Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While 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 Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through 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 Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in 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).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelsystem.org.

Overview

Date Run: October 25, 2017

Request Description: The purpose of this report was to compare the frequency of diagnoses for atrial fibrillation using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) versus International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. ICD-10-CM code definitions were determined by mapping from ICD-9-CM code definitions using the Centers for Medicare and Medicaid Services (CMS) General Equivalence Mappings (GEMs). Forward-backward mapping (FBM) was used to map ICD-9-CM to ICD-10-CM codes.[1]

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.0.5

Data Source: This request was run against data from 12 Data Partners contributing to the Sentinel Distributed Database (SDD). Data from October 1, 2010 to September 30, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to September 30, 2016; 2) April 1, 2015 to September 30, 2015; and 3) April 1, 2016 to September 30, 2016. This request was distributed to Data Partners on October 25, 2017. See Appendix A for a list of dates of available data for each Data Partner.

Study Design: We examined the incidence and prevalence across the ICD-9-CM era (October 2010 - September 2015) and ICD-10-CM era (October 2015 - September 2016) in the United States. Incidence was additionally evaluated from April 2015 to September 2015 and April 2016 to September 2016. See Appendix B for specific codes used to define atrial fibrillation in this request.

Cohort Eligibility Criteria: Members included in the cohort were required to be continuously enrolled in health plans with medical and drug coverage for at least six months (183 days) before their diagnosis date, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 21-64, 65-74, 75-84, and 85-99 years.

Incident Cohorts: Members included in the incident cohorts were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to atrial fibrillation diagnosis, during which gaps in coverage of up to 45 days were allowed. Incident atrial fibrillation was defined as no previous atrial fibrillation in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-CM codes.

Prevalent Cohorts: There was no enrollment time requirement for members in the prevalent cohorts. All qualifying diagnosis codes that occurred between October 1, 2010 and September 30, 2016 were included.

Please see Appendix C for detailed specifications of parameters used in the analyses for this request.

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

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

[1]Fung, K. W., et al. (2016). "Preparing for the ICD-10-CM Transition: Automated Methods for Translating ICD Codes in Clinical Phenotype Definitions." EGEMS (Wash DC) 4(1): 1211.

Sentinel

Table of Contents

Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Tool*

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

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). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator, forms the Care Setting/PDX parameter.

- **Ambulatory Visit (AV) -** includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.
- **Emergency Department (ED) -** includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.
- **Inpatient Hospital Stay (IP) -** includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.
- **Non-Acute Institutional Stay (IS) -** includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.
- **Other Ambulatory Visit (OA) -** includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

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

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.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

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

Event Deduplication - specifies how events are counted by the MP algorithm: 0: Counts all occurrences of an HOI during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions days are added after any episode gaps have been bridged

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

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

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 365.25.

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. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

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.

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

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified 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.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1. Comparison of Incident* Atrial Fibrillation Diagnoses in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras (April 1, 2015 - September 30, 2015 and April 1, 2016 - September 30, 2016)

	Members with Diagnosis	Eligible Members	Members with Diagnosis per 1,000 Eligible Members
Atrial Fibrillation			
ICD-9-CM: April 1, 2015 - September 30, 2015			
	242,164	31,948,376	7.58
ICD-10-CM: April 1, 2016 - September 30, 2016			
	250,869	33,297,452	7.53

*Incidence defined by a 183 day washout

Figure 1. Incidence of Atrial Fibrillation Diagnoses per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 183-Day Washout

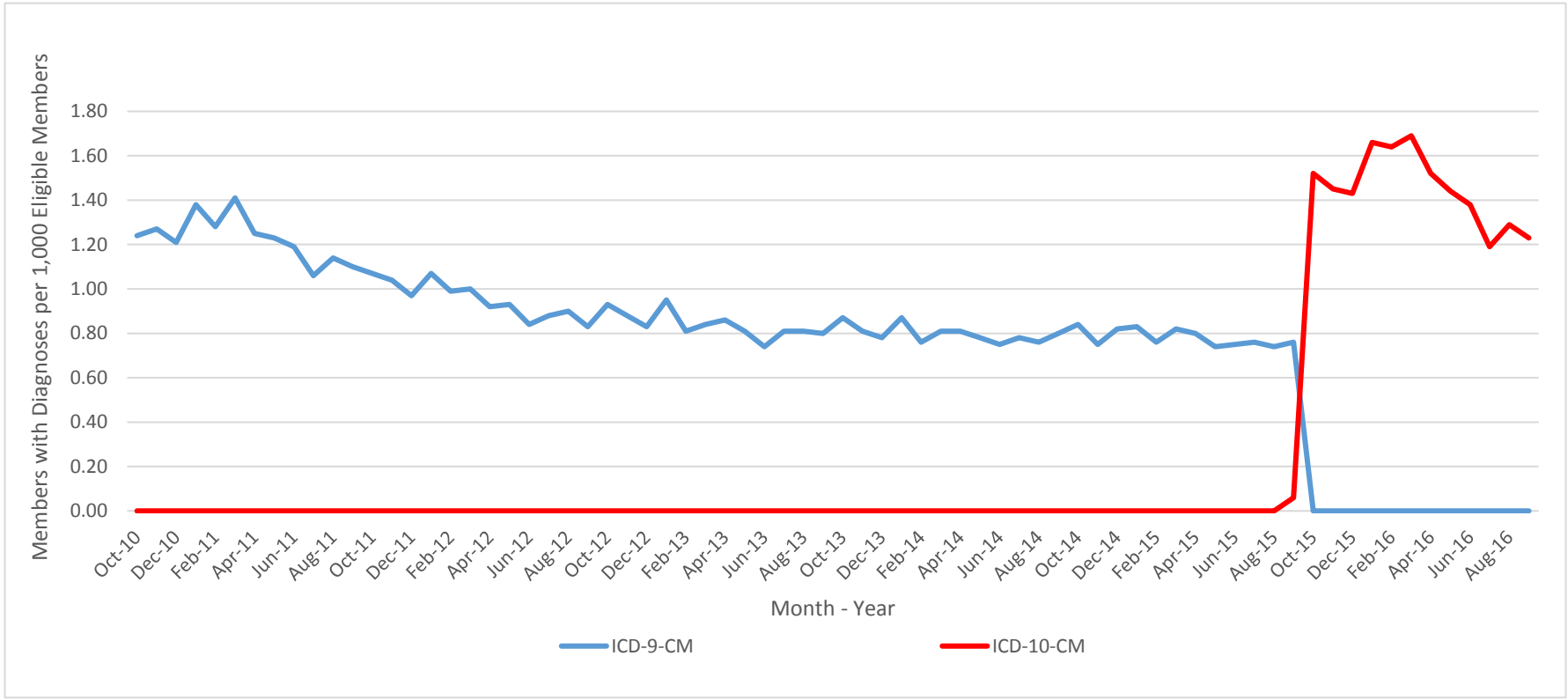
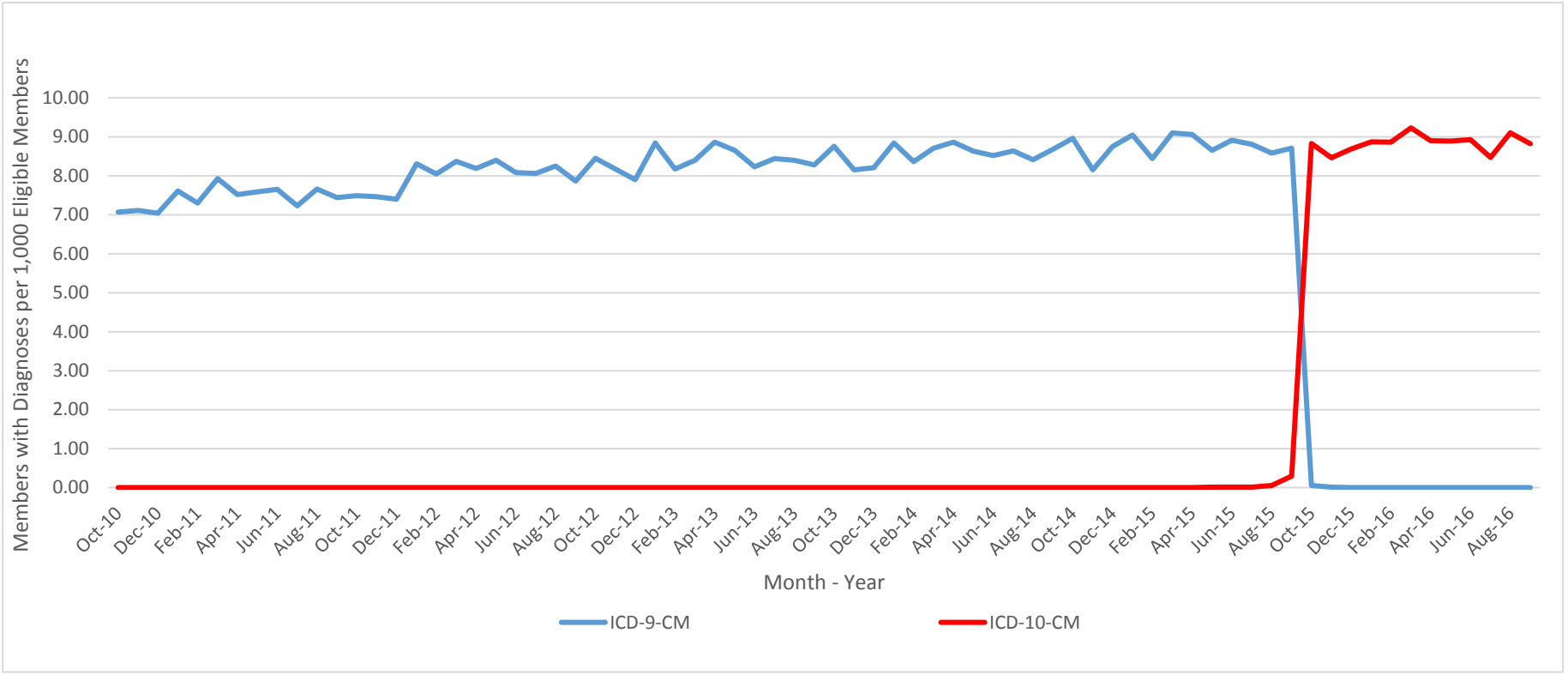


Figure 2. Prevalence of Atrial Fibrillation Diagnoses per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout



Appendix A. Dates of Available Data for Each Data Partner as of Request Distribution Date (October 25, 2017)

DP ID	Start Date[1]	End Date[1]
DP0001	10/1/2010	6/30/2016
DP0002	10/1/2010	6/30/2016
DP0003	10/1/2010	9/30/2016
DP0004	10/1/2010	9/30/2016
DP0005	10/1/2010	9/30/2016
DP0006	10/1/2010	9/30/2016
DP0007	10/1/2010	9/30/2016
DP0008	10/1/2010	9/30/2016
DP0009	10/1/2010	9/30/2016
DP0010	10/1/2010	9/30/2016
DP0011	10/1/2010	9/30/2016
DP0012	10/1/2010	9/30/2016

[1]The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Atrial Fibrillation

Code	Description	Code Type
	ICD-9-CM	
427.31	Atrial fibrillation	ICD-9-CM
427.32	Atrial flutter	ICD-9-CM
	ICD-10-CM	
I48.0	Paroxysmal atrial fibrillation	ICD-10-CM
I48.1	Persistent atrial fibrillation	ICD-10-CM
I48.2	Chronic atrial fibrillation	ICD-10-CM
I48.3	Typical atrial flutter	ICD-10-CM
I48.4	Atypical atrial flutter	ICD-10-CM
I48.91	Unspecified atrial fibrillation	ICD-10-CM
I48.92	Unspecified atrial flutter	ICD-10-CM

Appendix C. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool version 5.0.5 was used to compare the frequency of diagnoses for atrial fibrillation using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes.

Enrollment Gap: 45 days
Age Groups: 21-64, 65-74, 75-84, 85-99 years
Enrollment Requirement: 183 days for incidence scenarios; 0 days for prevalence scenarios
Coverage Requirement: Medical and drug coverage

			Event					
Scenario	**Query Start Date**	**Query End Date**	**Event**	**Event Code Type**	**Incident with Respect To:**	**Washout (days)**	**Cohort Definition**	**Care Setting**
1	4/1/2015	9/30/2015	Atrial Fibrillation	ICD-9-CM	ICD-9-CM	183	First valid event only	Any
2	4/1/2016	9/30/2016	Atrial Fibrillation	ICD-10-CM	ICD-10-CM	183	First valid event only	Any
3	10/1/2010	9/30/2016	Atrial Fibrillation	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	Any
4	10/1/2010	9/30/2016	Atrial Fibrillation	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	Any
5	10/1/2010	9/30/2016	Atrial Fibrillation	ICD-9-CM	N/A	0	Any valid events	Any
6	10/1/2010	9/30/2016	Atrial Fibrillation	ICD-10-CM	N/A	0	Any valid events	Any

ICD-9-CM and ICD-10-CM are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.