GRANT PROPOSAL CRITERIA
PATIENT OR SURVEY PROJECT

Select a Project/Research Category

- Patient
- Survey
- Other (Profession, Academics & Economics)

A. PROPOSAL CRITERIA

I. Title: Examination of actual paid amount for prescribed drugs in Medicaid and non-Medicaid expansion states and its relationship with actual acquisition cost paid by community pharmacies

II. Background/Rationale

Background

Medicaid was created as part of the Social Security Amendments of 1965 to serve low-income persons, including the disabled, pregnant women, parents with dependent children, and children 18 years of age or younger [1]. Since the federal and state governments have shared power to structure and characterize Medicaid’s programs, eligibility, benefit, and payment in each state is unique. Medicaid’s population and their needs are also diverse [1]. In 2012, Medicaid expenditures were approximately $421 billion with 52 million enrollments [2, 3]. Medicaid managed-care plans, inpatient hospital care, and long-term care facilities were the largest shares of the Medicaid expenditure. Each state has its own flexibility to manage these benefits. The effectiveness of Medicaid had been examined and the results showed various opportunities for improvement [1].

In the last few years, the Affordable Care Act (ACA) has changed Medicaid from a welfare-style program to the largest health insurance plan in the US that covers any individual with a family income at or below 138% of the federal poverty level [1]. As of May 2015, Medicaid enrollment exceeded 71 million people [4]. Generally, there have been two major challenges for Medicaid under the ACA [1]. First, healthcare providers are unwilling to participate in the program due to Medicaid’s low payment rates, paperwork burdens, and the clinical complexity of enrolled patients. A recent study revealed that only about 70% of physicians were willing to accept new Medicaid patients while more than 80% would accept new private insurance and Medicare patients [5]. Another challenge is Medicaid’s spending. It has increased from the beginning of the ACA with $475 billion in 2014 [1] and is projected to be $519 billion by 2023 [6]. Primarily, the increased spending was due to increased enrollment since there was an evidence of leveled off per-enrollee spending since 1998 [1]. Although Medicaid programs vary by state and the costs of newly eligible adults as a result of the ACA are mainly borne by the federal government, eventually states need to control costs, e.g., cutting reimbursement rates, and reducing benefits, since states still significantly share the spending [7]. These cost controls will first have an impact on healthcare providers and subsequently have negative effects on patients.

Community pharmacies are an important member of the health care provider network for Medicaid patients since they disproportionately locate in urban and rural areas where the patients live [8]. Changing Medicaid reimbursement would affect pharmacies’ sustainability and patient access to pharmacy services and their medications, which eventually can lead to more high-cost care. Although the Medicaid spending on prescription drugs was relatively small (approximately 2-4% of overall Medicaid expenditures), as compared to other expenditures [1] and it has slowly grown [9], historically it was an important component of Medicaid’s spending that received federal and state governments’ attention. Recently, a report showed that the number of Medicaid prescriptions increased approximately 17% in 2014 accounting for 70% of the growth in retail prescriptions [10].
The Medicaid reimbursement policies for prescription drugs are developed at both federal and state levels [9]. They include ingredient cost, dispensing fees, and beneficiaries’ cost sharing. Generally, the federal government sets rules for Medicaid reimbursement: the lower of the 1) estimated acquisition cost (EAC) plus reasonable dispensing fees or 2) the providers’ usual and customary charges to the general public [10]. The dispensing fee should cover a pharmacist’s services and other overhead costs for operating a pharmacy. It is set differently across varying states and it currently ranges from $2 to $10 per prescription [9]. Pharmacies tried to argue that the dispensing fees have been too low. However, these fees usually coincide with how states set the reimbursement of ingredient costs. For cost sharing, copayments usually are nominal in all states, although they are allowed to be up to $4 and $8 for preferred and non-preferred drugs, respectively. Also, if the Medicaid beneficiaries were not able to pay, they still could obtain their drugs. Most policies for the dispensing fee and cost sharing are relatively simple and ostensible since they usually are based on local contexts, e.g. operating cost, affordability, access, etc. On the other hand, the ingredient cost, which has been identified as a cost driver of Medicaid’s reimbursement for prescription drugs, requires more complex policies from federal and state governments.

Various benchmarks for the Medicaid reimbursement of ingredient costs have been used. While average wholesale price (AWP) and wholesale acquisition cost (WAC) have been used as benchmarks for the reimbursement, in 2012 the Centers for Medicare & Medicaid Services (CMS) proposed rules requiring states to use actual acquisition cost (AAC) to pay for ingredient costs since both AWP and WAC did not correctly reflect pharmacies’ acquisition costs. The CMS has posted National Average Drug Acquisition Cost (NADAC), calculated from a survey of community pharmacy invoices, for states to determine the reimbursement. The federal government also established federal upper limit (FUL) to cap the reimbursement for certain multiple-source drugs and almost all states set maximum allowable cost (MAC) to limit the ceilings on the Medicaid reimbursement for most drugs that do not have FUL.

There have been several efforts concerning the reimbursement methods at the federal and state levels to develop more effective drug ingredient costs [9]. Unfortunately, current methods tend to have negative impacts on pharmacy revenues, resulting in some pharmacies, especially independent pharmacies, operating at a loss [8]. For instance, there were some years that FULs remained unchanged and it caused unchanged MACs, which were usually set lower than FUL, and did not correspond to pharmacy acquisition costs. A study showed that there had been a steep drop in Medicaid gross margins between 2009 and 2010 that could threaten the viability of an independent pharmacy [12]. In 2010, the ACA directed the CMS to calculate a FUL at no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices (AMP) for multiple source drugs [13]. Since technically this new calculation replaces the lowest AMP as the basis for setting FUL, it may increase the reimbursement for these drugs. However, this FUL calculation has not been implemented and the National Community Pharmacists Association was skeptical about it [8].

There were several studies examining these pricing benchmarks [9, 14-17]. They found that the relationships among these benchmarks, and the relationships between each benchmark and Medicaid actual payments for drug ingredient costs primarily depended on drug types, e.g. single-source brand, multiple-source brand, or generic, and their therapeutic groups. However, only NADAC, as an AAC, has been newly used. A recent study reported that 12 states used a percentage reduction from AWP, 16 used a percentage increase to WAC, six states actual used AAC, and 17 states used the lower of the reduction from AWP and the increase to WAC to set the reimbursement for ingredient costs [9].

**Rationale**

While the issues of Medicaid reimbursement for drug ingredient costs have been evolving, another challenge for Medicaid is the increasing numbers of its enrollees under the Affordable Care Act (ACA). The Supreme Court’s 2012 decision ruled that states could choose whether or not to accept the ACA’s expansion of Medicaid eligibility. Thus far, only 30 states have expanded it and approximately two-thirds of Medicaid beneficiaries live in Medicaid expansion states. The average percent changes in the total monthly Medicaid enrollments before and after the ACA were approximately 31% and 9% for states expanding and not expanding Medicaid, respectively [4]. A report showed that the number of Medicaid prescriptions increased
more than 25% in states with Medicaid expansion and less than 3% in states with no expansion [10]. There is an evidence of different levels of cost containment between these two state types. A study showed that, under a certain policy, there might be an approximately 46% reduction in primary care fee for physicians in Medicaid expansion states, while it could be about 37% in non-Medicaid expansion states [18]. Although there is no comparison study or report about the Medicaid reimbursement to pharmacies between Medicaid and non-Medicaid expansion states, likely there should be some differences. Therefore, a research question arises whether or not reimbursements for drugs to pharmacies in Medicaid and non-Medicaid expansion states are different under these evolving policies. This study will help community pharmacies to understand the potential consequences of Medicaid reimbursement for drugs in Medicaid and non-Medicaid expansion states. It will shed light on the overall Medicaid reimbursement and drug ingredient costs in Medicaid and non-Medicaid expansion states. Also, it will examine the results of using NADAC, which is a national average (there can be some price differences across different states), as a potential reimbursement matrix for the prescription ingredient costs, since it has been implemented in some states and possibly continues to grow to other states as a cost saving tool, unlike the AMP-based FULs that have only been drafted thus far. The results of this study will coincide with the mission statement of Community Pharmacy Foundation – increasing awareness of community pharmacy owners in different states of factors affecting business viability.

III. Capacity, Readiness and Operations of your organization to implement the proposed project.

This project will be conducted at College of Pharmacy, South Dakota State University. Based on the university’s recent vision, it has committed to become a research intensive institution. The college’s mission is also to advance societal well-being and the profession of pharmacy through graduate education, research, scholarship, and service. Therefore, the university and the college have built supporting systems and resources that are ready for conducting this study. Especially, community pharmacy is one of the areas that the college has focused on. A community pharmacy residency program, which is designed to develop practitioners with a high level of skill and expertise required to manage patient care in the community pharmacy setting, is an example. It has been a successful program in various areas, including recruitment of high-quality candidates, development of continuing education opportunities, collaborative interprofessional practices, community pharmacy management, didactic and experiential teaching, and practice-based research.

The investigators of this study are composed of two faculty members. Dr. Middendorf is a faculty member who completed a community pharmacy practice residency and earned a master degree of business administration, while Dr. Ngorsuraches is a faculty member who has a doctoral degree in social and administrative pharmacy. Dr. Middendorf has currently spent his considerable amount of time practicing and developing services at two community pharmacies. He is able to connect community pharmacists’ needs and views to the study. Dr. Ngorsuraches has had more than 10-years experiences in leading research projects and publishing research results. One of his recent publications was to apply US drug prices (i.e. average wholesale prices and prices listed in National Average Drug Acquisition Cost) to determine equitable prices in Thailand [19]. This publication indicates that he has knowledge and experiences working with data that will be used in this study. The combination of these two disciplines or areas of expertise reflects capacity and readiness for conducting this study.

IV. Goal(s)
   To examine the Medicaid reimbursement for drugs in Medicaid and non-Medicaid expansion states

   a. Objectives
      1. To assess changes in the average reimbursement revenue amounts from 2011 to 2014 for prescription drugs to pharmacies and compare them between Medicaid and non-Medicaid expansion states
      2. To assess changes in the individual components of reimbursement revenue amount, e.g. average ingredient costs, dispensing fees, and cost sharing, from 2011 to 2014 and compare them between Medicaid and non-Medicaid expansion states
      3. To compare estimated reimbursement revenue amount changes between Medicaid and
V. Methods

a. Study design
This study will be a pre- and post-descriptive analysis of retrospective data from various sources to assess changes in the average pharmacy reimbursement revenue amounts and their individual components from 2011 to 2014 for prescription drugs and compare them between Medicaid and non-Medicaid expansion states.

b. Sample size
For the purpose of statistical tests, the study will use G*Power 3.1.9.2 to calculate sample size [20]. Based on the difference in increasing numbers of prescriptions between Medicaid and non-Medicaid expansion states [10] and the different levels of cost containment of primary care fees for physicians [18], we anticipate a large effect size (0.8) in this study. Using a conventional statistical power of 0.80 and a two-tailed significance level of 0.05, a total number of 52 drugs will be required for the minimum sample size.

We will use a market basket approach to assess a consistent set of drugs in order to capture only variations in reimbursement formulas during the study period. We will create the drug basket by pooling prescription data from all years and ranking them by the number of prescriptions and expenditures. We will then purposely select a representative sample of drugs dispensed to Medicaid patients to ensure that we will have a good mix of brand-name and generic drugs with some high number of prescriptions and high expenditures up to a total of 60 drugs. This number is higher than the numbers that the Office of Inspector General, Department of Health and Human Services used when they previously compared pharmacy reimbursement between Medicare Part D and Medicaid [21]. Therefore, there should be an adequate sample size from policy perspective as well. There is no contingency plan in this study since all data will be from secondary data sources previously collected.

c. Subject characteristics
This study will include brand-name and generic drugs in Medicaid and non-Medicaid expansion states. The brand-name drug is defined as a drug that has a trade name and is protected by a patent during the study period.

Although, as of July 31, 2015, there are 31 Medicaid expansion states, 19 non-Medicaid expansion states, and one state discussing about the expansion [22], we will define data from Medicaid and non-Medicaid expansion states by the first quarter after their governors signed into law since Medicaid covered outpatient prescription drug reimbursement information [23], which is the source of reimbursement methodologies, are also quarterly updated by CMS and there might be potential change in response to the expansion. For instance, if the governor of a state signed in May 2013, the data of this particular state starting from the 2013 quarter 3 will be included in the Medicaid expansion state group. However, we excluded five states (AR, IN, IA, MI, and NH) that expanded their Medicaid, because they use an alternative to traditional expansion or are in transition. We did not include WI since it uses different criterion for its expansion that might cause different policy implications.

d. Method of subject identification, recruitment, and retention.
N/A

e. Length of participation (number and frequency of visits or contacts)
This study will cover data from year 2011 to 2014.

f. Data collection (type and process)
We will use two major data sources in this study. The first data source will be Medicaid State Drug Utilization Data, which the CMS maintains [24]. The data are quarterly aggregated fee-for-service pharmacy claims records for covered outpatient drugs dispensed to Medicaid beneficiaries and paid for by State
Medicaid agencies in 50 states and the District of Columbia. Each record includes a record ID, state code, National Drug Code (NDC), period covered (year and quarter), drug name, number of units, number of prescriptions, total amount reimbursed, amount reimbursed by Medicaid, and amount reimbursed by non-Medicaid. The second data source will be the National Average Drug Acquisition Cost (NADAC) maintained by the CMS [25]. The NADAC data are collected by a survey of invoices from independent and chain retail pharmacies and the data have been updated on a weekly and monthly basis. Each record includes a drug description, NDC, NADAC per unit, effective date, pricing unit, pharmacy type indicator, over-the-counter (OTC) status, explanation code (pertain to how the NADAC was calculated), classification for brand or generic, corresponding generic drug NADAC per unit, and corresponding generic drug effective date.

We will first download state Medicaid drug utilization and payment from Medicaid State Drug Utilization Data from 2011 to 2014. The data are divided into four quarters for each state. The study will separate data from Medicaid and non-Medicaid expansion states. We will fill in state’s dispensing fee [23] and amount of cost sharing of each drug [26]. We will download the drug price list from the NADAC. We will combine the data and the list of NADAC, which have been available since November 2013, with drug type data from the Red Book [27] at the NDC level. We will then have a working file for each state. It will be composed of drug NDC, NDC description, number of units, number of prescriptions, total amount reimbursed, dispensing fee, cost sharing amount, drug type (classification for brand-name or generic drugs), and NADAC price.

g. Data analysis
For the first objective, we will first assume that community pharmacies will receive the cost sharing for each prescription drug at the amount indicated by each state. The claims data do not include the cost sharing portion of the revenue for prescriptions that pharmacies receive, so it is necessary to ‘recapture’ those amounts before analysis. We will add a total amount of cost sharing (relevant co-payment amounts multiplied by the numbers of relevant prescriptions) for each drug to the amount reimbursed for each drug from the Medicaid State Drug Utilization Data in each working file to estimate the pharmacy reimbursement revenues. This study will also validate these revenue amounts with the results calculated from the reimbursement formula [23] by using either average wholesale price (AWP) or wholesale acquisition cost (WAC) from the Red Book [27]. We will aggregate data from each working file to make an aggregated data of each year in the Medicaid and non-Medicaid expansion states. This study will calculate the average payment (revenue) amount for each study drug by dividing the total reimbursement revenue amount by the number of prescriptions. We will then calculate the changes from one year to its following year and compare them between Medicaid and non-Medicaid expansion states for each drug. We will perform a paired-samples t-test on the difference of the average reimbursement revenue amount between Medicaid and non-Medicaid expansion states across all study drugs for each year. We will also use analysis of variance (ANOVA) to examine the difference in the average reimbursement revenue amount between the Medicaid and non-Medicaid expansion states across three-year periods (2011-2012, 2012-2013, and 2013-2014).

For the second objective, we will first calculate the total Medicaid ingredient cost for each study drug by subtracting its total dispensing fee from the pharmacy reimbursement revenue amount of each drug calculated in the first objective. Our plan is to calculate the total dispensing fee by multiplying the state’s dispensing fee from the same period of time by the total number of prescription of each drug. We will aggregate the ingredient cost of each drug in each year. We will calculate the average ingredient cost for each study drug by dividing the aggregated Medicaid ingredient cost by its total number of prescriptions. This study will calculate the average dispensing fee for each drug by dividing the aggregated total amount of dispensing fee by its total number of prescriptions. Similarly, we will calculate the total amount of cost sharing by multiplying the state’s cost sharing from the same period of time by the total number of prescription of each drug. This study will calculate the average cost sharing for each drug by dividing the aggregated total amount of cost sharing by its total number of prescriptions. We will then calculate the changes of the average ingredient cost, dispensing fee, and cost sharing from one year to its following year and compare them between Medicaid and non-Medicaid expansion states for each drug. We will perform a paired-samples t-test of the difference of all three components between Medicaid and non-Medicaid expansion states across all study drugs for each year. We will also use analysis of variance (ANOVA) to examine the difference of all three components between Medicaid and non-Medicaid expansion states for each drug.

For the third objective, we first will calculate the estimated reimbursement revenue amount for each drug by multiplying its NADAC price per unit by its number of units, and adding the total dispensing fee. We can do this calculation only for 2014 data after the first NADAC was posted. Our plan is to aggregate the estimated reimbursement revenue amount for each drug and calculate the average reimbursement amount for each study drug by dividing the aggregated amount by the number of prescriptions. We will then calculate the difference between this estimated amount and the average reimbursement revenue amount calculated in the first objective. This study will calculate the changes from one year to its following year and compare them between Medicaid and non-Medicaid expansion states for each drug. We will perform a paired-samples t-test of difference of the average difference of reimbursement amount between Medicaid and non-Medicaid expansion states across all study drugs for each year. We will also use analysis of variance (ANOVA) to examine the difference of the average reimbursement amount between the Medicaid and non-Medicaid expansion states across three-year periods (2011-2012, 2012-2013, and 2013-2014).

VI. Dissemination Plan
a. Where you plan to publish or present the results?
   We plan to present the project results at the American Pharmacists Association’s Annual Meeting and Exposition and publish in the Journal of the American Pharmacists Association.

VII. Timetable

<table>
<thead>
<tr>
<th>Task</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2</td>
</tr>
<tr>
<td>1. Finalize proposal</td>
<td>X</td>
</tr>
<tr>
<td>2. Retrieve all data</td>
<td>X X X</td>
</tr>
<tr>
<td>3. Combine all data, prepare working file,</td>
<td></td>
</tr>
<tr>
<td>and validate data</td>
<td></td>
</tr>
<tr>
<td>4. Analyze data</td>
<td>X X X</td>
</tr>
<tr>
<td>5. Discuss results and write report</td>
<td></td>
</tr>
</tbody>
</table>

VIII. Budget
a. Expense categories and amounts
b. Proposed payment plan
   i. Provide a proposed breakdown of payments based upon anticipated expenses and achievement of objectives milestones
   ii. This should include an item for at least 15% of the total funds withheld until submission and review of final project deliverables

<table>
<thead>
<tr>
<th>Personnel Costs</th>
<th>Amount</th>
<th>Justifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Personnel cost and fringe benefits for Surachat</td>
<td>$19,435*</td>
<td>Required by South Dakota State University and based on % workload; 10% (4 hours per week) for</td>
</tr>
</tbody>
</table>
IX. References


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*$2,915.25 (15% of total budget) will be withheld until full report submission.
Grant Application # 71143
Applicant: S. Ngorsuraches


### B. CPF DOCUMENTATION ITEMS

<table>
<thead>
<tr>
<th>Item</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Required</td>
<td>Yes</td>
</tr>
<tr>
<td>Sustainability</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>This study intends to examine the Medicaid reimbursement for drugs in Medicaid and non-Medicaid expansion states, as a result of the ACA. Although the state Medicaid expansion is evolving policy, the study will inform both community pharmacists and state governments about the policy decision made.</td>
</tr>
<tr>
<td>Transferability</td>
<td>This study is transferable because the scope of the project covers 45 states and a good mix of brand-name and generic drugs with some high number of prescriptions and high expenditures to a total of 60 drugs.</td>
</tr>
<tr>
<td>Future implications</td>
<td>We propose to finish the study within 12 months because there will be major implications for pharmacies in Medicaid and non-Medicaid expansion states. If the Medicaid reimbursement for drugs is not set appropriately, the expansion will potentially have financial consequences on community pharmacies, especially independent community pharmacies that have served a lot of Medicaid patients.</td>
</tr>
</tbody>
</table>
### C. BUSINESS PLAN (APPENDIX 1)

<table>
<thead>
<tr>
<th>GOALS/OBJECTIVE</th>
<th>KEY ACTION STEPS</th>
<th>DATA SOURCE</th>
<th>OUTCOME &amp; EVALUATION</th>
<th>PERSON RESPONSIBLE</th>
<th>COMMENTS/NOTES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goal A.</strong> To examine the Medicaid reimbursement for drugs in Medicaid and non-Medicaid expansion states</td>
<td><strong>Obj:A1</strong> To assess changes in the average reimbursement revenue amounts from 2011 to 2014 for prescription drugs to pharmacies and compare them between Medicaid and non-Medicaid expansion states</td>
<td><strong>A1a</strong> Download data</td>
<td>Medicaid State Drug Utilization Data and the Redbook</td>
<td>- the average reimbursement revenue amounts for prescription drugs</td>
<td>Project Director &amp; co-investigator</td>
</tr>
<tr>
<td></td>
<td><strong>A1b</strong> Combine data</td>
<td><strong>A1c</strong> Analyze data</td>
<td><strong>A1d</strong> Discuss the study results</td>
<td>Evaluation:</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>A2a</strong> Download data</td>
<td>Medicaid State Drug Utilization Data and the Redbook</td>
<td><strong>A2b</strong> Combine data</td>
<td>- the difference of the average reimbursement revenue amounts between Medicaid and non-Medicaid expansion for each drug and perform a statistical test;</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>A2b</strong> Combine data</td>
<td><strong>A2c</strong> Analyze data</td>
<td><strong>A2d</strong> Discuss the study results</td>
<td>Performance:</td>
<td>- Difference found</td>
</tr>
<tr>
<td></td>
<td><strong>A2c</strong> Analyze data</td>
<td></td>
<td></td>
<td></td>
<td>Project Director &amp; co-investigator</td>
</tr>
<tr>
<td></td>
<td><strong>A2d</strong> Discuss the study results</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
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</tbody>
</table>

**Obj:A2** To assess changes in the individual components of reimbursement revenue amount, e.g. average ingredient costs, dispensing fees, and cost sharing, from 2011 to 2014 and compare them between Medicaid and non-Medicaid expansion states

**Evaluation:**
- the difference of the average ingredient costs, dispensing fees, and cost sharing between Medicaid and non-Medicaid expansion for each drug and perform a statistical test
<table>
<thead>
<tr>
<th>Obj:A3</th>
<th>To compare estimated reimbursement revenue amount changes between Medicaid and non-Medicaid expansion states if NADAC is used as an AAC</th>
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</thead>
<tbody>
<tr>
<td>A3a</td>
<td>Download data</td>
</tr>
<tr>
<td>A3b</td>
<td>Combine data</td>
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<tr>
<td>A3c</td>
<td>Analyze data</td>
</tr>
<tr>
<td>A3d</td>
<td>Discuss the study results</td>
</tr>
<tr>
<td>Medicaid State Drug Utilization Data, National Average Drug Acquisition Cost (NADAC), and the Redbook</td>
<td>Performance:</td>
</tr>
<tr>
<td>- Difference found</td>
<td>Performance:</td>
</tr>
<tr>
<td>- estimated reimbursement revenue amount changes when prices listed in NADAC are used</td>
<td>- Difference found</td>
</tr>
<tr>
<td>Evaluation:</td>
<td></td>
</tr>
<tr>
<td>- the difference of the changes between Medicaid and non-Medicaid expansion for each drug and perform a statistical test</td>
<td>Project Director &amp; co-investigator</td>
</tr>
</tbody>
</table>

**Performance:**
- Difference found