



Division of
Pharmacoepidemiology & Pharmacoeconomics

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Regulatory Science for Generic Drugs

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Disclosures

- No one in our Division has personal financial relationships with any pharmaceutical company
- Current research funding from AHRQ, NIH (NHLBI), FDA Office of Generic Drugs, Otsuka America, CVS Caremark
- Past research funding from PCORI, Merck and NACDS foundation

What is the Division of Pharmacoeconomics?

- Division has 18 faculty members, mixture of health services research, drug safety and outcomes research, methods development, law and policy research
- \$9 million in annual grants
 - Most Division funding comes from NIH, FDA, PCORI, AHRQ, and foundations. We have also received research support from Amgen, Boehringer Ingelheim, Bristol Myers Squibb, CVS Caremark, GlaxoSmithKline, Merck, Novo-Nordisk, Pfizer, and Teva
- Division programs include:
 - NaRCAD: National Resource Center for Academic Detailing
 - PORTAL: Program on Regulation, Therapeutics, and Law
 - C4HDS: Center for Healthcare Delivery Sciences
 - Other core faculty with leadership roles at PCORI, FDA Sentinel

Single/limited source generic products

- Over 1/3 of entities eligible for generic competition have 3 or fewer approved generics (Gupta et al, under review)
- RESEARCH QUESTION: Identify predictors of generic agents becoming available from only a single source
 - Identify possible targets for regulation and/or incentives
- RESEARCH QUESTION: How does a single source generic change utilization patterns or clinical outcomes compared to multi-source generics?
 - Define potential impact of policies to reduce frequency of single-source generics

Generic medication shortages

- Since 2010, >1,000 drug shortages have been reported to FDA (University of Utah Drug Information Service)
- RESEARCH QUESTIONS: How do prescribers and clinicians change treatment patterns in response to generic shortages? How do shortages affect medication adherence? Do these changes affect clinical outcomes?
 - Allow for contingency planning in the event of future medication shortages

Generic drug safety/effectiveness

- Clinically important drug recalls occur nearly once per month in the US (Wang B et al, Arch Intern Med 2012)
- RESEARCH QUESTION: Do any specific manufacturer characteristics predict which generic medications will have safety of effectiveness problems?
- Use of compounded drugs increased by 27% between 2012 and 2013 (McPherson et al, JMCP 2016)
- RESEARCH QUESTION: Do compounded generic medications differ in safety and effectiveness from other generic medications?
 - Guidance for regulatory priorities and safety interventions with manufacturers or clinicians

Prescriber and patient choices

- Patients and prescribers skeptical of generic drugs
(Shrank et al, Health Affairs 2009; Kesselheim et al, JAMA IM 2016)
- RESEARCH QUESTION: What prescriber or patient characteristics predict the decision to prescribe a medication “dispense as written?”
 - Identify areas for educational interventions
- Drug coupons: Used for 100’s of agents, usually with generic alternatives available (Ross and Kesselheim, NEJM 2013)
- RESEARCH QUESTION: How does the use of drug coupons change the rate of prescribing and dispensing of generic medications?
 - Inform policy debate on coupon regulation

Clinical importance of generic medications

- Generic statins improve adherence and outcomes
(Gagne et al, Ann Int Med 2014)
- RESEARCH QUESTION: Do patient outcomes differ based on the use of generic vs. branded medications across a range of therapeutic classes?
 - Critical information for clinicians, patients, payors and regulators making decisions about treatment and coverage

Summary of research opportunities

- Predictors and impact of single-source generics
- Impact of generic shortages on use and outcomes
- Potential predictors of recalls and other safety issues
- Safety and effectiveness of compounded medications
- Predictors of “dispense as written”
- Impact of drug coupons on generic use
- Clinical outcomes of generic vs. branded medication use across a range of therapeutic classes

Thank you!