Early Post-Approval Surveillance of New Molecular Entity Uptake in the Sentinel Distributed Database

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BACKGROUND

- Each year, the US Food and Drug Administration (FDA) approves a wide range of new drugs and biologic products
- New molecular entities (NMEs), containing active ingredients not previously approved, provide innovative treatment options and advances in healthcare
- Despite intensive pre-market safety research, no drug is risk-free, making the monitoring of newly approved drugs a public health priority
- Post-market active surveillance studies benefit from sufficient power, and are consequently restricted by variable sample size reflecting inconsistent uptake across NMEs
- The Sentinel System, FDA's medical product monitoring system, can rapidly access drug utilization information from electronic healthcare data for a large number of patients from a diverse group of commercial health plans

OBJECTIVE

To characterize the rate of uptake and market attributes for NMEs approved in 2013 and 2014, during their first 1-2 years on the market, using the Sentinel System

METHODS

Study Period: January 1, 2013 – December 31, 2015

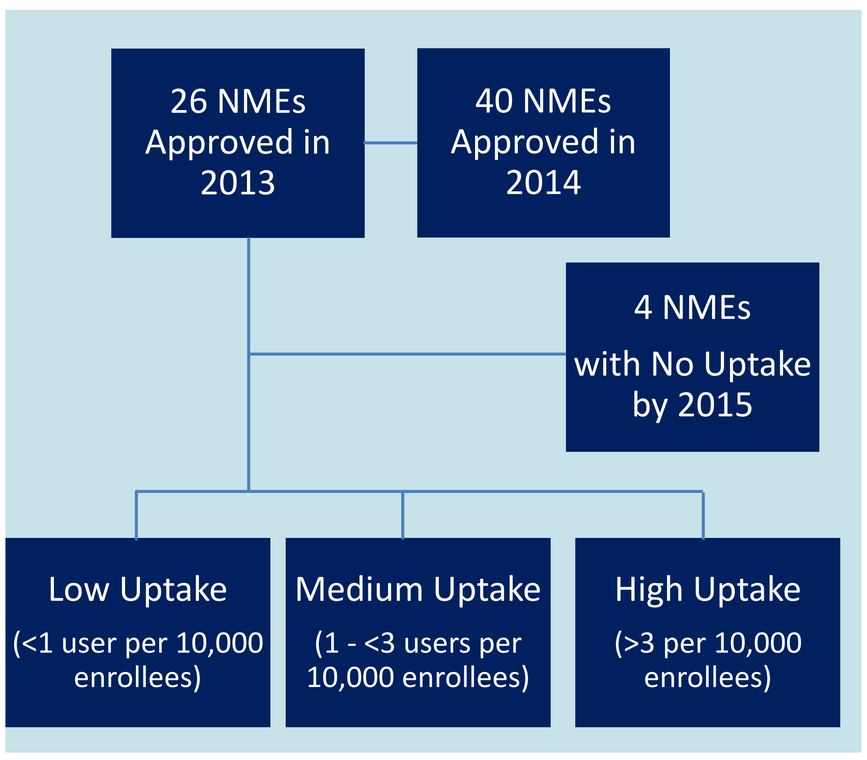
Sentinel Distributed Database (SDD)

- 16 Sentinel Data Partners
- Health plan insurance claims
- Over 42 million enrollees of all ages with medical and drug coverage, within the query period

NME Identification

- Nature Reviews Drug Discovery Journal
- NMEs defined by generic name with:
  - National Drug Codes (NDCs)
  - Healthcare Common Procedure Coding System (HCPCS) codes, when applicable
- NMEs categorized into levels of uptake, by 2015 prevalence **(Figure 1)** :
  - Low : less than 1 user per 10,000 enrollees
  - Medium : between 1 and 3 users per 10,000 enrollees
  - High : more than 3 users per 10,000 enrollees
- Indications and other drug market attributes reviewed for NMEs with high uptake

Figure 1. Collection and Categorization of NMEs



RESULTS

- 62 (93.9%) of NMEs approved in 2013 and 2014 were observed in the SDD by 2015
- The majority, 44 NMEs (66.7%), had low uptake; 18 NMEs (27.3%) had medium to high uptake by 2015 **(Figure 2)**
- Greatest uptake was seen for a first-in-class NME indicated for type 2 diabetes, with 409,711 dispensings among 87,544 users captured in 2015, two years post-approval **(Figure 3)**

Figure 2. 2015 Prevalence of NMEs Approved in 2013 and 2014, with More than 1 User per 10,000

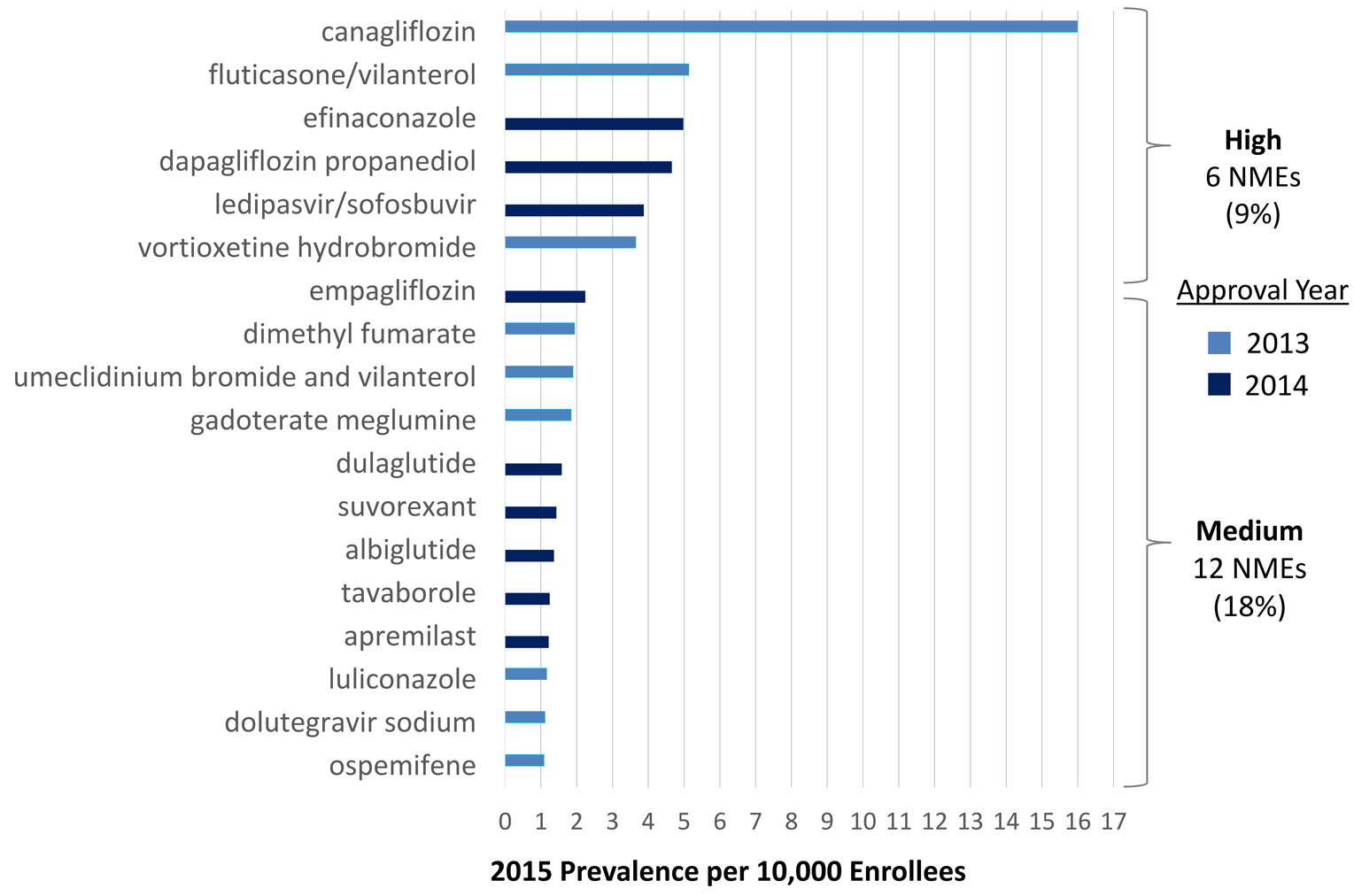
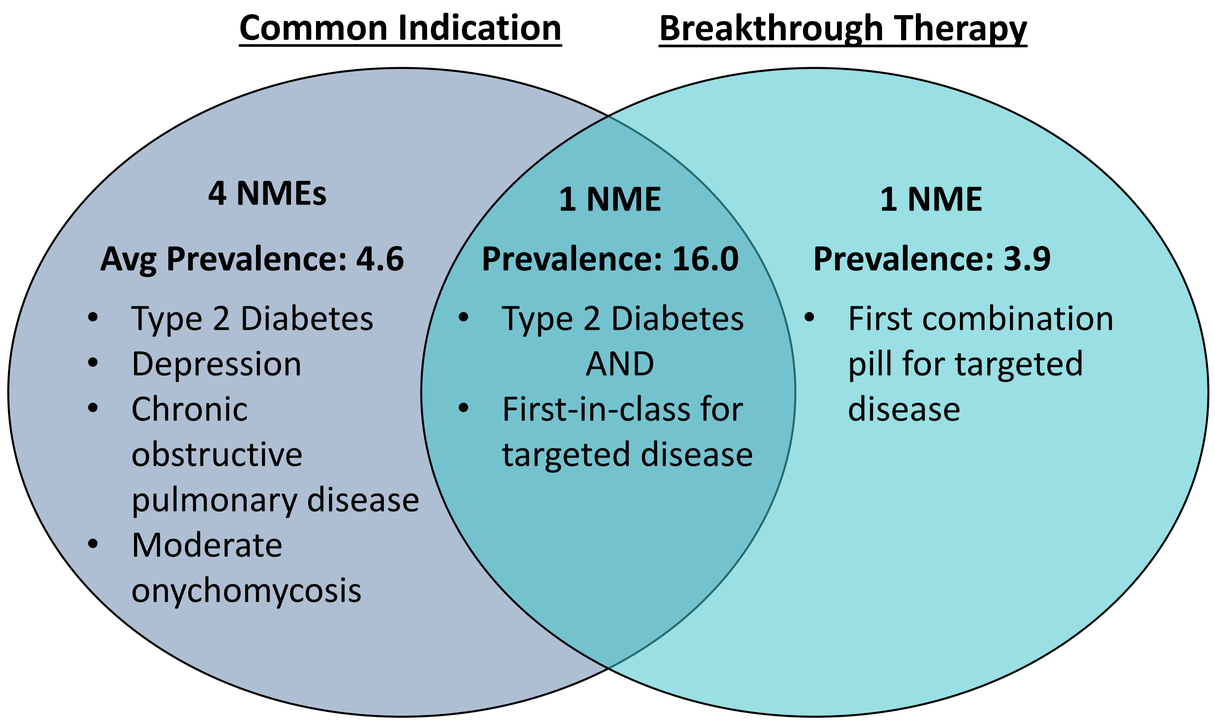


Figure 3. Market Attributes of the 6 NMEs with High Uptake



DISCLOSURE STATEMENT

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REFERENCES

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CONCLUSIONS

- Preliminary findings from NMEs approved in 2013 and 2014 are consistent with previous studies and indicate large variability in drug uptake[A]
- Breakthrough therapy designation and prevalence of drug indication were common characteristics of high uptake drugs
- Due to relatively higher utilization, NMEs with these characteristics are more suitable for early post-market safety monitoring

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