

BACKGROUND

- Generic drug utilization has saved the U.S. healthcare system nearly \$1.7 trillion between 2005 and 2014.¹
- As many fee-for-service healthcare systems become accountable-care organizations or adopt shared-savings programs, the promotion of outpatient generic drug utilization may progressively become an important strategy to control healthcare spending and serve as a metric for healthcare value.^{2,3}
- Generic drug utilization in the outpatient setting is typically measured through pharmacy claims data; however, not all healthcare delivery systems have access to these data for their clinical populations.

PURPOSE

- We sought to develop an algorithm that classifies whether a prescribed drug was dispensed as a brand or generic product in order to estimate generic utilization in the outpatient setting.

METHODS

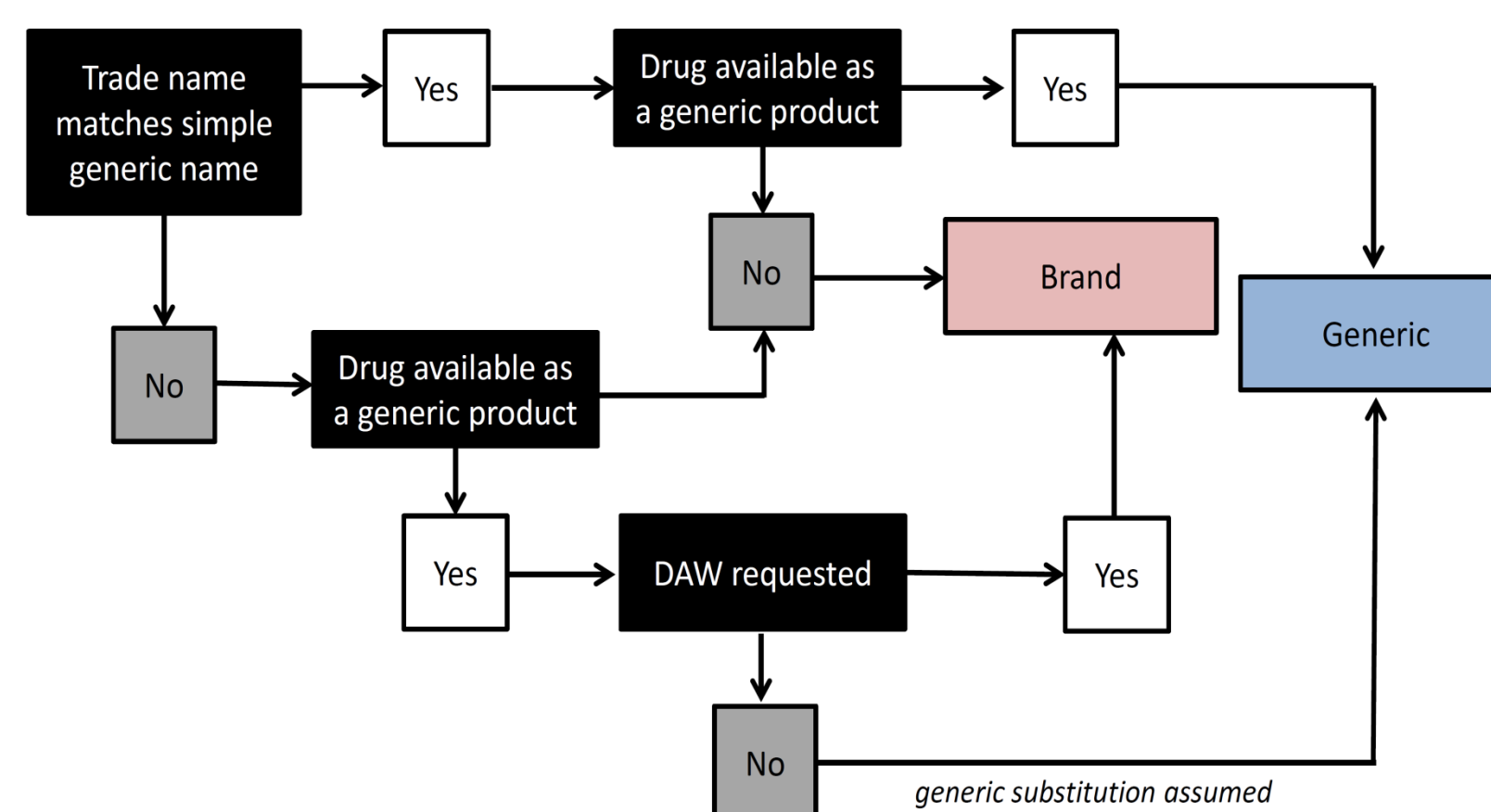
- Retrospective, cross-sectional analysis of electronic health records (EHR) data from 2013.
- Data are from managed-care beneficiaries from Sutter Health, a community-based mixed-payer healthcare delivery system in Northern California.
- Study population has both electronic prescribing and pharmacy dispensing data available.
- Analysis was focused on 25 American Hospital Formulary System therapeutic classes previously identified as having the potential for poor generic uptake (Table 1),⁴ inclusive of 189 active product ingredients and 660 unique dosage forms and strength combinations.

TABLE 1. Frequency Distribution of Prescriptions Across Therapeutic Classes	Prescriptions N = 104,859 n (%)
1.Adrenals & Combinations	5,893 (5.6)
2.Androgens & Combinations	526 (0.5)
3.Anticonvulsants, Hydantoin Derivative	206 (0.2)
4.Anticonvulsants, Succinimides	3 (0)
5.Anticonvulsants, Miscellaneous	6,189 (5.9)
6.Antiemetics	478 (0.5)
7.Antigout Agents	2,507 (2.4)
8.Antimanic Agents	90 (0.1)
9.Antiplatelet Agents	2,435 (2.3)
10.Anxiolytics/Sedatives/Hypnotics	19,462 (18.6)
11.Cardiac Drugs	7,560 (7.2)
12.Cardiac, Antiarrhythmic Agents	942 (0.9)
13.Anticoagulants	2,561 (2.4)
14.Estrogens & Combinations	4,953 (4.7)
15.Eye/Ear/Nose/Throat, Miscellaneous	1,949 (1.9)
16.Immunosuppressants	148 (0.1)
17.Muscle Relaxants, Smooth-Genitourinary	48 (0.1)
18.Parathyroid Hormones	121 (0.1)
19.Psychotherapeutics, Antidepressants	22,142 (21.1)
20.Psychotherapeutics,Tranquilizers/Antipsychotic	996 (1)
21.Stimulant, Amphetamine Type	834 (0.8)
22.Sympathomimetic Agents	9,899 (9.4)
23. Thyroid Agents	10,564 (10.1)
24.Vascular 5HT1 Agonist (Antimigraine Agents)	2,599 (2.5)
25.Vasodilating Agents	1,754 (1.7)

BUILDING & TESTING A GENERIC USE ALGORITHM

- We identified managed-care beneficiaries with a prescription for a product in the therapeutic classes of interest in 2013.
- Prescriptions were matched to pharmacy claims up to 180 days from the prescription date.
- An algorithm was developed to classify whether a drug is dispensed as a brand or generic product (Figure), using:
 - the name of the prescribed medication
 - request for “dispense as written” (DAW); and
 - availability of the drug in generic form as documented in the U.S. Food and Drug Administration’s Approved Drug Products (Orange) Book (Figure).

FIGURE. Generic Utilization Algorithm.



- Based on the algorithm, we estimated a generic utilization rate (GUR)

$$GUR = \frac{\text{generic prescriptions}}{\text{total prescriptions (regardless of generic availability)}}$$

- We assessed the performance of the algorithm in a stepwise manner, comparing the estimated GUR to the true GUR calculated from pharmacy claims data.
- Algorithm diagnostics were calculated

LIMITATIONS

- The algorithm was developed and validated in a small managed-care population from a mixed-payer healthcare system.
- We expect that the algorithm can be applied to patients with other insurance types, but we cannot know this for certain based on our analysis.
- We cannot know if the GUR estimated in this study is generalizable to health systems in other parts of the U.S. or to other therapeutic classes, but this should not affect the validity of the algorithm, as its theoretical framework should apply.
- The algorithm assumes generic substitutions are performed whenever possible in states with permissive substitution laws, like California; however, this is consistent with current evidence from the literature.^{5,6}

RESULTS

Description of Study Cohort

- We identified 153,506 electronic prescriptions in 2013 for products within the therapeutic classes of interest; 104,859 (68.3%) matched to pharmacy claims.
- The majority of patients was female (67.9%), 40 years of age or older (88.0%), and non-Hispanic white (69.3%).

Performance of the Algorithm

- The algorithm performed optimally when using the three components combined, with a total agreement of 95% and Cohen’s Kappa 0.87 (Table 2).
- With the complete algorithm, the estimated GUR was 73.7%, compared with 73.1% when calculated from pharmacy claims data.

TABLE 2. Algorithm Diagnostics	1 Medication Name	2 + DAW	3 + Generic Availability
Estimated Generic Utilization Rate	92.6%	95.7%	73.7%
Sensitivity	0.978	0.984	0.969
Specificity	0.216	0.117	0.892
Positive Predictive Value	0.772	0.752	0.961
Negative Predictive Value	0.785	0.725	0.913
Total Percent Agreement	0.773	0.751	0.948
Kappa (95% Confidence Limits)	0.252 (0.246, 0.258)	0.137 (0.132, 0.142)	0.868 (0.864, 0.871)

CONCLUSIONS

- An algorithm that classifies brand versus generic prescribing using EHR data performs well in estimating generic drug utilization among managed-care beneficiaries.
- The estimated GUR (73%) for the therapeutic classes of interest is indicative of potential areas of opportunity to improve generic drug use.
- Healthcare delivery systems may apply these methods to quantify generic drug use in their ambulatory-care population for quality improvement and research initiatives, particularly when pharmacy claims are unavailable.

DISCLOSURES

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REFERENCES

- Generic Pharmaceutical Association. Generic Drug Savings in the U.S. 7th Annual Edition. 2015.
- Colla CH, et al. Role of Pharmacy Services in Accountable Care Organizations. *J Manag Care Pharm.* 2015; 21:338-44.
- Dubois RW, et al. Are ACOs Ready to be Accountable for Medication Use? *J Manag Care Pharm.* 2014 ;20:17-21.
- Segal JB, et al. Therapeutic class differences in generic usage. *Pharmacoepidemiol Drug Saf.* 2015; 24:1-587.
- Song Y, et al. The Power of Not Asking: How Generic Drug Substitution Laws Affect Patient’s Demand for Generic Drugs. *Social Science Research Network.* 2015.
- Shrank WH, et al. State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid. *Health Aff (Millwood).* 2010; 29: 1383–1390.