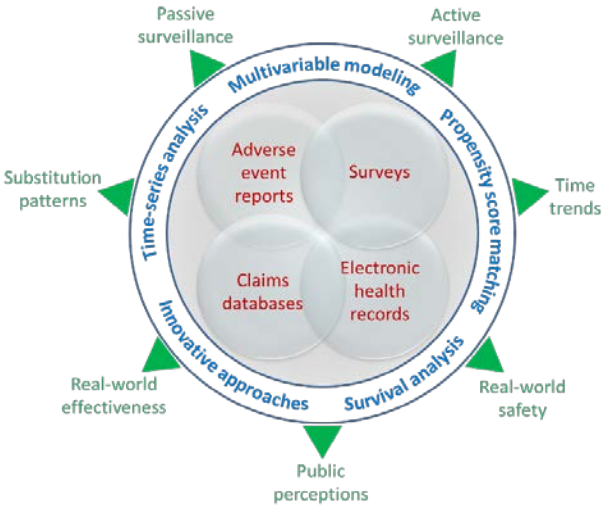
FYs 2013 - 2017 Regulatory Science Report: Analysis of Generic Drug Utilization and Substitution

Introduction

Effective postmarketing surveillance of generic drugs is essential to ensure that, when substituted for the brand-name drug, the FDA-approved generic drug is safe and effective. The purpose of drug surveillance is to monitor use, clinical effectiveness, and safety issues of drugs on the market. It is imperative that the public and the scientific community have confidence that generic drugs are therapeutically equivalent to brand-name products and each other.

Surveillance of generic drugs is more complex than that of brand-name drugs because many more factors need to be considered. The generic drug must have no significant differences from its brand-name counterpart, and identifying a significant difference can be challenging. Brand-name products are surveilled to identify new and unexpected adverse events not found in the limited and controlled studies submitted to the new drug application (NDA). Generics are subject to the expected adverse events listed in the brand-name drug product label, as well as possible adverse events or therapeutic failure due to allowable differences in formulation, manufacturing, pharmacokinetics not thought to be significant, or patient perception. Surveillance of generic drugs must include an extensive investigation of all aspects of the abbreviated new drug application (ANDA) review, from considerations of critical quality attributes and manufacturing to critical elements of absorption, distribution, metabolism, and excretion. The critical elements of clinical performance of the brand-name drug must be fully understood and investigated during surveillance of a marketed generic drug. Thorough analysis can bring to light evidence of unanticipated significant differences between the generic and its brand-name reference product.

The Office of Generic Drugs (OGD) uses complementary approaches to generic drug surveillance that involve the identification of suitable data sources and development of various data analysis methods. Data sources may include: case reports of adverse events from the FDA Adverse Event Reporting System (FAERS), published literature, administrative claims databases, electronic health records, or survey/registry data. To analyze the data, a variety of approaches are used including, literature and case report reviews; meta-analyses; passive surveillance evaluations; surveys of patients, pharmacists, and physicians; and active surveillance, which includes retrospective analyses of secondary data and prospective data collection. Postmarketing investigations often require complex statistical approaches for analyzing the data. These investigations may include interrupted time-series analysis, multivariable modeling, propensity-score matching, survival analysis, machine learning, and other innovative statistical methods (Figure 1).



(Figure 1) Analyzing data for postmarketing surveillance of generics

Accomplishments (2012-2017)

Generic Drug User Fee Amendments (GDUFA) funded studies developed methodologies and approaches to analyze utilization and evaluate substitutability of generic drugs. Several studies are ongoing and results will provide additional information on the utility of specific statistical approaches for analyzing observational data and the use and substitution practices of generics in specific patient subgroups.

Postmarketing surveillance of generic equivalency is relatively new, with many areas still in development. Under GDUFA, individual data sources have been employed in various studies and multiple complementary data sources have been linked together to improve FDA's capability to rigorously evaluate generic drug substitutability. Each generic drug has unique considerations for monitoring, requiring ongoing development of data resources and methodologic tools to adequately assess substitutability.

Research Projects and Collaborations

Extramural Projects

Assessing clinical equivalence for generic drugs approved by innovative methods

FDA awarded Grant 1U01FD004856 to Dr. Aaron Kesselheim at Brigham & Women's Hospital on September 15, 2013 and the study was completed in September 2015. The study sought to conduct a systematic review and retrospective data analysis to proactively monitor the safety, efficacy, usage, and substitution patterns of recently approved generic drugs. Researchers looked at six drugs approved based on modified bioequivalence approaches: venlafaxine extended-release (ER) tablet, calcitonin salmon nasal spray, enoxaparin injection, acarbose tablet, vancomycin capsule, and sodium ferric gluconate injection.

The systematic review of the literature found no consistent evidence of adverse clinical outcomes of generic versions of these drugs in the United States or internationally, but the data are limited in scope and high susceptibility to bias. The researchers conducted retrospective data analysis using medical and pharmacy administrative claims data from commercially-insured individuals.

Results showed that patients were not more likely to systematically switch back from generic to brand-name versions of the study drugs as compared to control drugs. There was also no evidence of worse clinical outcomes associated with generic products versus the brand-name products. Analysis of switch-back patterns and time-series methodology may be useful for screening and assessing major safety and efficacy concerns with generic drugs (Figure 2).

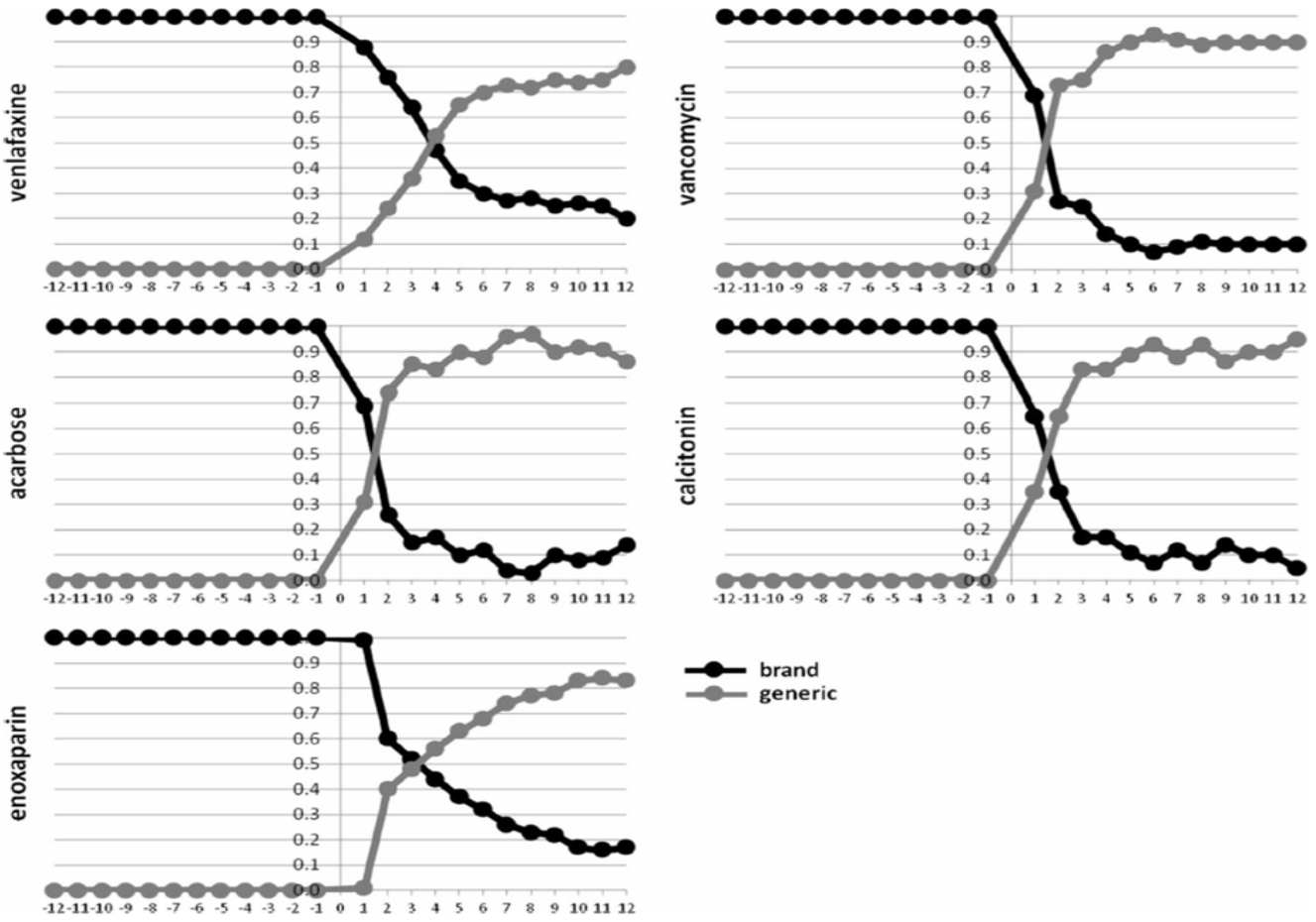


Figure 2. Relative monthly proportions of individuals initiating brand-name and generic versions of venlafaxine, vancomycin, acarbose, calcitonin salmon, and enoxaparin in the year prior to and following the introduction of the first generic. Adapted from Gagne JJ, et al. Outcomes Associated with Generic Drugs Approved Using Product-Specific Determinations of Therapeutic Equivalence. Drugs. 2017 Mar;77(4):427-433, with permission from Springer.

Postmarketing surveillance of generic drug usage and substitution patterns

FDA awarded Grant 1U01FD004855 to Ilene H. Zuckerman at University of Maryland (Baltimore/IMPAQ International) on September 15, 2013 and the study was completed in October 2015. The study sought to conduct a systematic review and analysis of Medicare administrative claims data to proactively monitor the drug safety, efficacy, usage, and substitution patterns of recently approved generic drugs. Drugs approved based on modified bioequivalence approaches were included: acarbose tablet, calcitonin nasal spray, and venlafaxine ER tablet. Investigators found minimal information available via scientific publications on bioequivalence and post-approval clinical studies conducted with generic versions of the study drugs in the U.S. The analysis showed varied results when using switchback patterns to assess substitutability, but findings suggest that a composite outcome of switching back to the brand-name, to other dosage forms, or to other drugs in the same class may be sensitive to detecting potential generic equivalency concerns. Additional studies are needed to further evaluate these results.

Transplant outcomes using generic and brand-name immunosuppressants (TOGBI)

FDA awarded Grant 1U01FD005274 to Alan B. Leichtman at University of Michigan at Ann Arbor on September 10, 2014 and the study was completed in August 2017. The goal of this study was to investigate outcomes and savings with the introduction of generic immunosuppressant medications among U.S. kidney, liver, and heart transplant recipients between 2008 and 2013. Data sources used in this analysis included the Scientific Registry of Transplant Recipients (SRTR) database, which identified kidney, liver, and heart recipients transplanted between 1987 and 2013 and records linked to the Colorado All Payer Claims Database (CO APCD), and the Medicare Part D database to identify use of mycophenolate mofetil and tacrolimus.

Uptake of each immunosuppressant remained similar across all three transplant organs, while use of generic tacrolimus was more gradual than mycophenolate mofetil. Use of both generic immunosuppressants increased rapidly after the introduction of the first few generics. Evaluation of clinical outcomes could not be conducted due to the large amount of missing data, due to unique insurance benefit structures regarding transplant coverage. Further studies using different methodologies would be helpful in evaluating clinical outcomes.

Assessing the postmarketing safety of authorized generic drug products
FDA awarded Grant 1U01FD005279 to Joshua J Gagne at Brigham & Women's Hospital on September 1, 2014 and the study was completed in June 2017. The goal of this project was to explore the role authorized generics (AGs) can play in evaluation of generic drug substitutability, and to use AGs to determine whether any potential bias against generic drugs is involved in generic drug complaints or affects generic substitution. Using administrative claims data from a commercially insured population from 2004 – 2013, investigators studied eight drugs: alendronate, amlodipine, amlodipine-benazepril, calcitonin salmon, escitalopram, glipizide ER, quinapril, and sertraline. In substitution analysis, AGs and generics for most of these drugs gained and maintained a majority of use within the first six months of generic availability. Analyses of brand-generic-brand switchback rates showed consistently lower rates of switchback among AG users compared to generic users. Despite the lower switchback rates among AG users, there was no difference in risk of adverse clinical outcomes between users of AGs and generics. This study provides additional evidence that generics produce equivalent clinical benefit comparable to brand-name products.

Effect of therapeutic class on generic drug substitutions
FDA awarded Grant 1U01FD005267 to Jodi B. Segal at Johns Hopkins University on September 10, 2014 and the study was completed in April 2017. The study aimed to investigate and understand barriers that inhibit widespread uptake of generic drug use and to identify class-specific determinants of incomplete generic uptake.

Investigators used data from administrative claims and found that some therapeutic classes had lower generic uptake, such as estrogens, androgens, thyroid hormones, and immunosuppressants. Determinants of generic drug substitution varied widely across classes. Some factors related to the interaction with the health-system, such as filling a prescription through a mail-order pharmacy or refilling a prescription, were associated with lower generic substitution for many therapeutic classes.

The algorithms developed by researches to evaluate generic drug use in electronic health records may be used in the future research studies to evaluate generic drug use in additional data sources.

Postmarketing authorized generic evaluation
FDA awarded Grant 1U01FD005267 to Richard A. Hansen at Auburn University on September 10, 2014 and the study was completed in August 2017. The goal of this project was to compare use, substitution, safety, and efficacy of authorized generics (AGs) compared with generics approved via the U.S. FDA

Abbreviated New Drug Application (ANDA) Pathway. Investigators linked administrative claims data to electronic health records from a regional integrated health care system for the years 1999-2014 to study 10 drugs: alendronate, amlodipine, citalopram, gabapentin, glimepiride, losartan, metformin ER, paroxetine, sertraline, and simvastatin. In a pooled analysis of brand-generic-brand switchback rates, investigators found no statistical difference between generic and AG users, although some individual drugs had a conditional effect on switchback rates. Results from adjusted analyses of health services outcomes showed that individuals who switched from a brand-name drug to a generic drug did not have worse outcomes than those who switched from brand-name drug to an AG drug. Findings indicate similar efficacy and tolerability profiles for brand-name and generic drugs, and support the utility of AGs as a comparison group in observational studies of generic drugs.

A model- and systems-based approach to efficacy and safety questions related to generic substitution
FDA awarded Grant 1U01FD005210 to Lawrence Lesko at the University of Florida on September 10, 2014 and the study is ongoing. The goal of this project is to develop a systematic, risk-based, and mechanistic approach to investigate clinical observations of potential bio-inequivalence after generic drug substitution for a brand-name product. The investigators proposed three integrated pillars that support investigation of potential bio-inequivalence:

- A bioinformatics pillar used for data mining FAERS and administrative claims databases for clinical outcomes.
- A physiologically based pharmacokinetic model pillar for simulating pharmacokinetic (PK) profiles and conducting sensitivity analysis of active ingredient and formulation variables related to in vitro dissolution and in vivo bioequivalence.
- A pharmacokinetic/ pharmacodynamics pillar to determine the clinical inferences of differences in PK profiles related to bio-inequivalence between two different formulations.

The investigators are focusing on the following products: immediate-release and ER metoprolol; the anti-epileptic drugs phenytoin, carbamazepine, levetiracetam and gabapentin, which span the Biopharmaceutics Classification System (BCS) I-IV; and newer oral anticoagulants dabigatran, rivaroxaban, apixaban, and edoxaban, compared to warfarin, for comparison of relative risk of bio-inequivalence.

Pharmacometric modeling and simulation for generic drug substitutability and post marketing risk assessment
FDA awarded Grant 1U01FD005192 to Jogarao V. Gobburu at the University of Maryland on September 10, 2014 and the study was completed August 2017. The goal of this project is to devise an approach for objective assessment of generic ineffectiveness complaints and to develop a computer application to simplify the decision to investigate these complaints.

The objectives of this study were the following:

- to devise a methodology to rank order drugs based on signal-to-noise ratio and group drugs based on priority,
- to explore signal detection methods and devise a drug-specific signal threshold, and
- to apply and verify methods developed in the first two objectives by applying them to databases.

Investigators classified 68 drugs from seven therapeutic areas into priority bins. This grouping was achieved by linear mixed effect modeling analysis of the active drug to placebo response-rate ratio (relative risk) followed by categorization of the model-estimated typical relative risks. Using the Proportional Reporting Ratio (PRR), investigators determined that the threshold number of adverse

event reports depends on the following: the ratio of adverse event reports to the total number in the treated population, the signal-to-noise ratio, the steepness of dose-response curve, and the variability of PK parameters. Researchers developed a prototype computer application to classify drugs into priority bins, detect signals of drug ineffectiveness as measured by PRR, and identify if the ineffectiveness signal is due to a generic version.

Novel approaches for confounding control in observational studies of generic drugs
FDA awarded Grant 1U01FD005555 to Rishi J Desai and Joshua J Gagne at Brigham & Women's Hospital on September 15, 2015 and the study is ongoing. The goal of this study is to improve methodological approaches for postmarketing research of generic drugs that uses observational data. This project involves the linking and integration of multiple data sources, including administrative claims, electronic health records, and census data to identify confounders relevant to comparative studies of generic drugs. This project will also evaluate the performance of several statistical analysis techniques involving matching based on confounder summary scores. Results from this project will enable researchers to further minimize bias and improve validity in postmarketing evaluation of generic drugs using observational data.

Structural nested models for assessing the safety and effectiveness of generic drugs
FDA awarded Grant 1U01FD005556 to Ravi Varadhan at Johns Hopkins University on September 15, 2015 and the study is ongoing. The goal of this study is to develop a causal inference approach to evaluate the safety and efficacy of generic drugs versus brand-name drugs. Investigators are using administrative claims data and assessing the added value of linking these data with electronic medical records. Investigators are developing methodologic and statistical approaches, specifically using survival analysis, that allows incorporation of time-varying confounders and address the issue of temporal confounding. The methodology developed in this study have the potential to enhance FDA's ability to make valid causal inferences using claims data in observational studies for generic drug research.

Comparative surveillance of generic drugs by machine learning
FDA awarded Contract HHSF223201510112C to Peggy Peissig at Marshfield Clinic on September 30, 2015 and the study is ongoing.

The goals of this project are to:

- develop a surveillance system that compares generic drug experience to brand-name drug experience for early differential signal detection,
- apply machine learning algorithms to predict which patients may suffer known adverse drug events following exposure to a generic medication, and
- apply reverse machine learning to detect adverse drug events and differences in drug efficacy between initiated generic and brand-name drugs.

These objectives are being supplemented with analyses of FAERS data and evaluation of ambiguous case reports by a clinician expert panel to improve validity and accuracy of the established algorithms. The surveillance system will be developed, implemented, and tested within linked electronic health records and administrative claims data from a regional integrated health care delivery system. The system will also be adapted and replicated in the Innovation in Medical Evidence and Development Surveillance (IMEDS) lab. This project has the potential to create an integrated surveillance system with the capacity to systematically sift through data captured in electronic health care data to monitor generic drug safety and efficacy in the postmarketing setting.

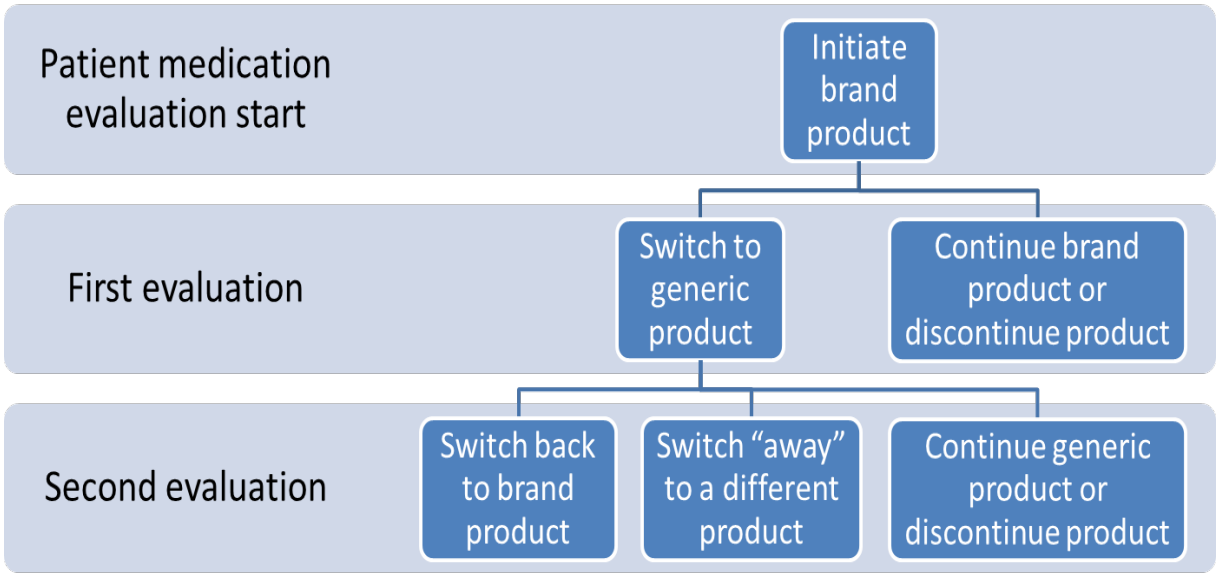
Generic drug substitution in specific populations

FDA awarded Contract 1U01FD005875 to Ilene Harris at IMPAQ International and Jingjing Qian at Auburn University on September 5, 2016 and the study is ongoing. The goal of this study is to use mixed methods to collect information on practice patterns in specific populations to assess possible barriers to generic substitution. Specific populations include pediatric patients, women, older adults taking multiple medications, and individuals with impaired kidney or liver function. Investigators are comparing clinical practice with labeled drug administration information in selected specific populations to identify factors that raise issues for safety and efficacy with generic substitution. Investigators are analyzing generic drug utilization and substitution patterns and identifying the impact of product-level, patient-level, and provider-level factors on generic drug substitution among specific populations.

Internal Projects

Identify and evaluate manufacturer-level drug utilization and switching patterns in Sentinel

The Sentinel Initiative is FDA's national electronic health data system. It uses active surveillance to monitor FDA-regulated products. In 2016, OGD began collaborating with FDA's Office of Surveillance and Epidemiology on a methods project to evaluate utilization of and switching between therapeutically equivalent products. This project's goal is to design, develop, test, and evaluate a flexible and reusable prototype analytic tool that can be used to characterize utilization and switching patterns of brand-name and equivalent generic drugs[1]. FDA selected two use-cases for tool development: metoprolol ER and lamotrigine ER. The performance of the prototype tool will be evaluated against expected patterns of utilization and switching, based on prior knowledge of these drugs. If successful, this tool will enable OGD to quickly and efficiently analyze utilization and substitution among different generic products at a population level by providing information about the context for complaints of inequivalence and allowing for identification of potential substitutability concerns for future examination (Figure 3).



[1] Popovic JR, Dutcher S, Nguyen M, Sandhu S, Weissfeld J, Gagne JJ, Izem R, Jiang W, Wang Z, Zhao Y. Identify and Evaluate Manufacturer-Level Drug Utilization and Switching Patterns in Sentinel. December 12, 2016. Available at: https://www.sentinelinitiative.org/sentinel/methods/identify-and-evaluate-manufacturer-level-drug-utilization-and-switching-patterns

Figure 5. Evaluation of patterns of medication use and switching events. Adapted from Popovic JR, et al. Identify and Evaluate Manufacturer-Level Drug Utilization and Switching Patterns in Sentinel. (https://www.sentinelinitiative.org/sites/default/files/Methods/Sentinel_Methods_Manufacturer-Level-Drug-Utilization-Switching-Patterns.pdf).

Characterizing use, safety and efficacy of brand-name and generic drugs used to treat hypothyroidism (CERSI-Mayo Clinic/Yale)

The goal of this study is to conduct comparative effectiveness and safety research to better understand generic drug products. This project will use administrative claims and electronic health data from 2007-2016, specifically laboratory results, from OptumLabs Data Warehouse. It will focus on adults with thyroid disease to: characterize the patterns of use of generic and brand Levothyroxine products, to identify factors associated with generic and brand-name drug use, and to compare the effectiveness and safety of generic and brand levothyroxine among new users and recent switchers.

Key Outcomes

Analyses of brand-generic-brand switchback rates showed consistently lower rates of switchback among AG users compared to generic users. Researchers hypothesize this is related to negative perception of generic drugs since these studies showed that individuals who switched from a brand-name drug to a generic drug did not have worse outcomes than those who switched from brand-name drug to an AG drug. In addition, there were no significant differences in clinical outcomes and switch-back rates between brand-name and generic products that were approved based on product-specific pathways to determine therapeutic equivalence. Despite the possible negative perception of generics that lead to lower switchback rates for AG, surveys have shown that, overall, patients and physicians have confidence in the approval and quality of generic products.

Future Directions

Future research is needed for the development of data mining methods for secondary data sources, to help identify potential signals in the postmarketing setting. Work remains to be done exploring additional tools, such as machine learning and natural language processing, to handle more complex and unstructured data sources. Lessons learned and methodologies developed under GDUFA-funded studies can be applied to internal resources, such as the Sentinel Initiative, to streamline the analysis of generic drug utilization and substitution.

Outcomes

Publications

- Gagne JJ, Polinski JM, Jiang W, Dutcher S, Xie J, Lii J, Fulchino LA, Kesselheim AS. Outcomes Associated With Generic Drugs Approved Using Product-Specific Determinations Of Therapeutic Equivalence. Drugs. 2017;77(4):427-433.
- Gagne JJ, Polinski JM, Jiang W, Dutcher SK, Xie J, Lii J, Fulchino LA, Kesselheim AS. Switch-Backs Associated With Generic Drugs Approved Using Product-Specific Determinations Of Therapeutic Equivalence. Pharmacoepidemiology and Drug Safety. 2016;25(8):944-952.
- Hansen RA, Qian J, Berg RL, Linneman JG, Seoane-Vazquez E, Dutcher S, Raofi S, Page CD, Peissig PL. Comparison Of Clinical Outcomes Following A Switch From A Brand To An Authorized Vs. Independent Generic Drug. Clin Pharmacol Ther. 2018;103(2):310-317.
- Hansen RA, Qian J,Berg R, Linneman J, Seoane-Vazquez E, Dutcher S, Raofi S, Page CD, Peissig P. Comparison Of Generic-To-Brand Switchback Patterns For Generic And Authorized Generic Drugs. Pharmacotherapy. 2017;37(4):429-437.

- Kesselheim AS, Eddings W, Raj T, Campbell EG, Franklin JM, Ross KM, Fulchino LA, Avorn J, Gagne JJ. Physicians' Trust In The FDA's Use Of Product-Specific Pathways For Generic Drug Approval. PLoS One. 2016;11(10).
- Kesselheim AS, Gagne JJ, Eddings W, Franklin JM, Ross KM, Fulchino LA, Campbell EG. Prevalence And Predictors Of Generic Drug Skepticism Among Physicians: Results Of A National Survey. JAMA Internal Medicine. 2016;176(6):845-847.
- Kesselheim AS, Gagne JJ, Franklin JM, Eddings W, Fulchino LA, Avorn J, Campbell EG. Variations In Patients' Perceptions And Use Of Generic Drugs: Results Of A National Survey. Journal of General Internal Medicine. 2016;31(6):609-614.
- Kesselheim AS, Gagne JJ. Product-Specific Regulatory Pathways To Approve Generic Drugs: The Need For Follow-Up Studies To Ensure Safety And Effectiveness. Drug Saf. 2015;38(10):849-853.
- Kesselheim AS, Polinski JM, Fulchino LA, Isaman DL, Gagne JJ. Modified Regulatory Pathways To Approve Generic Drugs In The Us And A Systematic Review Of Their Outcomes. Drugs. 2015;75(6):633-650.
- Lee CY, Chen X, Romanelli RJ, Segal JB. Forces Influencing Generic Drug Development In The United States: A Narrative Review. Journal of Pharmaceutical Policy and Practice. 2016;9:26.
- Nimbal V, Segal JB, Romanelli RJ. Estimating Generic Drug Use with Electronic Health Records Data from a Health Care Delivery System: Implications for Quality Improvement Research. Journal of Managed Care Specialty Pharmacy. 2016;22(10):1143-1147.
- Rahman MM, Alatawi Y, Cheng N, Qian J, Plotkina AV, Peissig PL, Berg RL, Page D, Hansen RA. Comparison of brand versus generic antiepileptic drug adverse event reporting rates in the U.S. Food and Drug Administration Adverse Event Reporting System (FAERS). Epilepsy Res.2017;135:71-78.
- Romanelli RJ, Nimbal V, Dutcher SK, Pu X, Segal JB. Provider and Patient Determinants of Generic Levothyroxine Prescribing: An Electronic Health Records-Based Study. Ann Pharmacother. 2017;51(8):640-648.

Presentations

- Daubresse M, Lee CY, Moechtar M, Dutcher S, Romanelli R, Segal JB. Predictors of Generic Thyroid Hormone Utilization Among the Commercially Insured. International Society for Pharmacoepidemiology Mid-Year Meeting, April 10-12, 2016, Baltimore, MD.
- Hansen RA, Qian J, Berg RL, Linneman JG, Seoane-Vazquez E, Dutcher S, Raofi S, Page CD, Peissig P. Comparison of outcomes following a switch from a brand to an authorized vs. independent generic drug. 32nd International Conference on Pharmacoepidemiology and Therapeutic Risk Management. August 25-28, 2016, Dublin, Ireland.
- Romanelli RJ, Nimbal V, Segal JB. Provider-level variation and determinants of outpatient generic prescribing in a mixed-payer healthcare system. 22nd Annual Health Care Systems Research Network Conference. April 13-16, 2016. Atlanta, GA.

Posters

- Helmuth M, Turenne M, Park J, Liu Q, Oguntimein O, Dutcher S, Balkrishnan R, Zee J, Smith A, Leichtman A. Immunosuppressant Costs for Medicare Part D and Kidney Transplant Recipients Since the Introduction of Generic Formulations in an Incident Kidney Transplant Population. 2017 American Transplant Congress. April 29-May 3, 2017. Chicago, IL.
- Iyer G, Marimuthi S, Segal JB, Singh S. Identification Of Generic Drugs In The FDA Adverse Event Reporting System. 32nd International Conference on Pharmacoepidemiology, August 22-26, 2016, Dublin, Ireland, Abstract 696.
- Liu Q, Smith A, Park J, Oguntimein O, Dutcher S, Bello G, Helmuth M, Turenne M, Balkrishnan R, Fava M, Sharma P, Beil C, Leichtman A, Zee J. The Adoption of Generic Immunosuppressant Medications Among Kidney and Liver Transplant Recipients Using the Colorado All Payer Claims Database. 2017

American Transplant Congress. April 29-May 3, 2017. Chicago, IL. http://atcmeetingabstracts.com/abstract/the-adoption-of-generic-immunosuppressant-medications-among-kidney-and-liver-transplant-recipients-using-the-colorado-all-payer-claims-database/

- Marimuthu S, Iyer G, Segal JB, Singh S. Patient Relevant Outcomes Associated with Generic Drugs in FDA'S Adverse Event Reporting System. 32nd International Conference on Pharmacoepidemiology, August 22-26, 2016, Dublin, Ireland, Abstract 723.
- Nimbal V, Segal JB, Romanelli RJ. Estimating Generic Drug Utilization with Electronic Health Records from a Mixed-Payer Ambulatory Healthcare Delivery System. 22nd Annual Health Care Systems Research Network Conference, April 13-16, 2016, Atlanta, GA.
- Park JY, Kiptanui Z, Palumbo F, Zuckerman I, Pradel F, Khokhar B, Jiang W, Cai W, Dutcher S. Comparing Clinical Outcomes Of Brand And Generic Drugs: Systematic Literature Review Of Acarbose, Calcitonin Nasal Spray And Venlafaxine ER Tablets. American Society of Health System Pharmacists (ASHP), December 7-10, 2014, Anaheim, California.
- Segal JB, Daubresse M, Lee CY, Moechtar M, Dutcher S, Jiang W, Romanelli R. Therapeutic Class Differences In Generic Usage. 31st International Conference on Pharmacoepidemiology, August 22-26, 2015, Boston, MA, Abstract 245.
- Segal JB, Daubresse M, Onasanya O. Determinants of Generic Drug Substitution in The United States. 32nd International Conference on Pharmacoepidemiology, August 22-26, 2016, Dublin, Ireland, Abstract 612.
- Zee J, Bello GA, Oguntimein O, Beil C, Liu Q, Park J, Saulles AR, Goel S, Balkrishnan R, Fava M, Merion RM, Leichtman AB, Sharma P. Comparison of the effects of brand name versus generic immunosuppressants on long-term graft failure risk among U.S. kidney and liver transplant recipients: Analysis of SRTR and Medicare claims data. The Transplant Society Congress Conference. August 18-23, 2016. Hong Kong.