ARIC Manuscript Proposal #2316

PC Reviewed: 2/11/14	**Status: A**	**Priority: 2**
SC Reviewed: _____	**Status: _____**	**Priority: ____**

1.a. Full Title: Assessing Medicare Part D Claim Completeness Using Medication Self-reports

b. Abbreviated Title (Length 26 characters): **Assessing Part D completeness**

2. Writing Group:

Writing group members: Lei Zhou, Sally Stearns, Jo Ellen Rodgers, Emily Thudium, Khalid Alburikan, Carla Sueta. Others welcome.

I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. __LZ__ **[please confirm with your initials electronically or in writing]**

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3. Timeline: 3 months for draft; 1 year for publication (assuming revisions)

4. Rationale:

Pharmaceutical administrative claims data are widely used for both research and quality monitoring purposes (1). Furthermore, the Centers for Medicare & Medicaid Services (CMS) has adopted an adherence quality metrics system developed by the Pharmacy Quality Alliance (PQA). The system utilizes pharmacy claims to measure patients' adherence to long-term therapy. Medicare Part D sponsors receive financial incentives contingent on a star rating system (2). CMS star ratings include adherence measurements focusing on oral diabetes medications, angiotensin-converting enzyme inhibitors (ACEIs), angiotension II receptor blockers (ARBs), and statins.

The accuracy of the pharmaceutical claims data has become a concern for analysts due to the implementation of generic drug discount programs (GDDP) by large retail chain pharmacies (1). GDDPs are often referred to as "$4 generics." Several studies have been conducted to assess the impact of GDDPs on the completeness of pharmaceutical claims data (3-5); however, the reports are conflicting. To our knowledge, no investigation comparing Part D claims to self-reports of medications has been conducted.

To assess the impact of $4 generics on the completeness of Medicare Part D claims, we will evaluate the degree of agreement between Part D claims and self-reported medications during the annual follow-up interview (AFU) for a set of medications that were commonly included in GDDP plans in 2009 and a set that were commonly not included in GDDP plans in 2009.

5. Main Hypothesis/Study Questions:

We will use Medicare Part D data from 2006-2009 and AFU reports from 2009 to investigate three questions:

1. From 2006-2009, what was the rate at which Part D claims were filed, and were filed with payment only at a low rate (e.g., $4) for the drugs in Table 1?

2. Describe the medication concordance between self-reports during the 2009 AFU and Medicare Part D claims in drug categories listed in Table 1 (antihypertensives and antihyperlipidemics).

3. For the drug classes listed in Table 1, use regression analysis to investigate whether medication concordance differs significantly by whether medications were available through GDDP plans or not, controlling for other covariates.

Table 1. Selected Medications For Concordance Measurement		
Drug Class	**Commonly on GDDP Drug List**	**Not usually on GDDP Drug List**
Antihypertensives (1)	Generic: Lisinopril (Brand available: Prinivil, Zestril)	Generic: Valsartan Brand: Diovan
Antihypertensives (2)	Generic: Atenolol (Brand available: Tenormin)	Generic: Amlodipine Brand: Norvasc
Antihyperlipidemics	Generic: Simvastatin (Brand available: Zocor)	Generic: Atorvastatin Brand: Lipitor

6. Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodological limitations or challenges if present).

Study Population:

The first research question will be addressed using Part D claims data for ARIC cohort members who were enrolled in Medicare Part D at any point from 2006-2009. ARIC cohort members who were enrolled in Part D and reported medications during their 2009 AFU will be used for the second two questions. ARIC cohort members who did not provide medication information during 2009 AFU or who did not have Medicare Part D coverage at least 90 days prior to their AFU will be excluded from the analysis.

Selected Medications:

The medications were selected by pharmacists at UNC based on the frequency in AFU self-reports and prescribing habits as determined by guideline directed therapy. The selected drugs in Table 1 were available on GDDP lists in 2009 across major pharmacies including Walmart, CVS, Walgreens, Target, and Kroger. The selected non-GDDP drugs were not on the GDDP lists at the aforementioned major pharmacies in 2009.

While GDDP lists focus on generics, we will consider for reports and claims for brand names as well as generics since ARIC cohort members may self-report brand names even they are taking generics, and vice versa. Sensitivity analysis will be conducted to exclude brand counterparts.

Analysis:

The first research question will be addressed using frequencies and descriptive statistics of the rates of prescription claims and the distributions of person out-of-pocket and

Medicare payments over time (2006-2009) for the various drugs. We will also determine when a person is in the "donut hole."

For the second research question, medication concordance is determined based on the brand or generic name of self-reported medications and the brand or generic name in Medicare Part D claims. We treat the matched medication claims and reports as being in agreement if the interview date is within the value of "days supplied" on the Part D prescription medication claim. Descriptive medication concordance statistics will be calculated according to three categories: concordance between claims and self-report, claims only and self-report only.

For the third research question, multinomial logistic regression analysis will be conducted to determine whether concordance (three categories as defined above) differs significantly for GDDP versus non-GDDP drugs while controlling for other covariates. Covariates will include year, ARIC study site interacted with race, and socio-demographics (age, gender, income, marital status, and whether the person is a veteran).

Challenges:

The study will be subject to several limitations. Most importantly, the self-reports may not be accurate since cohort members may fail to report medications they are taking, or participants may report medications that were previously prescribed but they are not currently taking. Furthermore, while the GDDP categorization provides an important comparison, GDDPs are not the only reason why Part D claims may be missing. Overall, this study will increase our understanding of the completeness and validity of Part D prescription claims. The study is important because Part D claims are being utilized by organizations and researchers, as well as implemented as a quality measure by CMS.

7.a. Will the data be used for non-CVD analysis in this manuscript?
____ Yes __X__ No

b. If Yes, is the author aware that the file ICTDER03 must be used to exclude persons with a value RES_OTH = "CVD Research" for non-DNA analysis, and for DNA analysis RES_DNA = "CVD Research" would be used?
____ Yes ____ No
(This file ICTDER has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript?
____ Yes __X__ No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER03 must be used to exclude those with value RES_DNA = "No use/storage DNA"?
____ Yes ____ No

9. **The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status.** ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: http://www.cscc.unc.edu/ARIC/search.php

___X___ Yes _____ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?

None to our knowledge.

11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? ____ Yes __X__ No

11.b. If yes, is the proposal

___ A. primarily the result of an ancillary study (list number* _____)

___ B. primarily based on ARIC data with ancillary data playing a minor role (usually control variables; list number(s)* _____ _____ _____)

*ancillary studies are listed by number at http://www.cscc.unc.edu/aric/forms/

12a. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.

12b. The NIH instituted a Public Access Policy in April, 2008 which ensures that the public has access to the published results of NIH funded research. It is **your responsibility to upload manuscripts to PUBMED Central** whenever the journal does not and be in compliance with this policy. Four files about the public access policy from http://publicaccess.nih.gov/ are posted in http://www.cscc.unc.edu/aric/index.php, under Publications, Policies & Forms. http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to Pubmed central.

References:

1. Choudhry NK, Shrank WH. Four-dollar generics--increased accessibility, impaired quality assurance. N Engl J Med 2010, Nov 11;363(20):1885-7.
2. PQA measures used by CMS in the star ratings & as display ratings program; Available from: http://pqaalliance.org/measures/cms.asp. Accessed 1 January 2014.
3. Zhu VJ, Belsito A, Tu W, Overhage JM. Data for drugs available through low-cost prescription drug programs are available through pharmacy benefit manager and claims data. BMC Clin Pharmacol 2012;12:12.

4. Tungol A, Starner CI, Gunderson BW, Schafer JA, Qiu Y, Gleason PP. Generic drug discount programs: Are prescriptions being submitted for pharmacy benefit adjudication? J Manag Care Pharm 2012;18(9):690-700.
5. Lauffenburger JC, Balasubramanian A, Farley JF, Critchlow CW, O'Malley CD, Roth MT, et al. Completeness of prescription information in US commercial claims databases. Pharmacoepidemiol Drug Saf 2013, Aug;22(8):899-906.