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Health outcomes coding trends in the US Food and Drug Administration's Sentinel System during transition to International Classification of Diseases-10 coding system: A brief review

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[Correction added on 20 March 2021, after first online publication: The first author name has been corrected to Young Hee Nam in this version.]

Abstract

Background and purpose: The transition from International Classification of Diseases, 9th revision, clinical modification (ICD-9-CM) to ICD-10-CM poses a challenge to epidemiologic studies that use diagnostic codes to identify health outcomes and covariates. We evaluated coding trends in health outcomes in the US Food and Drug Administration's Sentinel System during the transition.

Methods: We reviewed all health outcomes coding trends reports on the Sentinel website through November 30, 2019 and analyzed trends in incidence and prevalence across the ICD-9-CM and ICD-10-CM eras by visual inspection.

Results: We identified 78 unique health outcomes (22 acute, 32 chronic, and 24 acute or chronic) and 140 time-series graphs of incidence and prevalence. The reports also included code lists and code mapping methods used. Of the 140 graphs reviewed, 81 (57.9%) showed consistent trends across the ICD-9-CM and ICD-10-CM eras, while 51 (36.4%) and 8 (5.7%) graphs showed inconsistent and uncertain trends, respectively. Chronic HOIs and acute/chronic HOIs had higher proportions of consistent trends in prevalence definitions (83.9% and 78.3%, respectively) than acute HOIs (28.6%). For incidence, 55.6% of acute HOIs showed consistent trends, while 41.2% of chronic HOIs and 39.3% of acute/chronic HOIs showed consistency.

Conclusions: Researchers using ICD-10-CM algorithms obtained by standardized mappings from ICD-9-CM algorithms should assess the mapping performance before use. The Sentinel reports provide a valuable resource for researchers who need to develop and assess mapping strategies. The reports could benefit from additional information about the algorithm selection process and additional details on monthly incidence and prevalence rates.

Key points

- We reviewed health outcomes coding trends reports on the US FDA Sentinel website through November 30, 2019 and analyzed trends in incidence and

prevalence across the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) and ICD-10-CM eras by code mapping method and the type of health outcomes of interest (acute, chronic, acute or chronic).

- More than a third of the 140 time-series graphs of incidence and prevalence of health outcomes showed inconsistent or uncertain trends. Consistency in trends varied by code mapping method, type of health outcomes of interest, and whether the measurement was incidence or prevalence.
- Studies using ICD-9-CM-based algorithms mapped to ICD-10-CM codes need to assess the performance of the mappings and conduct manual refinement of the algorithms as needed before using them.

KEYWORDS

administrative health care claims, code mapping, coding trends, health outcomes, incidence, International Classification of Diseases, 9th revision and 10th revision (ICD-9, ICD-10), prevalence, US FDA Sentinel

1 | INTRODUCTION

Accurate identification of health outcomes of interest (HOIs) is critical in analyses of medical product use, effectiveness, and safety that use administrative health care claims and electronic health record data. The transition from the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) coding system to ICD-10-CM in the United States in October 2015 created a knowledge gap due to a lack of validated ICD-10-CM algorithms in US-based data. Since the transition to ICD-10-CM, the US Food and Drug Administration (FDA)'s Sentinel System ("Sentinel"), a national electronic surveillance system for monitoring the performance of FDA-regulated medical products,[1] has routinely conducted ICD-9-CM to ICD-10-CM mappings and trend analyses of incidence and prevalence of HOIs ("coding trend analyses"), and provided reports ("trend reports") to the Sentinel website.[2] The trend reports include time-series graphs of monthly incidence and prevalence of HOIs across the ICD-9-CM and ICD-10-CM eras and methods used for analyses, including ICD code lists and HOI phenotype definitions. The reports use standardized mapping approaches from the Centers for Medicare and Medicaid Services (CMS).[3]

These Sentinel HOI coding trend reports are an important resource for public health researchers. They can also be used for purposes such as analyzing trends in counts or rates (such as frequency, incidence and prevalence) of health outcomes that span before and after the ICD-10-CM transition; constructing homogeneous study cohorts; comparing study results across ICD-9-CM and ICD-10-CM eras; exploring feasibility of future studies; and detecting potential changes in health outcomes coding practices.

This study analyzes the publicly available Sentinel HOI trend reports to assess patterns in the performance of mapping approaches.

2 | METHODS

We reviewed all HOI coding trend analyses reports published on the Sentinel website[2] through November 30, 2019 (n = 78) and summarized data and methods used in the analyses. We categorized HOIs into acute, chronic, and acute or chronic based on the descriptors of ICD codes listed in the reports, that is, whether the descriptors refer to only acute conditions (e.g., acute myocardial infarction), only chronic conditions (e.g., type 2 diabetes mellitus), or acute or chronic conditions (e.g., ischemic heart disease). Additionally, we characterized trends in the incidence and prevalence of HOIs across the ICD-9-CM and ICD-10-CM eras as consistent, inconsistent, or uncertain trends based on visual inspection of the time-series graphs. Visual inspection was used because the time-series data were only presented graphically; the monthly data values were not included in the reports. We considered slopes of linear trends, patterns of periodicity (e.g., seasonality), magnitudes of variation over time, and irregularity/ambiguousness in patterns, without use of specific numeric thresholds, to assess consistency of trends.

Data sources used in the reports were (a) IBM® MarketScan® Research Databases Commercial Claims and Encounters Database and Medicare Supplemental Database (IBM MarketScan) and (b) Sentinel Distributed Database.[4] These databases are similar in enrolled members' demographic characteristics, health plan enrollment characteristics (e.g., medical or drug coverage), and health care utilization characteristics.[5]

We extracted information from each report and characterized HOIs (consistency in incidence/prevalence trend, data source, query end date, etc.) by HOI phenotype, operationally defined as a combination of (a) measurement of interest, that is, incidence or prevalence, and (b) ICD-9-CM to ICD-10-CM mapping method, that is, simple forward mapping (SFM) or forward-backward mapping (FBM).[3] For example, the report of "allergic reactions"[6] provided information for four HOI definitions; that is, incidence using SFM; incidence using FBM; prevalence using SFM; and prevalence using FBM. Age groups, care setting, wash-out period for incidence, and period of analyses also were extracted and reviewed.

TABLE 1 Consistency of trends in monthly incidence and prevalence of health outcomes of interest across ICD-9-CM and ICD-10 CM eras in the FDA Sentinel reports

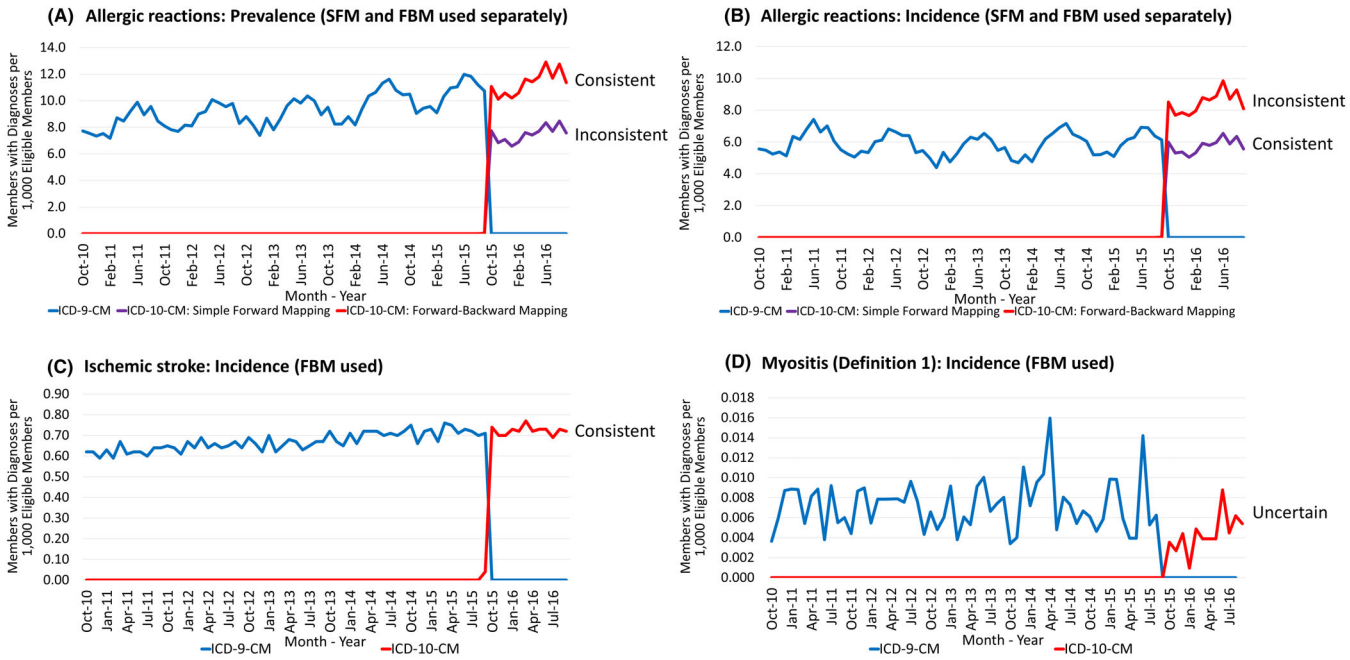
	Acuteness of HOI[a]			
	Acute	Chronic	Acute/chronic	Total
Number of HOI Definitions (% of column)	41 (100.0)	48 (100.0)	51 (100.0)	140 (100.0)
Consistent[b]	19 (46.3)	33 (68.8)	29 (56.9)	81 (57.9)
Inconsistent[b]	19 (46.3)	12 (25.0)	20 (39.2)	51 (36.4)
Uncertain[b]	3 (7.3)	3 (6.3)	2 (3.9)	8 (5.7)
Incidence, number of HOI (% of column)	27 (100.0)	17 (100.0)	28 (100.0)	72 (100.0)
Consistent	15 (55.6)	7 (41.2)	11 (39.3)	33 (45.8)
Inconsistent	11 (40.7)	8 (47.1)	15 (53.6)	34 (47.2)
Uncertain	1 (3.7)	2 (11.8)	2 (7.1)	5 (6.9)
Prevalence, number of HOI (% of column)	14 (100.0)	31(100.0)	23 (100.0)	68 (100.0)
Consistent	4 (28.6)	26 (83.9)	18 (78.3)	48 (70.6)
Inconsistent	8 (57.1)	4 (12.9)	5 (21.7)	17 (25.0)
Uncertain	2 (14.3)	1 (3.2)	0 (0.0)	3 (4.4)

Note: FDA Sentinel reports posted on the Sentinel website through November 30, 2019 were analyzed. The sum of percentages within a category may not be 100.0% because of rounding.

Abbreviations: FBM, forward-backward mapping; FDA, Food and Drug Administration; HOI, health outcome of interest; ICD-10-CM, International Classification of Diseases, 10th revision, clinical modification; ICD-9-CM, International Classification of Diseases, 9th revision, clinical modification; SFM, simple forward mapping.

[a]Acuteness of HOIs was determined by authors based on the descriptors of the codes listed in the Sentinel reports.

[b]We determined consistency in the rates based on visual inspection of graphs presented in the Sentinel reports.



FBM: Forward-backward mapping. FDA: Food and Drug Administration. ICD-9-CM: International Classification of Diseases, 9th revision, Clinical Modification. ICD-10-CM: International Classification of Diseases, 10th revision, Clinical Modification. SFM: Simple forward mapping.
Note: Graphs are screen captures of the Sentinel reports. To improve the quality of the figure, the line width of graphs and fonts of axis labels and titles, and legends are increased.
Source: FDA Sentinel Coding Trend Analyses. https://www.sentinelinitiative.org/sentinel/surveillance-tools/validations-lit-review.[6-8]

FIGURE 1 Examples of determination by visual inspection of consistency in incidence or prevalence trend of health outcomes across ICD-9-CM and ICD-10-CM eras in the FDA Sentinel trend reports. FBM, forward-backward mapping; FDA, Food and Drug Administration; ICD-10-CM, International Classification of Diseases, 10th revision, clinical modification; ICD-9-CM, International Classification of Diseases, 9th revision, clinical modification; SFM, simple forward mapping. *Source:* US Food and Drug Administration Sentinel. Health outcome of interest validation and literature reviews. Coding trend analyses. https://www.sentinelinitiative.org/sentinel/surveillance-tools/validations-lit-review[6-8] [Colour figure can be viewed at wileyonlinelibrary.com]

3 | RESULTS

Of the 78 HOIs, 22 were acute HOIs, 32 chronic HOIs, and 24 acute or chronic HOIs (Table S1). The IBM MarketScan Database was used for 59 (75.6%) HOIs, and Sentinel Distributed Database was used for 19 (24.4%) HOIs. For all HOIs, the query start date was October 1, 2010, and the query end date varied from March 31, 2016 to March 31, 2018. The FBM approach was used for most HOIs; SFM was used for 13 HOI definitions, including eight for incidence and five for prevalence, and all analyses using SFM were conducted earlier in the period of ICD-10-CM transition (i.e., pre 2018). The incidence definition used a 183-day wash-out, and about 9% of the HOI definitions were limited to the inpatient setting.

The 78 reports presented graphs of monthly incidence, prevalence, or both for a total of 140 HOI definitions (i.e., 140 time-series graphs). Table 1 presents the number of HOI definitions with consistent, inconsistent, and uncertain trends based on visual inspection. Of the 140 graphs, 81 (57.9%) showed consistent trends, while 51 (36.4%) and 8 (5.7%) showed inconsistent and uncertain trends, respectively. Overall, prevalence definitions were more commonly found to be consistent (70.6% consistent) compared to incidence definitions (45.8%). Chronic HOIs and acute/chronic HOIs had higher proportions of consistent trends in prevalence definitions (83.9% and 78.3%, respectively) than acute HOIs (28.6%). For incidence, 55.6% of acute HOIs showed consistent trends, while 41.2% of chronic HOIs and 39.3% of acute/chronic HOIs showed consistency.

Figure 1 presents examples of time-series graphs that were used to assess consistency in HOI incidence and prevalence trends across ICD-9-CM and ICD-10-CM eras. Panel A shows prevalence of allergic reactions with two different mapping approaches; the FBM appears consistent with the ICD-9-CM trend whereas the SFM generates an inconsistent trend line as compared to the ICD-9-CM era.[6] Panel B shows incidence of allergic reactions with the same two mapping approaches, but in this case the FBM appears inconsistent with the ICD-9-CM era trend whereas the SFM generates a more consistent trend line.[6] Panel C shows incidence of ischemic stroke with FBM generating a consistent trend (consistent in prevalence as well; not shown).[7] Finally, Panel D shows incidence of myositis with FBM as an example of uncertain trends.[8]

4 | DISCUSSION

We reviewed coding trend analyses reports on the FDA Sentinel website and examined the consistency in trends in incidence and prevalence across the ICD-9-CM and ICD-10-CM eras. More than a third of the standardized code mappings appeared to produce inconsistent or uncertain trends. In addition, we noted potentially important differences in performance based on the type of HOIs and whether the definition was incidence or prevalence. Our findings suggest that all studies using ICD-9-CM-based algorithms mapped to ICD-10-CM codes should assess the performance of the mapping and undertake detailed reviews before using them. Although prior studies found that FBM may be generally more sensitive compared to SFM,[2,9-11] our findings argue for careful review of all mapping approaches. Notably, a mapping method that is generally better than others may not be the best for all HOIs. Mapping methods should be customized for individual studies and specific HOIs. Also, consistency in incidence and prevalence trends may be influenced by multiple factors, including parameters in study design, such as cohort re-entry conditions, length of wash-out period, care settings examined (e.g., inpatient, emergency department, outpatient), and code position in claims (e.g., primary position, any position), in addition to the performance of ICD code algorithms/code mappings and the granularity of ICD codes, which warrants further studies. With longer-term post-transition data, determination of consistency in trends will become more reliable.

An important study limitation was that we were only able to use visual inspection of time-series graphs to determine consistency in trends, which was challenged by the fact that the unit of incidence or prevalence in the graphs varied; e.g., members with diagnoses per 1000 eligible members, members with diagnoses per 10 000 eligible members. The scales and intervals of the vertical axis were also diverse. In addition, information on the context of original studies and the rationale or references of selection of ICD-9-CM or ICD-10-CM phenotypes were not available in the reports, thus we could not assess the rigor of the code lists used for mapping.

The Sentinel's health outcomes coding trend analyses reports are an important instrument that can help identify issues with mapping HOI algorithms from ICD-9-CM to ICD-10-CM and investigate HOI trends across the ICD-9-CM to ICD-10-CM eras. Inclusion of additional information in the reports (e.g., tables of monthly incidence and prevalence, intended use of the HOI) will help researchers make better decisions on whether or how to use the HOI algorithms for their studies.

Furthermore, additional analyses of these reports would enhance our understanding of the value of manual code curation, as recommended by a prior study that reported manual refinement of a mapped ICD-10 algorithm of meningitis improved the consistency in prevalence,[11] and the best methods for assessing changes in incidence and prevalence across the ICD-9-CM and ICD-10-CM eras. A more in-depth analysis of the existing reports, or future reports, would include analysis of monthly incidence and prevalence data to allow more systematic assessment of changes in level and trend (i.e., beyond visual inspection) and investigation of whether manual curation can improve HOI phenotype performance as compared to prior trends. FDA continues to provide these trend reports, making continued investigation a high priority for the research community.

In summary, our findings suggest that researchers mapping ICD-9-CM codes to ICD-10-CM codes using standardized mapping methods need to assess the performance of the mappings and conduct manual refinement of the algorithms as needed before using them. Additional research can further clarify the performance of different mapping approaches for different types of HOIs.

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CONFLICT OF INTEREST

All authors declared no conflict of interests.

AUTHOR CONTRIBUTIONS

Jeffrey S. Brown and Young Hee Ham designed the study. Young Hee Ham performed the analyses, and all authors interpreted the results. Young Hee Ham drafted the manuscript. All authors revised the manuscript for important intellectual content and approved the final manuscript to be submitted for publication.

ETHICS STATEMENT

The authors state that no ethical approval was needed.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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