

# Early Lessons on ICD-10-CM/PCS Transition in Claims-Based Drug Safety Assessments

**Ting-Ying Jane Huang, PhD**

Research Scientist

Department of Population Medicine

Harvard Medical School and Harvard Pilgrim Health Care Institute

8/26/2018

# Disclosure

- This study was supported by the U.S. Food and Drug Administration (FDA) through the Department of Health and Human Services Contract No. HHSF223201400030I
- Conflicts of interest: none for all authors

# Disclaimer

- The views expressed in this presentation are the authors' and do not necessarily reflect the views of the U.S. FDA

# Acknowledgements

DEPARTMENT OF POPULATION MEDICINE



**HARVARD**  
MEDICAL SCHOOL



Harvard Pilgrim  
Health Care Institute



**U.S. FOOD & DRUG**  
ADMINISTRATION

## Co-author

- Emily C. Welch

## Additional support

- Tancy Zhang
- Michael Dizinno

## Co-authors

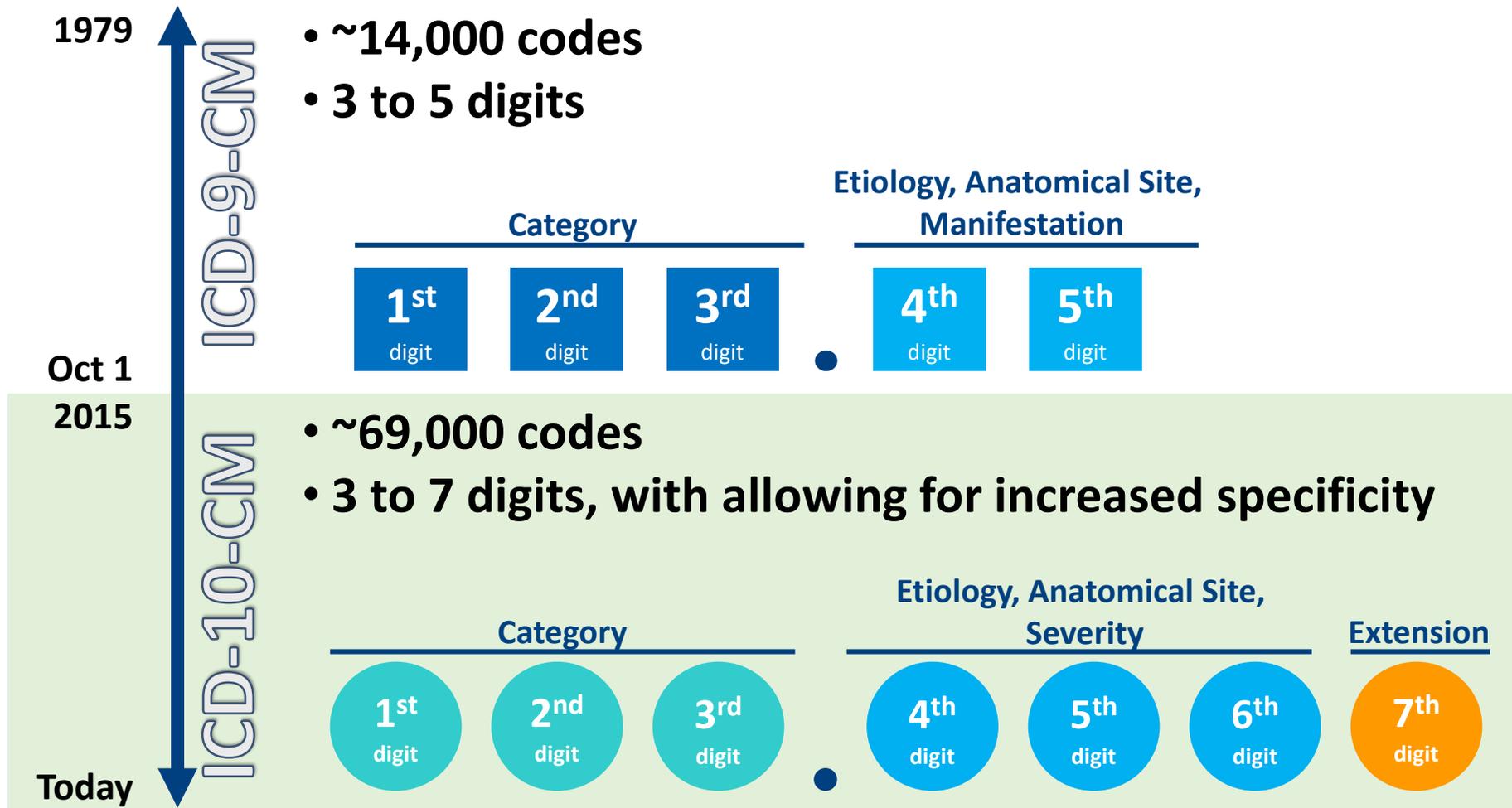
- Marie Bradley
- Rongmei Zhang
- Margie Goulding
- David J. Graham

# Impact of ICD-10-CM Transition on Selected Cardiovascular-Related Events in the Sentinel System

Tiffany Siu Woodworth, MPH,  
Catherine A. Panozzo, PhD, Emily C. Welch, MPH,  
Ting-Ying Jane Huang, PhD, BSPHarm, Qoua L. Her, PharmD, MSc,  
Catherine Rogers, MPH, Max Ehrmann, MPH, Talia Menzin,  
Nicole Haug, MPH, Katherine Freitas, Sengwee Darren Toh, ScD

*Harvard Pilgrim Health Care Institute, Boston, MA, USA*

# Transitioning to ICD-10-CM in the U.S.



[www.roadto10.org/icd-10-basics](http://www.roadto10.org/icd-10-basics)

# Sentinel System

[sentinelinitiative.org](https://sentinelinitiative.org)

- A component of the U.S. FDA Sentinel Initiative
- Active surveillance system to monitor regulated products
  - Pre-existing electronic healthcare data from multiple sources
  - Routine querying tools (pre-tested, parameterizable *modular programs*)
- Sentinel Distributed Database
  - 66.9 million members with medical and drug coverage currently accruing new data
  - 14.4 billion pharmacy dispensings
  - 13.3 billion medical encounters



# Background

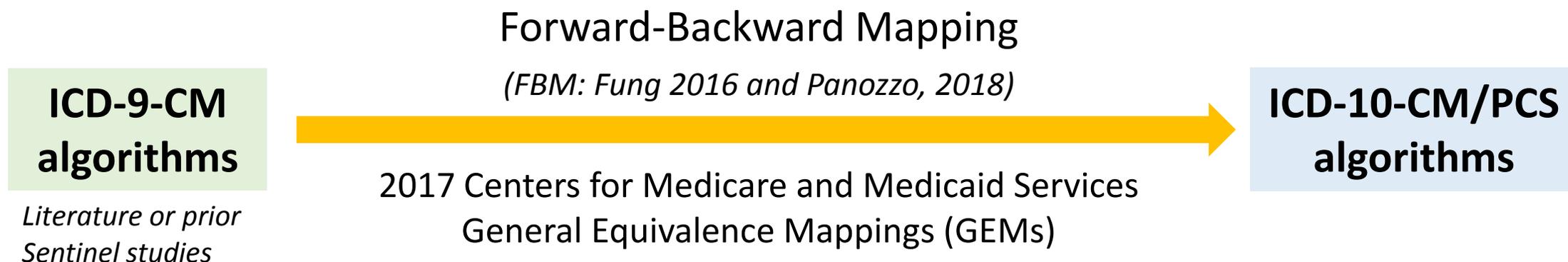
- Need for a systematic approach to rapidly assess use of previously validated ICD-9-CM algorithms in newer data encoded with ICD-10-CM/PCS codes
  - ICD: International Classification of Diseases
  - ICD-9-CM: ICD, 9<sup>th</sup> Revision, Clinical Modification
  - ICD-10-CM: ICD, 10<sup>th</sup> Revision, Clinical Modification
  - ICD-10-PCS: ICD, 10<sup>th</sup> Revision, Procedure Coding System

## Study Objective

- To explore methods for crude evaluation of algorithm performance in identifying medical conditions across the ICD eras

# Methods

- Data: MarketScan<sup>®</sup> Databases (converted to Sentinel Common Data Model)
- Sentinel tool used: Cohort Identification and Descriptive Analysis v5.4.3
- Test case: medical conditions commonly examined in anticoagulant safety studies and identifiable by diagnosis and procedure codes recorded in claims
  1. Outcome: gastrointestinal bleeding (GIB), intracranial hemorrhage (ICH)
  2. Inclusion: atrial fibrillation (AFib)
  3. Exclusion: dialysis (outpatient care setting only; Dia), deep vein thrombosis (DVT), and joint replacement (JntR)



*Literature or prior  
Sentinel studies*

# Forward-Backward Mapping

## Ischemic stroke example

1. Utilize GEMs forward mapping files
2. Map ICD-9-CM codes 434.91 to ICD-10-CM codes I63.50
3. Utilize GEMs backward mapping files
4. Find ICD-10-CM codes pointing back to 434.91
5. Define FBM algorithm using ICD-10-CM codes found in Steps 2 and 4

[www.sentinelinitiative.org/sentinel/methods/building-internal-processes-and-planning-validation-activities-related-use-icd-10](http://www.sentinelinitiative.org/sentinel/methods/building-internal-processes-and-planning-validation-activities-related-use-icd-10)

[www.cms.gov/Medicare/Coding/ICD10/2017-ICD-10-CM-and-GEMs.html](http://www.cms.gov/Medicare/Coding/ICD10/2017-ICD-10-CM-and-GEMs.html)

GEMs Forward Mapping File		
ICD-9-CM	ICD-10-CM	Flag
43490	I669	10000
43491	I6350	10000
4350	G450	10000
4351	G450	10000

GEMs Backward Mapping File		
ICD-10-CM	ICD-9-CM	Flag
I6349	43411	10000
I6350	43491	10000
I63511	43491	10000
I63512	43491	10000
I63513	43491	10000
I63519	43491	10000
I63521	43491	10000
I63522	43491	10000
I63523	43491	10000
I63529	43491	10000
I63531	43491	10000
I63532	43491	10000
I63533	43491	10000
I63539	43491	10000
I63541	43491	10000
I63542	43491	10000
I63543	43491	10000
I63549	43491	10000
I6359	43331	10000

# Methods

- Per condition, conduct two analyses that separately identifies
  1. Members with a qualifying ICD-9-CM code
  2. Members with a qualifying ICD-10-CM/PCS code
- For each analysis, visualize trend in monthly occurrence per 1,000 eligible members of the following:

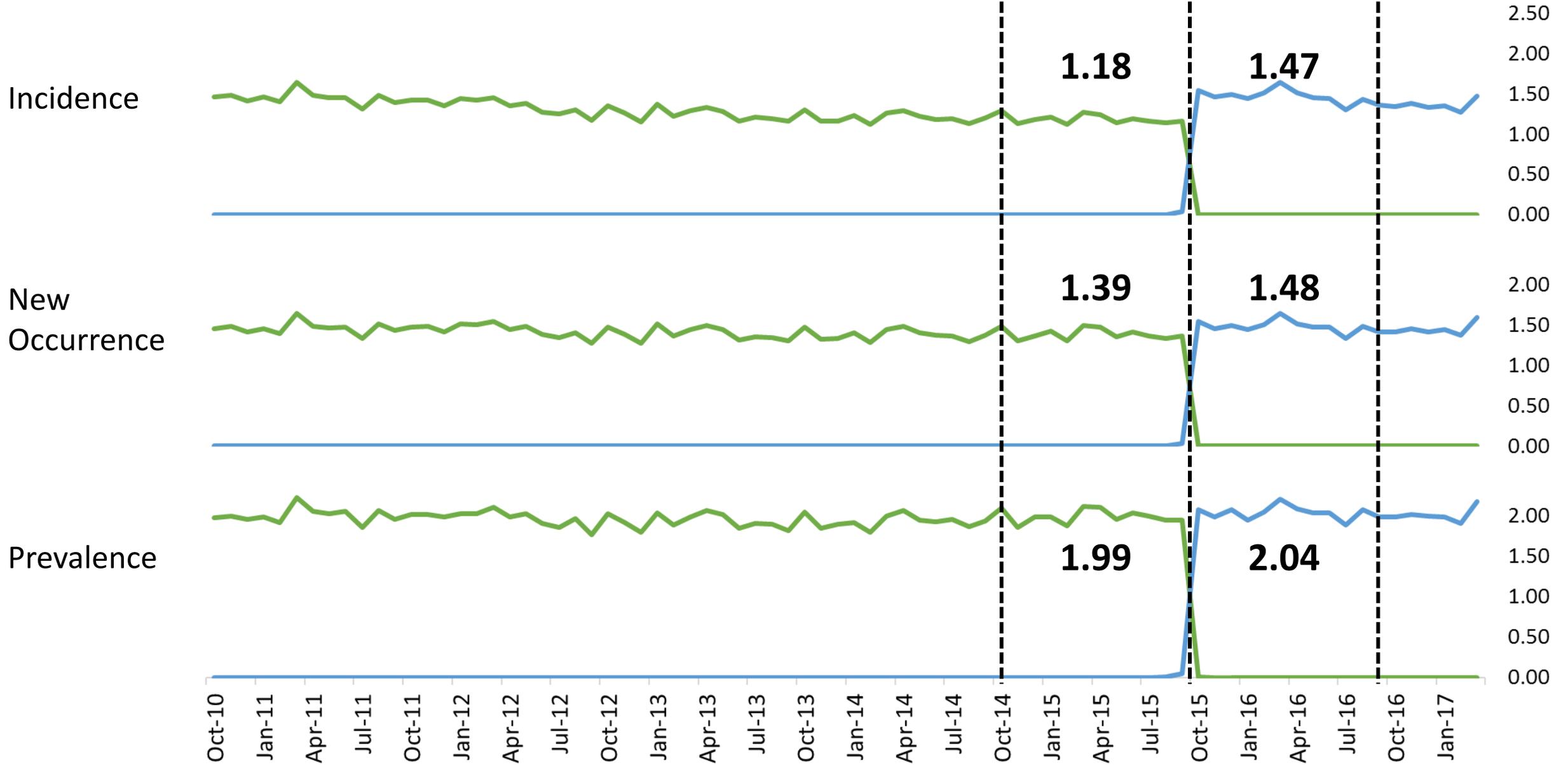
	Washout period	Washout codes	Observation sequence	Cohort re-entry
<b>Incidence</b>	183 days	ICD-9-CM and ICD-10-CM/PCS	1 <sup>st</sup>	No
<b>New occurrence</b>	183 days		Any	Yes
<b>Prevalence</b>	None		Any	Yes

# Results

# GIB

— ICD-9-CM codes (algorithm)  
— ICD-10-CM codes (FBM results)

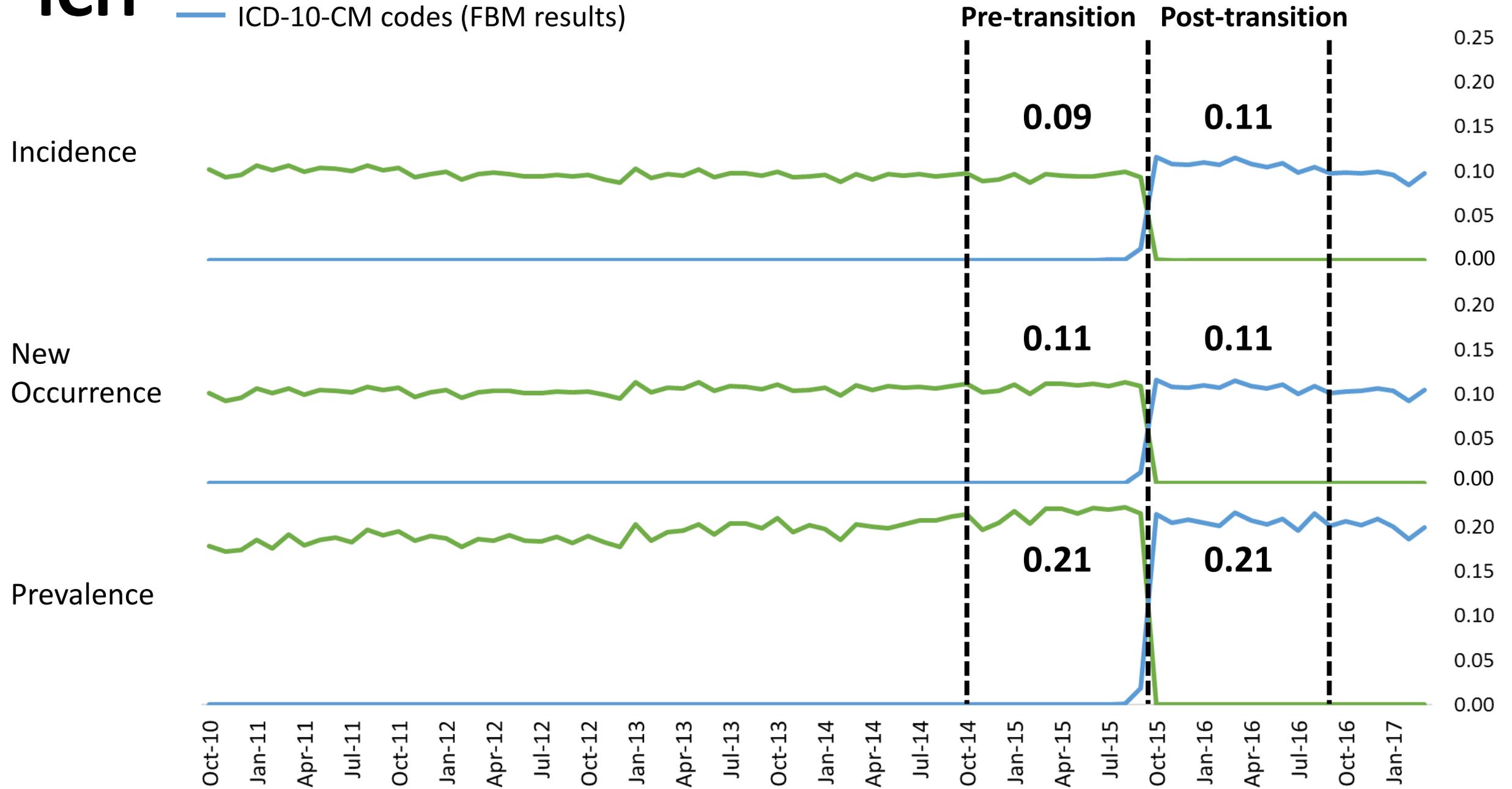
## Occurrence per 1,000 Eligible Members (12-month average)



# ICH

- ICD-9-CM codes (algorithm)
- ICD-10-CM codes (FBM results)

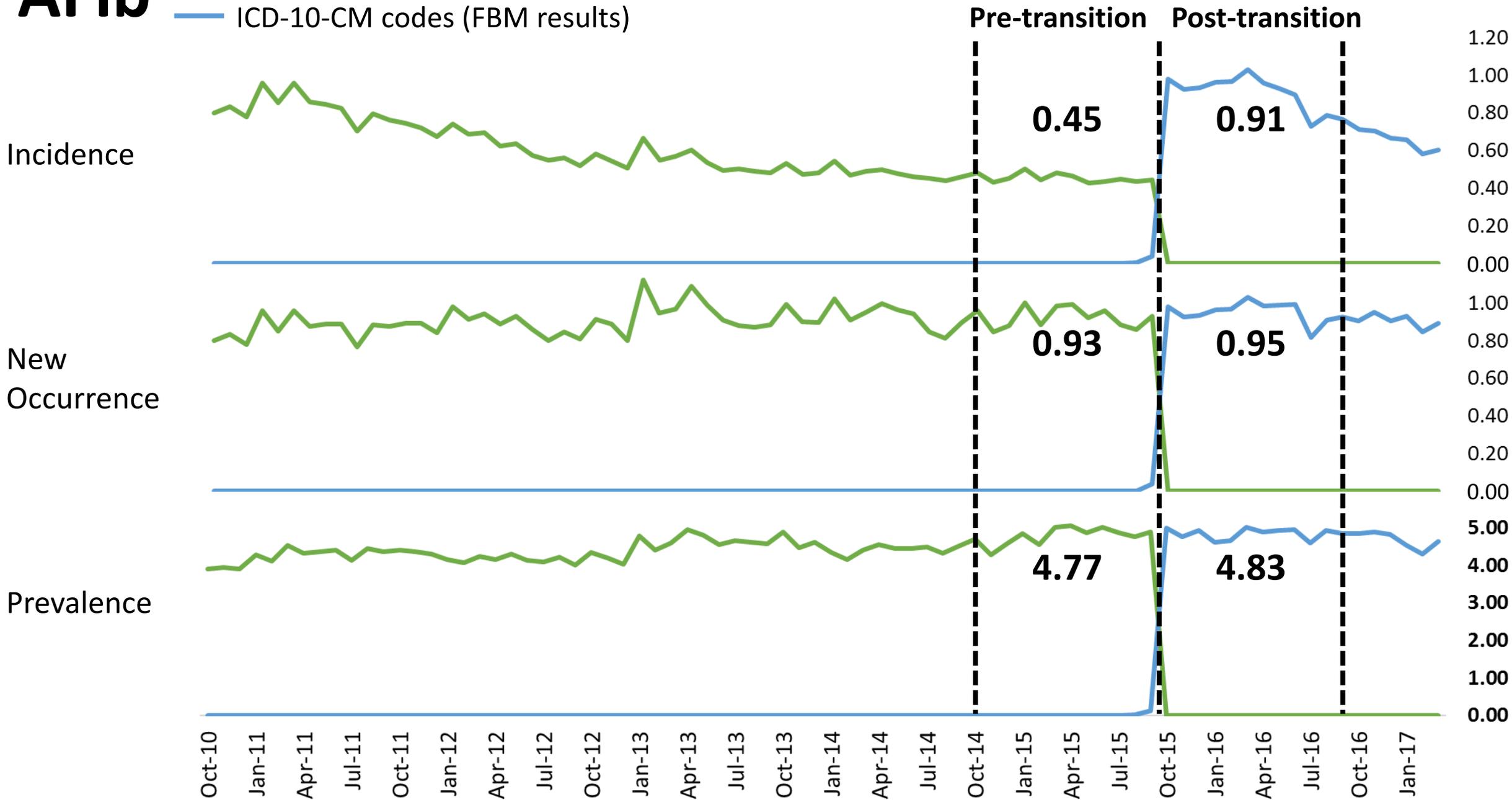
## Occurrence per 1,000 Eligible Members (12-month average)



# AFib

- ICD-9-CM codes (algorithm)
- ICD-10-CM codes (FBM results)

## Occurrence per 1,000 Eligible Members (12-month average)

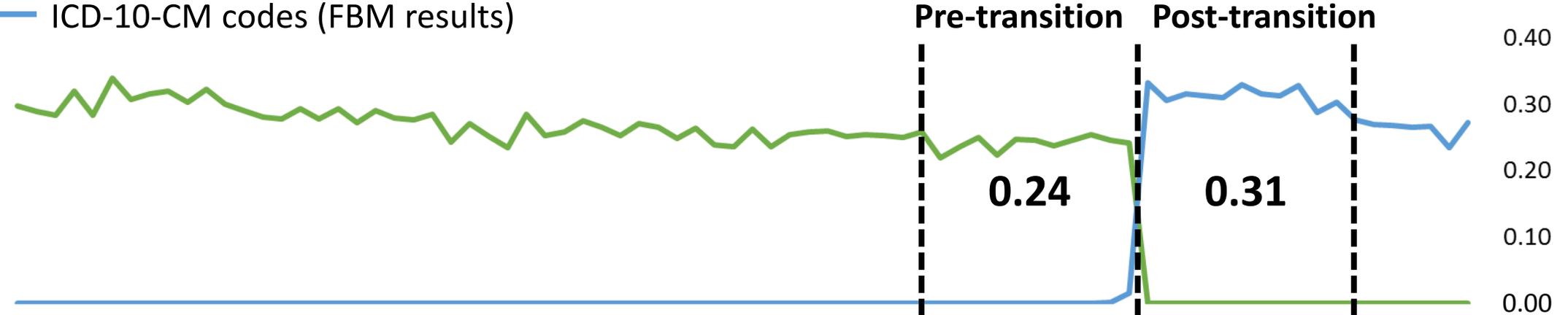


# DVT

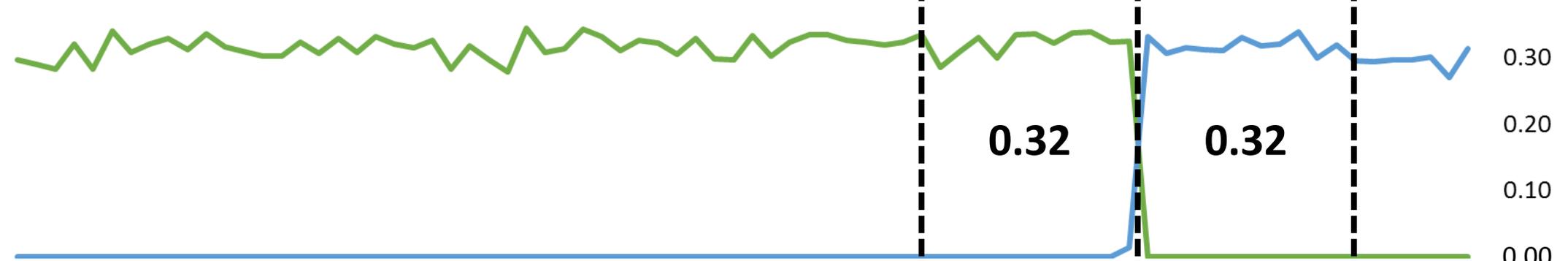
— ICD-9-CM codes (algorithm)  
— ICD-10-CM codes (FBM results)

## Occurrence per 1,000 Eligible Members (12-month average)

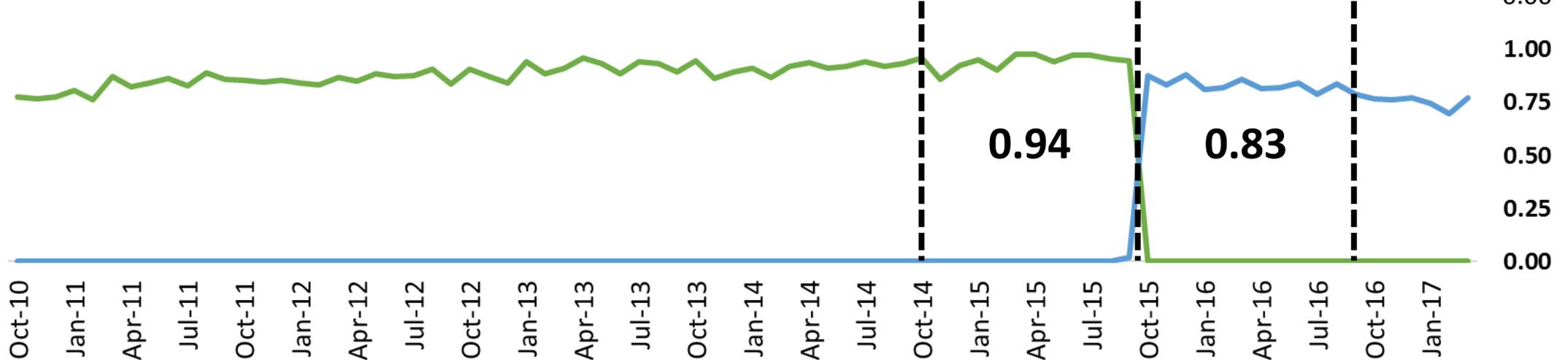
Incidence



New Occurrence



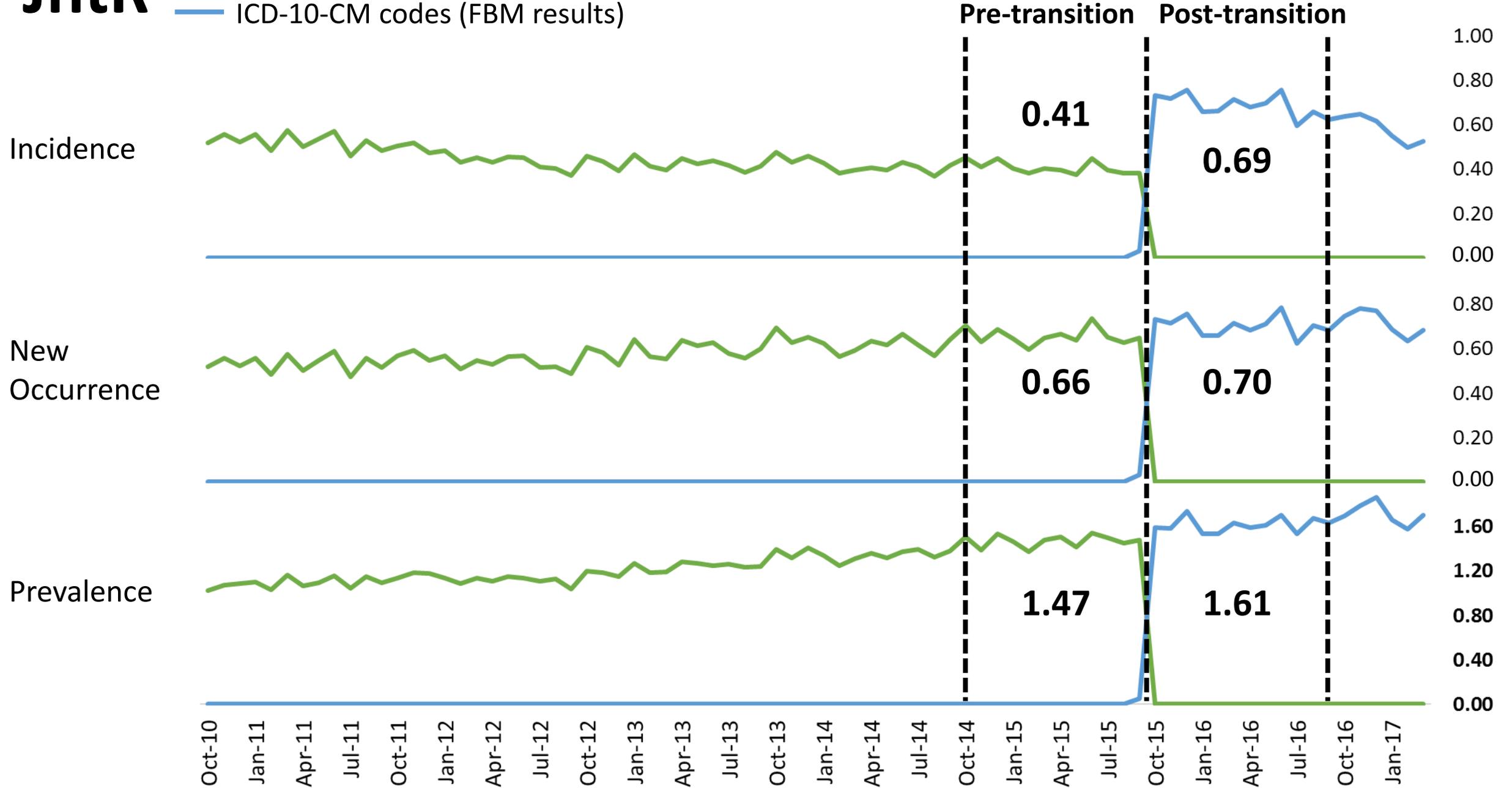
Prevalence



# JntR

— ICD-9-CM codes (algorithm)  
— ICD-10-CM codes (FBM results)

## Occurrence per 1,000 Eligible Members (12-month average)



# Dia

ICD-9-CM

ICD-10-CM

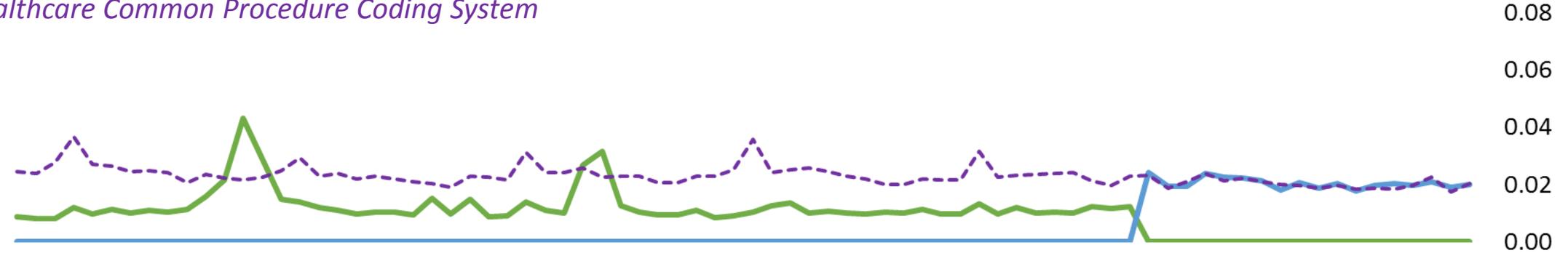
HCPCS



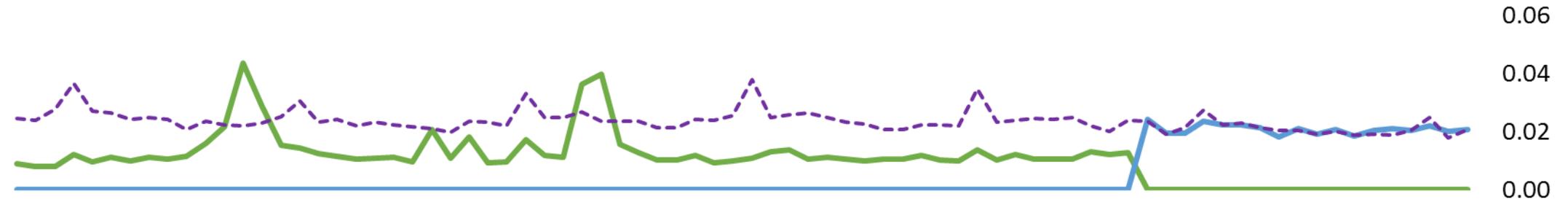
*Healthcare Common Procedure Coding System*

## Occurrence per 1,000 Eligible Members

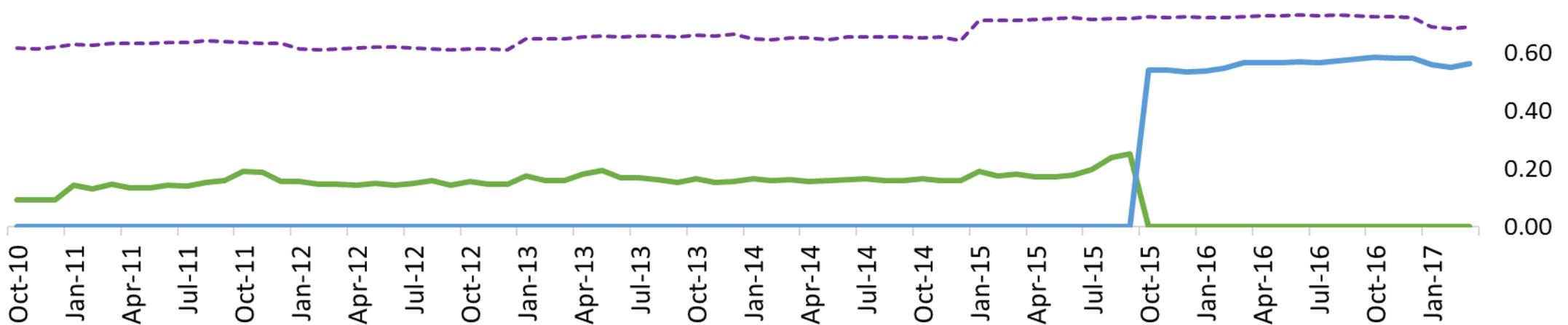
Incidence



New Occurrence



Prevalence



# Dia

ICD-9-CM

HCPCS

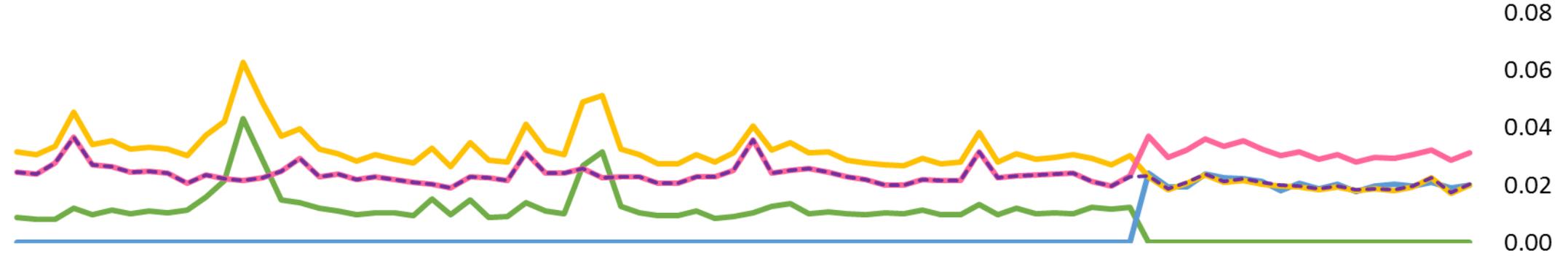
ICD-9-CM/HCPCS

## Occurrence per 1,000 Eligible Members

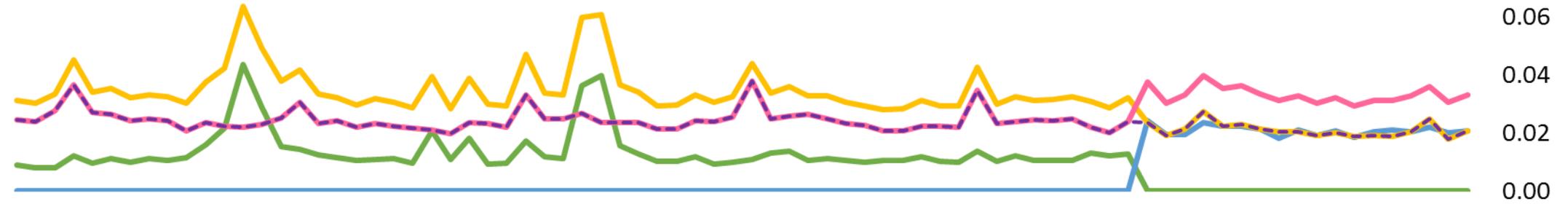
ICD-10-CM

ICD-10-CM/HCPCS

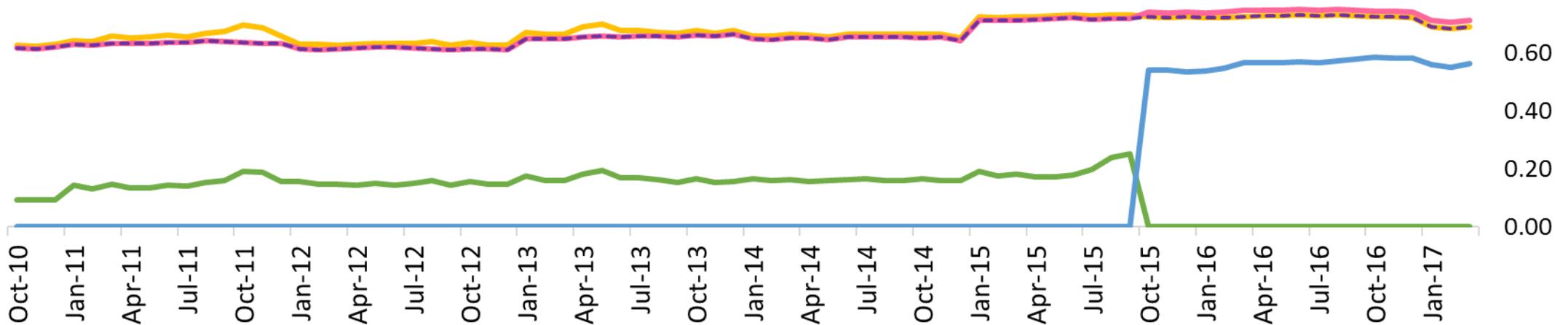
### Incidence



### New Occurrence



### Prevalence



# Dia

ICD-9-CM

HCPCS

ICD-9-CM/HCPCS

Occurrence per 1,000 Eligible Members (12-month average)

ICD-10-CM

ICD-10-CM/HCPCS

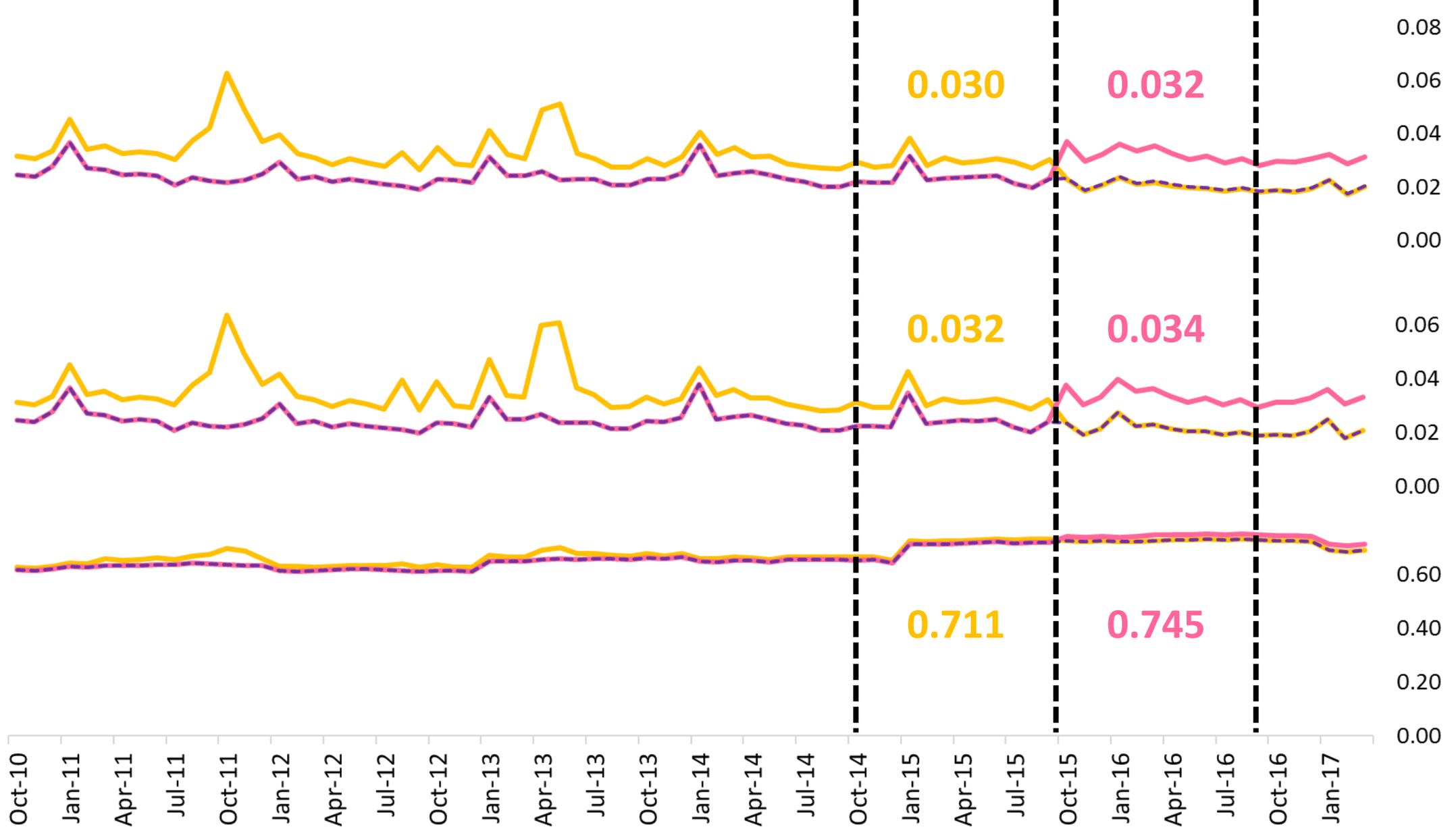
Pre-transition

Post-transition

Incidence

New Occurrence

Prevalence



# Summary

- *Incidence*: moderate-to-high increases after ICD transition
  - Trends affected by left-censoring in the beginning of each ICD era
- *New occurrence*: attenuated increases from *incidence* findings
- *Prevalence*: mostly consistent across ICD transition time
  - DVT changed from increasing to decreasing trend after ICD transition
- Dialysis
  - A condition more frequently identified by procedure codes than diagnosis codes
  - Trends aligned better when using
    - 1) non-ICD procedure codes only (not affected by ICD transition), or
    - 2) both mapped ICD diagnosis and non-ICD procedure codes

# Strengths

- A systematic approach to rapidly assessing use of previously validated ICD-9-CM algorithms in newer data encoded with ICD-10-CM/PCS codes
- A fast solution to trend evaluation of medical condition occurrence in database population
- Ready for implementation in Sentinel System (or any dataset transformed to Sentinel Common Data Model)

# Limitations

- Study results may not be generalizable to algorithm-mapping schemes other than Forward-Backward Mapping via CMS GEMs
- Our study method did not involve formal statistical tests on data trends

# Recommendations

- A simple algorithm performance check, such as methods proposed by this study, is a necessary step before using data crossing the ICD eras
- A trend analysis on *prevalence* is highly recommended in general
- A trend analysis on *new occurrence* is preferred, when application of a washout period prior to code occurrence is of interest
- For conditions more frequently coded by non-ICD procedure codes, both the mapped results and the non-ICD procedure codes are recommended to be used in trend analyses

**Questions?**