 | 102.9 | 38.1 | 1.1 |
| 85+ years | 922 | 2,439 | 86,414 | 84,945 | 2 | 79,040 | 14,501,050 | 11.7 | 2.6 | 93.7 | 35.4 | 2.4 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 155 | 328 | 10,460 | 11,481 | 0 | 11,732 | 1,603,515 | 13.2 | 2.1 | 67.5 | 31.9 | 0.0 |
| 41 to 54 years | 1,085 | 2,545 | 82,762 | 87,008 | 0 | 37,778 | 5,545,393 | 28.7 | 2.3 | 76.3 | 32.5 | 0.0 |
| 55 to 64 years | 2,526 | 6,852 | 237,907 | 239,008 | 0 | 70,897 | 10,928,108 | 35.6 | 2.7 | 94.2 | 34.7 | 0.0 |
| 65 to 74 years | 3,112 | 8,119 | 302,289 | 295,569 | 1 | 104,010 | 16,853,753 | 29.9 | 2.6 | 97.1 | 37.2 | 0.3 |
| 75 to 84 years | 2,651 | 7,162 | 272,849 | 262,190 | 3 | 118,876 | 20,611,567 | 22.3 | 2.7 | 102.9 | 38.1 | 1.1 |
| 85+ years | 922 | 2,441 | 86,474 | 85,025 | 2 | 79,050 | 14,505,093 | 11.7 | 2.6 | 93.8 | 35.4 | 2.4 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 401 | 1,011 | 35,089 | 36,014 | 2 | 11,712 | 1,598,561 | 34.2 | 2.5 | 87.5 | 34.7 | 5.6 |
| 41 to 54 years | 2,907 | 7,383 | 262,308 | 267,979 | 3 | 37,666 | 5,516,183 | 77.2 | 2.5 | 90.2 | 35.5 | 1.1 |
| 55 to 64 years | 7,462 | 19,061 | 735,417 | 737,201 | 11 | 70,644 | 10,854,685 | 105.6 | 2.6 | 98.6 | 38.6 | 1.5 |
| 65 to 74 years | 12,809 | 32,745 | 1,406,419 | 1,369,119 | 29 | 103,566 | 16,746,843 | 123.7 | 2.6 | 109.8 | 43.0 | 2.1 |
| 75 to 84 years | 14,686 | 38,102 | 1,637,414 | 1,591,069 | 36 | 118,366 | 20,470,688 | 124.1 | 2.6 | 111.5 | 43.0 | 2.3 |
| 85+ years | 5,639 | 15,327 | 604,357 | 588,592 | 24 | 78,694 | 14,418,056 | 71.7 | 2.7 | 107.2 | 39.4 | 4.1 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 401 | 1,014 | 35,179 | 36,110 | 2 | 11,732 | 1,603,515 | 34.2 | 2.5 | 87.7 | 34.7 | 5.5 |
| 41 to 54 years | 2,907 | 7,396 | 262,828 | 268,470 | 3 | 37,778 | 5,545,393 | 76.9 | 2.5 | 90.4 | 35.5 | 1.1 |
| 55 to 64 years | 7,465 | 19,095 | 736,666 | 738,415 | 11 | 70,897 | 10,928,108 | 105.3 | 2.6 | 98.7 | 38.6 | 1.5 |
| 65 to 74 years | 12,813 | 32,835 | 1,410,814 | 1,372,617 | 29 | 104,010 | 16,853,753 | 123.2 | 2.6 | 110.1 | 43.0 | 2.1 |
| 75 to 84 years | 14,692 | 38,184 | 1,641,772 | 1,594,265 | 36 | 118,876 | 20,611,567 | 123.6 | 2.6 | 111.7 | 43.0 | 2.3 |
| 85+ years | 5,643 | 15,375 | 606,013 | 590,054 | 24 | 79,050 | 14,505,093 | 71.4 | 2.7 | 107.4 | 39.4 | 4.1 |

Table 2c. Summary of Incident Dabigatran and Warfarin Use and GIH or ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Age Group

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH or ICH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New GIH or ICH Events/ 100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|-----------------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|---|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 155 | 328 | 10,460 | 11,481 | 0 | 11,732 | 1,602,709 | 13.2 | 2.1 | 67.5 | 31.9 | 0.0 |
| 41 to 54 years | 1,082 | 2,536 | 82,432 | 86,601 | 1 | 37,769 | 5,539,794 | 28.6 | 2.3 | 76.2 | 32.5 | 1.2 |
| 55 to 64 years | 2,521 | 6,833 | 237,337 | 238,426 | 1 | 70,881 | 10,918,189 | 35.6 | 2.7 | 94.1 | 34.7 | 0.4 |
| 65 to 74 years | 3,108 | 8,099 | 301,689 | 294,778 | 5 | 103,994 | 16,845,805 | 29.9 | 2.6 | 97.1 | 37.3 | 1.7 |
| 75 to 84 years | 2,646 | 7,141 | 271,799 | 260,916 | 11 | 118,853 | 20,602,836 | 22.3 | 2.7 | 102.7 | 38.1 | 4.2 |
| 85+ years | 919 | 2,433 | 86,234 | 84,695 | 3 | 79,038 | 14,500,255 | 11.6 | 2.6 | 93.8 | 35.4 | 3.5 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 155 | 328 | 10,460 | 11,481 | 0 | 11,732 | 1,603,483 | 13.2 | 2.1 | 67.5 | 31.9 | 0.0 |
| 41 to 54 years | 1,082 | 2,540 | 82,612 | 86,821 | 1 | 37,778 | 5,545,264 | 28.6 | 2.3 | 76.4 | 32.5 | 1.2 |
| 55 to 64 years | 2,522 | 6,839 | 237,517 | 238,595 | 1 | 70,897 | 10,927,827 | 35.6 | 2.7 | 94.2 | 34.7 | 0.4 |
| 65 to 74 years | 3,109 | 8,114 | 302,139 | 295,183 | 5 | 104,012 | 16,853,480 | 29.9 | 2.6 | 97.2 | 37.2 | 1.7 |
| 75 to 84 years | 2,646 | 7,145 | 271,919 | 261,049 | 11 | 118,872 | 20,610,410 | 22.3 | 2.7 | 102.8 | 38.1 | 4.2 |
| 85+ years | 919 | 2,435 | 86,294 | 84,775 | 3 | 79,048 | 14,504,298 | 11.6 | 2.6 | 93.9 | 35.4 | 3.5 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 399 | 1,006 | 34,729 | 35,567 | 4 | 11,728 | 1,600,744 | 34.0 | 2.5 | 87.0 | 34.5 | 11.2 |
| 41 to 54 years | 2,896 | 7,353 | 261,308 | 266,696 | 7 | 37,724 | 5,523,954 | 76.8 | 2.5 | 90.2 | 35.5 | 2.6 |
| 55 to 64 years | 7,420 | 18,953 | 731,415 | 732,149 | 27 | 70,779 | 10,881,992 | 104.8 | 2.6 | 98.6 | 38.6 | 3.7 |
| 65 to 74 years | 12,731 | 32,504 | 1,396,907 | 1,358,632 | 61 | 103,830 | 16,795,500 | 122.6 | 2.6 | 109.7 | 43.0 | 4.5 |
| 75 to 84 years | 14,602 | 37,897 | 1,629,755 | 1,580,176 | 108 | 118,735 | 20,551,205 | 123.0 | 2.6 | 111.6 | 43.0 | 6.8 |
| 85+ years | 5,608 | 15,230 | 601,034 | 583,720 | 49 | 78,933 | 14,474,750 | 71.0 | 2.7 | 107.2 | 39.5 | 8.4 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 0 to 40 years | 399 | 1,009 | 34,819 | 35,663 | 4 | 11,732 | 1,603,483 | 34.0 | 2.5 | 87.3 | 34.5 | 11.2 |
| 41 to 54 years | 2,896 | 7,366 | 261,828 | 267,187 | 7 | 37,778 | 5,545,264 | 76.7 | 2.5 | 90.4 | 35.5 | 2.6 |
| 55 to 64 years | 7,423 | 18,985 | 732,554 | 733,233 | 27 | 70,897 | 10,927,827 | 104.7 | 2.6 | 98.7 | 38.6 | 3.7 |
| 65 to 74 years | 12,735 | 32,593 | 1,401,272 | 1,362,090 | 61 | 104,012 | 16,853,480 | 122.4 | 2.6 | 110.0 | 43.0 | 4.5 |
| 75 to 84 years | 14,608 | 37,979 | 1,634,113 | 1,583,372 | 108 | 118,872 | 20,610,410 | 122.9 | 2.6 | 111.9 | 43.0 | 6.8 |
| 85+ years | 5,612 | 15,278 | 602,690 | 585,182 | 49 | 79,048 | 14,504,298 | 71.0 | 2.7 | 107.4 | 39.4 | 8.4 |

Table 3a. Summary of Incident Dabigatran and Warfarin Use and GIH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Sex

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New GIH Events/ 100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|--------------------------------------|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| Female | 3,688 | 9,835 | 351,601 | 342,605 | 8 | 181,794 | 31,883,348 | 20.3 | 2.7 | 95.3 | 35.7 | 2.3 |
| Male | 6,768 | 17,635 | 642,015 | 637,784 | 8 | 223,390 | 38,090,177 | 30.3 | 2.6 | 94.9 | 36.4 | 1.3 |
| Unknown | 4 | 13 | 390 | 450 | 0 | 177 | 35,437 | 22.6 | 3.3 | 97.5 | 30.0 | 0.0 |
| Multiple Incidence Type | | | | | | | | | | | | |
| Female | 3,688 | 9,841 | 351,781 | 342,803 | 8 | 181,804 | 31,894,560 | 20.3 | 2.7 | 95.4 | 35.7 | 2.3 |
| Male | 6,768 | 17,660 | 642,825 | 638,593 | 8 | 223,416 | 38,114,139 | 30.3 | 2.6 | 95.0 | 36.4 | 1.3 |
| Unknown | 4 | 13 | 390 | 450 | 0 | 177 | 35,437 | 22.6 | 3.3 | 97.5 | 30.0 | 0.0 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| Female | 18,549 | 49,158 | 1,985,276 | 1,943,445 | 64 | 181,662 | 31,810,957 | 102.1 | 2.7 | 107.0 | 40.4 | 3.3 |
| Male | 25,272 | 64,446 | 2,690,404 | 2,636,841 | 89 | 223,197 | 37,981,083 | 113.2 | 2.6 | 106.5 | 41.7 | 3.4 |
| Unknown | 15 | 18 | 780 | 893 | 0 | 177 | 35,203 | 84.7 | 1.2 | 52.0 | 43.3 | 0.0 |
| Multiple Incidence Type | | | | | | | | | | | | |
| Female | 18,549 | 49,273 | 1,990,222 | 1,947,716 | 64 | 181,804 | 31,894,560 | 102.0 | 2.7 | 107.3 | 40.4 | 3.3 |
| Male | 25,272 | 64,599 | 2,697,616 | 2,642,371 | 89 | 223,416 | 38,114,139 | 113.1 | 2.6 | 106.7 | 41.8 | 3.4 |
| Unknown | 15 | 18 | 780 | 893 | 0 | 177 | 35,437 | 84.7 | 1.2 | 52.0 | 43.3 | 0.0 |

Table 3b. Summary of Incident Dabigatran and Warfarin Use and ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Sex

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New ICH Events | Eligible Members | Member-Days | New Users/1K Eligible Members | Dispensings/User | Days Supplied/User | Days Supplied/Dispensing | New ICH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|-------------------------------|------------------|--------------------|--------------------------|----------------------------------|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| Female | 3,686 | 9,821 | 351,181 | 342,454 | 3 | 181,795 | 31,883,826 | 20.3 | 2.7 | 95.3 | 35.8 | 0.9 |
| Male | 6,759 | 17,582 | 640,180 | 636,370 | 3 | 223,391 | 38,091,350 | 30.3 | 2.6 | 94.7 | 36.4 | 0.5 |
| Unknown | 4 | 13 | 390 | 450 | 0 | 177 | 35,437 | 22.6 | 3.3 | 97.5 | 30.0 | 0.0 |
| Multiple Incidence Type | | | | | | | | | | | | |
| Female | 3,686 | 9,827 | 351,361 | 342,652 | 3 | 181,805 | 31,895,057 | 20.3 | 2.7 | 95.3 | 35.8 | 0.9 |
| Male | 6,759 | 17,607 | 640,990 | 637,179 | 3 | 223,417 | 38,115,312 | 30.3 | 2.6 | 94.8 | 36.4 | 0.5 |
| Unknown | 4 | 13 | 390 | 450 | 0 | 177 | 35,437 | 22.6 | 3.3 | 97.5 | 30.0 | 0.0 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| Female | 18,585 | 49,160 | 1,988,154 | 1,948,412 | 50 | 181,208 | 31,706,882 | 102.6 | 2.6 | 107.0 | 40.4 | 2.6 |
| Male | 25,305 | 64,452 | 2,692,100 | 2,640,671 | 55 | 222,608 | 37,861,382 | 113.7 | 2.5 | 106.4 | 41.8 | 2.1 |
| Unknown | 14 | 17 | 750 | 891 | 0 | 177 | 35,128 | 79.1 | 1.2 | 53.6 | 44.1 | 0.0 |
| Multiple Incidence Type | | | | | | | | | | | | |
| Female | 18,585 | 49,276 | 1,993,120 | 1,952,739 | 50 | 181,805 | 31,895,057 | 102.2 | 2.7 | 107.2 | 40.4 | 2.6 |
| Male | 25,305 | 64,606 | 2,699,402 | 2,646,301 | 55 | 223,417 | 38,115,312 | 113.3 | 2.6 | 106.7 | 41.8 | 2.1 |
| Unknown | 14 | 17 | 750 | 891 | 0 | 177 | 35,437 | 79.1 | 1.2 | 53.6 | 44.1 | 0.0 |

Table 3c. Summary of Incident Dabigatran and Warfarin Use and GIH or ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Sex

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH or ICH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New GIH or ICH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|-----------------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|---|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| Female | 3,677 | 9,799 | 350,461 | 341,407 | 11 | 181,790 | 31,882,450 | 20.2 | 2.7 | 95.3 | 35.8 | 3.2 |
| Male | 6,750 | 17,558 | 639,100 | 635,040 | 10 | 223,392 | 38,090,076 | 30.2 | 2.6 | 94.7 | 36.4 | 1.6 |
| Unknown | 4 | 13 | 390 | 450 | 0 | 177 | 35,437 | 22.6 | 3.3 | 97.5 | 30.0 | 0.0 |
| Multiple Incidence Type | | | | | | | | | | | | |
| Female | 3,677 | 9,805 | 350,641 | 341,605 | 11 | 181,800 | 31,893,662 | 20.2 | 2.7 | 95.4 | 35.8 | 3.2 |
| Male | 6,750 | 17,583 | 639,910 | 635,849 | 10 | 223,418 | 38,114,038 | 30.2 | 2.6 | 94.8 | 36.4 | 1.6 |
| Unknown | 4 | 13 | 390 | 450 | 0 | 177 | 35,437 | 22.6 | 3.3 | 97.5 | 30.0 | 0.0 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| Female | 18,469 | 48,844 | 1,976,408 | 1,933,205 | 113 | 181,658 | 31,810,226 | 101.7 | 2.6 | 107.0 | 40.5 | 5.8 |
| Male | 25,173 | 64,082 | 2,677,990 | 2,622,844 | 143 | 223,199 | 37,981,089 | 112.8 | 2.5 | 106.4 | 41.8 | 5.5 |
| Unknown | 14 | 17 | 750 | 891 | 0 | 177 | 35,203 | 79.1 | 1.2 | 53.6 | 44.1 | 0.0 |
| Multiple Incidence Type | | | | | | | | | | | | |
| Female | 18,469 | 48,958 | 1,981,324 | 1,937,462 | 113 | 181,800 | 31,893,662 | 101.6 | 2.7 | 107.3 | 40.5 | 5.8 |
| Male | 25,173 | 64,235 | 2,685,202 | 2,628,374 | 143 | 223,418 | 38,114,038 | 112.7 | 2.6 | 106.7 | 41.8 | 5.4 |
| Unknown | 14 | 17 | 750 | 891 | 0 | 177 | 35,437 | 79.1 | 1.2 | 53.6 | 44.1 | 0.0 |

Table 4a. Summary of Incident Dabigatran and Warfarin Use and GIH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Year

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New GIH Events/100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|----------------------------------|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 2010 | 881 | 3,258 | 118,230 | 119,632 | 5 | 233,897 | 13,653,694 | 3.8 | 3.7 | 134.2 | 36.3 | 4.2 |
| 2011 | 9,579 | 24,225 | 875,776 | 861,207 | 11 | 349,346 | 56,355,268 | 27.4 | 2.5 | 91.4 | 36.2 | 1.3 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 2010 | 881 | 3,258 | 118,230 | 119,632 | 5 | 233,897 | 13,653,694 | 3.8 | 3.7 | 134.2 | 36.3 | 4.2 |
| 2011 | 9,589 | 24,256 | 876,766 | 862,214 | 11 | 349,540 | 56,390,442 | 27.4 | 2.5 | 91.4 | 36.1 | 1.3 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 2010 | 11,455 | 35,489 | 1,483,828 | 1,494,100 | 51 | 233,897 | 13,653,694 | 49.0 | 3.1 | 129.5 | 41.8 | 3.4 |
| 2011 | 32,381 | 78,133 | 3,192,632 | 3,087,079 | 102 | 347,664 | 56,173,549 | 93.1 | 2.4 | 98.6 | 40.9 | 3.3 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 2010 | 11,455 | 35,489 | 1,483,828 | 1,494,100 | 51 | 233,897 | 13,653,694 | 49.0 | 3.1 | 129.5 | 41.8 | 3.4 |
| 2011 | 32,525 | 78,401 | 3,204,790 | 3,096,880 | 102 | 349,540 | 56,390,442 | 93.1 | 2.4 | 98.5 | 40.9 | 3.3 |

Table 4b. Summary of Incident Dabigatran and Warfarin Use and ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Year

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New ICH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New ICH Events/ 100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|----------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|--------------------------------------|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 2010 | 876 | 3,234 | 117,510 | 119,193 | 0 | 233,897 | 13,654,248 | 3.7 | 3.7 | 134.1 | 36.3 | 0.0 |
| 2011 | 9,573 | 24,182 | 874,241 | 860,081 | 6 | 349,352 | 56,356,365 | 27.4 | 2.5 | 91.3 | 36.2 | 0.7 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 2010 | 876 | 3,234 | 117,510 | 119,193 | 0 | 233,897 | 13,654,248 | 3.7 | 3.7 | 134.1 | 36.3 | 0.0 |
| 2011 | 9,583 | 24,213 | 875,231 | 861,088 | 6 | 349,546 | 56,391,558 | 27.4 | 2.5 | 91.3 | 36.1 | 0.7 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 2010 | 11,462 | 35,440 | 1,482,946 | 1,495,551 | 23 | 233,200 | 13,610,270 | 49.2 | 3.1 | 129.4 | 41.8 | 1.5 |
| 2011 | 32,442 | 78,189 | 3,198,058 | 3,094,423 | 82 | 346,819 | 55,993,122 | 93.5 | 2.4 | 98.6 | 40.9 | 2.6 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 2010 | 11,462 | 35,440 | 1,482,946 | 1,495,551 | 23 | 233,897 | 13,654,248 | 49.0 | 3.1 | 129.4 | 41.8 | 1.5 |
| 2011 | 32,589 | 78,459 | 3,210,326 | 3,104,380 | 82 | 349,546 | 56,391,558 | 93.2 | 2.4 | 98.5 | 40.9 | 2.6 |

Table 4c. Summary of Incident Dabigatran and Warfarin Use and GIH or ICH Events for Individuals with a Pre-Existing Condition of Atrial Fibrillation in the MSDD between October 19, 2010 to December 31, 2011, by Drug, Incidence Type, and Year

| | New Users | Dispensings | Total Days Supplied | Days at Risk | New GIH or ICH Events | Eligible Members | Member-Days | New Users/ 1K Eligible Members | Dispensings/ User | Days Supplied/ User | Days Supplied/ Dispensing | New GIH or ICH Events/ 100k Days at Risk |
|-------------------------|-----------|-------------|---------------------|--------------|-----------------------|------------------|-------------|-----------------------------------|----------------------|------------------------|------------------------------|---|
| Dabigatran | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 2010 | 876 | 3,234 | 117,510 | 118,935 | 5 | 233,888 | 13,652,857 | 3.7 | 3.7 | 134.1 | 36.3 | 4.2 |
| 2011 | 9,555 | 24,136 | 872,441 | 857,962 | 16 | 349,352 | 56,355,106 | 27.4 | 2.5 | 91.3 | 36.1 | 1.9 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 2010 | 876 | 3,234 | 117,510 | 118,935 | 5 | 233,888 | 13,652,857 | 3.7 | 3.7 | 134.1 | 36.3 | 4.2 |
| 2011 | 9,565 | 24,167 | 873,431 | 858,969 | 16 | 349,546 | 56,390,280 | 27.4 | 2.5 | 91.3 | 36.1 | 1.9 |
| Warfarin | | | | | | | | | | | | |
| Single Incidence Type | | | | | | | | | | | | |
| 2010 | 11,410 | 35,274 | 1,476,701 | 1,486,083 | 74 | 233,888 | 13,652,857 | 48.8 | 3.1 | 129.4 | 41.9 | 5.0 |
| 2011 | 32,246 | 77,669 | 3,178,447 | 3,070,857 | 182 | 347,672 | 56,173,661 | 92.7 | 2.4 | 98.6 | 40.9 | 5.9 |
| Multiple Incidence Type | | | | | | | | | | | | |
| 2010 | 11,410 | 35,274 | 1,476,701 | 1,486,083 | 74 | 233,888 | 13,652,857 | 48.8 | 3.1 | 129.4 | 41.9 | 5.0 |
| 2011 | 32,390 | 77,936 | 3,190,575 | 3,080,644 | 182 | 349,546 | 56,390,280 | 92.7 | 2.4 | 98.5 | 40.9 | 5.9 |

Appendix. ICD-9-CM Diag for ICH and GIH

| Event | Diagnosis Code | Description |
|--------------|-----------------------|---|
| GIH | | |
| | 531.0 | Acute gastric ulcer with hemorrhage |
| | 531.2 | Acute gastric ulcer with hemorrhage and perforation |
| | 531.4 | Chronic or unspecified gastric ulcer with hemorrhage |
| | 531.6 | Chronic or unspecified gastric ulcer with hemorrhage and perforation |
| | 532.0 | Acute duodenal ulcer with hemorrhage |
| | 532.2 | Acute duodenal ulcer with hemorrhage and perforation |
| | 532.4 | Chronic or unspecified duodenal ulcer with hemorrhage |
| | 532.6 | Chronic or unspecified duodenal ulcer with hemorrhage and perforation |
| | 533.0 | Acute peptic ulcer of unspecified site with hemorrhage |
| | 533.2 | Acute peptic ulcer of unspecified site with hemorrhage and perforation |
| | 533.4 | Chronic or unspecified peptic ulcer of unspecified site with hemorrhage |
| | 533.6 | Chronic or unspecified peptic ulcer of unspecified site with hemorrhage and perforation |
| | 534.0 | Acute gastrojejunal ulcer with hemorrhage |
| | 534.2 | Acute gastrojejunal ulcer with hemorrhage and perforation |
| | 534.4 | Chronic or unspecified gastrojejunal ulcer with hemorrhage |
| | 534.6 | Chronic or unspecified gastrojejunal ulcer with hemorrhage and perforation |
| | 578.0 | Hematemesis |
| ICH | | |
| | 431 | Intracerebral hemorrhage |