

# Effects of Brand vs. Generic Immunosuppressants on Graft Failure among U.S. Kidney Transplant Recipients: Analysis of SRTR and Medicare Claims Data

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# Disclosures

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# Introduction

- Generic immunosuppressant (IS) use for kidney transplantation (KT) has increased in some countries following expiration of brand patents.
- Reports of risks and benefits of generic IS substitution have been inconsistent.
  - Bioequivalence requirements differ across countries.
  - Only small, short-term studies have examined the effects of substitution on transplant outcomes.
- Goal: compare effects of brand and generic tacrolimus and mycophenolate (mofetil or sodium) on the long-term risk of graft failure in a large, national cohort of U.S. KT recipients



# Study Sample

- Data Sources
  - Scientific Registry of Transplant Recipients (SRTR) for kidney transplant recipient identification and graft failure events
  - Centers for Medicare & Medicaid Services (CMS), Part D claims for generic or brand IS prescriptions
- Inclusion Criteria
  - Kidney transplant in 2008-2012
  - At least one Medicare Part D claim for tacrolimus or mycophenolate (mofetil or sodium) prescription
  - Graft function 30 days after transplant



# Sample Characteristics

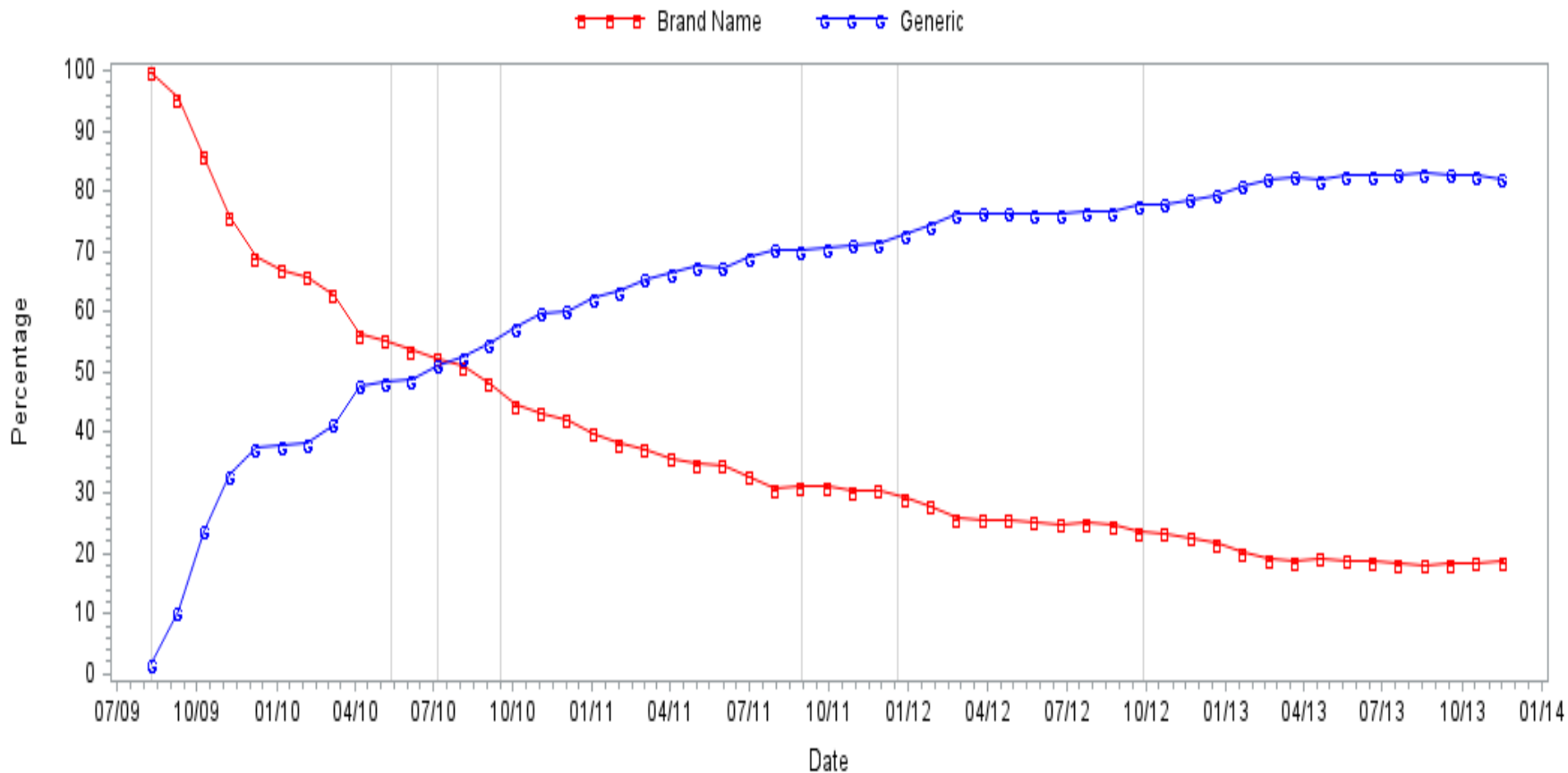
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<b>N</b>	<b>8781</b>
<b>Age, years, Mean(SD)</b>	<b>51.0 (16.4)</b>
<b>Male, %(N)</b>	<b>58.5 (5135)</b>
<b>Race/Ethnicity, %(N)</b>	
<b>White</b>	<b>46.9 (4119)</b>
<b>Black</b>	<b>27.5 (2414)</b>
<b>Asian/Other</b>	<b>8.1 (714)</b>
<b>Hispanic</b>	<b>17.5 (1534)</b>
<b>BMI, Mean(SD)</b>	<b>27.5 (5.8)</b>
<b>Previous Kidney Transplant, %(N)</b>	<b>10.9 (961)</b>
<b>Cause of ESRD (primary), %(N)</b>	
<b>Diabetes</b>	<b>28.4 (2494)</b>
<b>Hypertension</b>	<b>23.1 (2026)</b>
<b>Polycystic Kidney Disease</b>	<b>7.0 (612)</b>
<b>Lupus/Nephritis</b>	<b>22.9 (2009)</b>
<b>Other</b>	<b>18.4 (1619)</b>
<b>Missing</b>	<b>0.2 (21)</b>
<b>Follow-up Time, years, Median (IQR)</b>	<b>3.7 (2.5-4.9)</b>
<b>Graft failures (per 1000 person-years)</b>	<b>36.6</b>

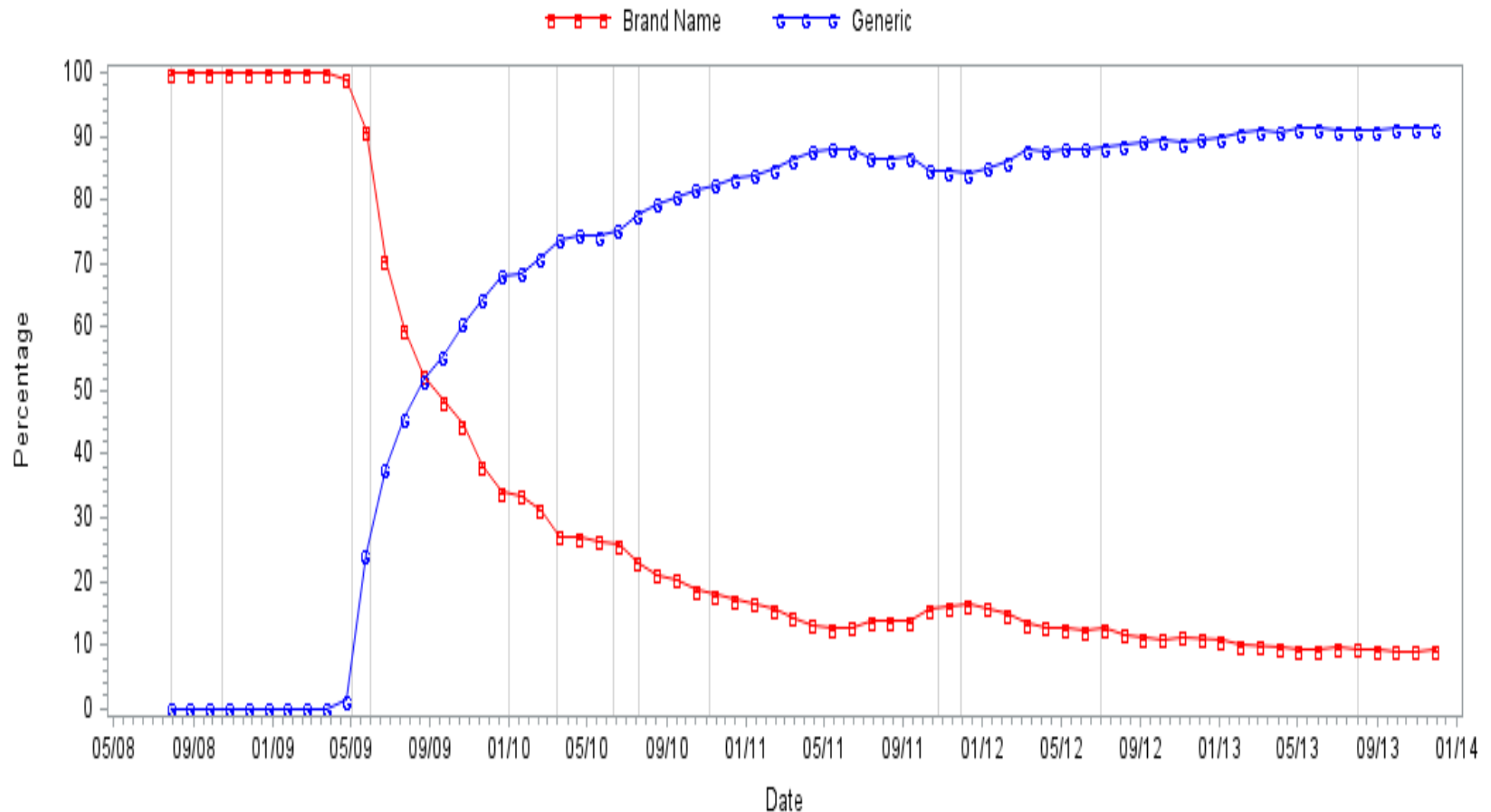
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# Generic/Brand Tacrolimus Uptake Over Time



# Generic/Brand Mycophenolate Uptake Over Time



# Statistical Methods

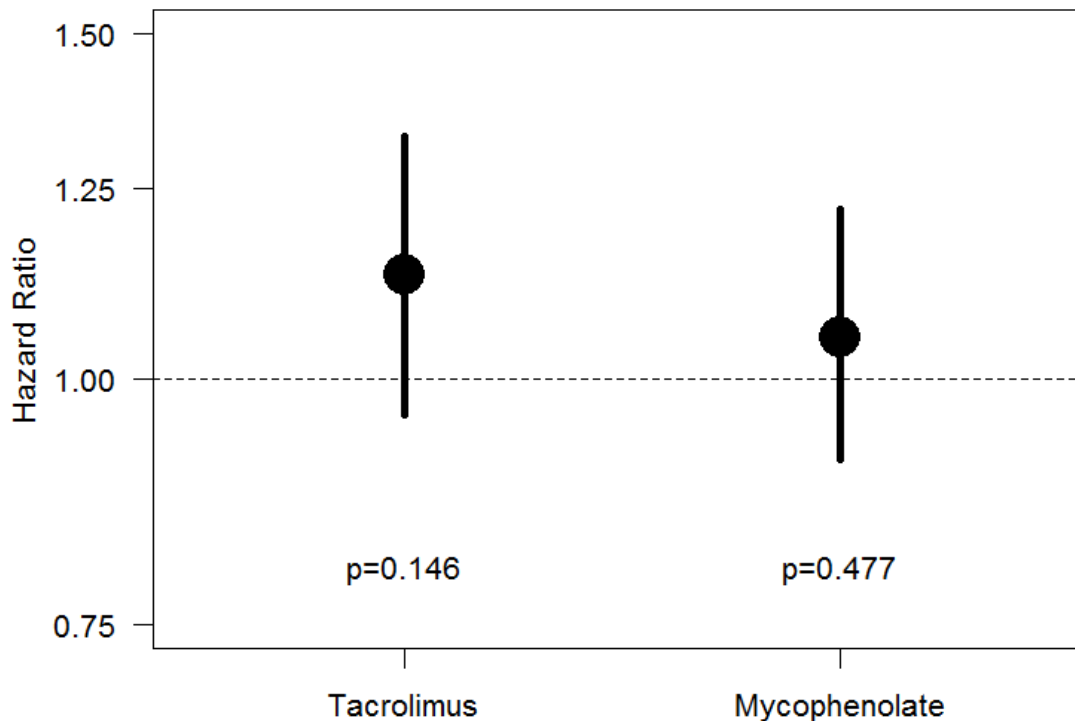
- Time-dependent Cox Proportional Hazards models
  - Generic vs. Brand status updated at each new claim
- Only consider time at risk when both brand and generic were available
- Model selection for adjustment covariates, including recipient and donor characteristics





# Model Results

Hazard ratios and 95% confidence intervals of graft survival comparing generic to brand IS, by drug



Each model stratified by transplant date and adjusted for recipient race, age, BMI, cause of ESRD, donor age and type (deceased, living related, living unrelated)

# Conclusions

- **No significant difference in risk of long-term graft failure among KT recipients between generic and brand IS prescriptions**
- **Limitations & Future Work**
  - Number of Medicare Part D claims for each patient is low
  - Unknown generalizability to other U.S. or world-wide transplant populations
  - Adherence to prescriptions unknown
  - Cost analyses
  - Factors associated with uptake of generics and patient and provider acceptance after introduction

