

Title of Project: Prescribing Errors in Ambulatory Pediatric Care

Principal Investigator and Team Members:

Basco, William T. = PI

Simpson, Kit = Mentor

Hulsey, Thomas = Mentor, Director of Masters Degree Program

Ebeling, Myla = Co-investigator and Data Manager

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A. ABSTRACT

Purpose: To evaluate the frequencies of prescribing errors in ambulatory pediatric care.

Scope: Use of statewide South Carolina Medicaid administrative data, totaling over 1.4 million prescriptions and over 700,000 enrollees.

Methods: The study devised processes to estimate frequencies of look-alike, sound-alike (LASA) drug substitution errors and to estimate frequencies of dosing errors among narcotic-containing preparations prescribed for children. For 11 LASA drug pairs, we identified patients who experienced a first dispensing of one drug in the pair after receiving the other drug (screening alert). We then added diagnostic data to determine the frequency of true error. For dosing frequency determination, we focused on narcotic-containing drugs prescribed to children 0-36 months old.

Results: Among the LASA drug pairs evaluated, there were 1,420,091 prescriptions to 173,005 subjects. There were 395 screening alerts generated, representing a screening alert frequency of 0.28 screening alerts per 1,000 prescriptions. We identified 43 true LASA errors. In the dataset, the overall LASA error rate is estimated to be approximately 0.00003%, or 0.03 LASA errors per 1,000 prescriptions. Dosing errors for narcotic-containing preparations occurred in 5% of all prescriptions to children 0-3 years old.

Key Words: medication error, children

B. Purpose of Study: This study had four Specific Aims: Aim 1. Validation of a method for imputing weights for determining overdose and underdose for pediatric medications. Aim 2. Define and determine the frequency of ambulatory pediatric prescribing errors. Aim 3. Identify provider and patient characteristics associated with pediatric prescribing errors. Aim 4. Evaluate whether electronic medical records that include a prescribing module reduce the rate of pediatric prescribing errors among trainees.

C. Scope:

C-1 Background: Among pediatric medication errors, look-alike, sound-alike (LASA) errors have received little attention. LASA errors are the erroneous prescription or delivery of a drug because the name of the drug (generic or brand) is similar in appearance to or sounds like another drug. (1-4) The increasing availability of health information technology (HIT) at the provider and pharmacy levels has the potential to reduce LASA errors by improving legibility of prescriptions and by improving the ability to cross-check any new prescription with those a patient has received before. (5;6) Automated screening for LASA errors, therefore, appears to be a reasonable goal for tomorrow's HIT. There are relatively more data on pediatric outpatient dosing errors, with one study demonstrating dosing errors in 15% of outpatient prescriptions. (7) Choice of incorrect drug is also a common error, occurring in up to 5% of potential adverse drug events in one inpatient study. (8) The Institute for Safe Medication Practices publishes LASA drug pairs, and a 2008 report by the US Pharmacopeia identified over 1,500 drug pairs with LASA potential. (9;10)

C-2 Context: Pharmacy HIT has the potential to allow screening for LASA errors without reviewing each prescription for LASA potential. We undertook this preliminary study with the following objectives. First, we wanted to estimate how often a real-time pharmacy screening program would alert a pharmacist to potential pediatric LASA errors, using a test list of LASA drugs known to have caused errors. Second, the estimated rates could be compared with published rates of other pediatric error types to qualitatively compare how LASA errors fit into the overall picture of pediatric prescribing error. For the dosing work, we calculated the total daily dose of either codeine- or hydrocodone-containing preparations prescribed to children 0-3 years old. Using CDC weights by age and gender, we were able to estimate the percentage of young children who were prescribed potential overdoses (total daily dose dispensed exceeded recommended dose).

C-3 Settings, Participants: This study used 2000-2006 South Carolina (SC) Medicaid paid claims data for patients < 20 years old obtained from the SC Office of Research and Statistics (ORS). (11) The dataset contained unique encrypted patient identifiers used to link enrollees to pharmacy and diagnostic data. We began with outpatient dispensed prescriptions and then matched patient data (from enrollee files) to each prescription. We obtained subjects' encounter diagnoses from outpatient, inpatient, and emergency department visits. The data were provided as SAS datasets for Windows, Version 9. A data manager (ME) experienced with SC Medicaid data reviewed the files and removed duplicated entries. The Institutional Review Board of the Medical University of South Carolina and South Carolina ORS approved the study.

D. Methods:

D-1: Identification of Drugs and Creation of Analytic Datasets: To determine drug prescribed, we utilized the variable "drugname" in the dataset, a text string variable. We scanned the drugname variable for any portion of the drug name that matched brand or generic names for the test drugs. Searching by the drugname variable identified more prescriptions than searching by National Drug Code (NDC) code numbers (data not presented). We identified all formulations (concentrations, etc.) of the drugs, including the name (brand or generic, depending on drug), the generic form of the drug, and all brand versions of generic forms. We utilized "Medline Plus" (<http://www.nlm.nih.gov/medlineplus/druginformation.html>) to identify all brand names.

D-2. Determining LASA pairs for analyses: We began with the List of Confused Drug Names, compiled by the Institute for Safe Medication Practices. (10) The list contains drug pairs confused by either orthographic similarity or phonographic similarity, published in the Institute's newsletter when they have resulted in a known LASA substitution. The list examined for this study contained 179 LASA pairs, but the list was expanded in 2009. Our pilot study goal was to identify 10-20 drug pairs used in ambulatory pediatrics to test our analysis approach. Therefore, we eliminated any pair including a parenteral preparation. Then, we sought pairs that met the following general criteria: a) one of the drugs was

commonly prescribed to children and generally meant to be taken daily; b) the paired drug was prescribed less often for children or was not expected to be taken daily; c) the paired drugs were generally not prescribed for the same disease or indications, meaning that one would not expect a patient to be receiving both drugs for the same diagnoses.

D-3. Estimating the rate of screening alerts for LASA Substitutions: We considered any patient who received at least three dispensings of a drug in a LASA pair within a 12-month period (to account for quarterly dispensing) to have been appropriately prescribed that drug (a "usual drug"). One goal of the project was to estimate frequencies of "screening alerts" that a pharmacist might experience if screening for LASA errors were occurring in real time. For our study, a patient triggered a screening alert (a potential LASA error) if he or she received a usual drug and then presented with a first prescription for the paired drug within 6 months of a usual drug. Either drug in a LASA pair could serve as the usual drug. We did not use a rolling count of prescriptions, meaning that each drug pair for a patient could account for only one potential error. In determining the numerators and denominators for the per prescription rate calculations, we censored any dispensing after a subject triggered a screening alert. This approach had the effect of censoring $< 0.01\%$ of prescriptions for the 22 drugs. For patients who did not trigger a screening alert, we counted all prescriptions (dispensings) of the 22 drugs.

D-4: Estimating the rate of true LASA errors: Because a screening approach would be expected to have false positives, we evaluated additional drug and diagnostic information in the database to determine true errors. We calculated the positive predictive value (PPV) of screening alerts by the following definition: "true error" = a patient who triggered a screening alert, received only ONE dispensing of the paired drug in 6 months, and had no diagnoses tied to the dispensing date that supported use of the paired drug. In order to link a prescription to a diagnoses, we searched for diagnoses in the data that occurred within 30 days before or after the dispensing date using the following hierarchy: 3 days before the dispensing date, then 3 days after the dispensing date; 7 days before, then 7 days after; 30 days before, then 30 days after. When we identified screening alerts for which the subject did not go on to receive additional dispensings of the drug that triggered the alert within 6 months, two clinicians with > 10 years of practice experience each reviewed the diagnoses linked to these prescriptions. The clinicians independently determined whether the subject had a supporting diagnosis for the drug that triggered the alert. We calculated the kappa statistic as a measure of agreement. When a disagreement occurred, the two investigators discussed the case and came to consensus. With this information, we were then able to estimate the frequency of "true-positive" LASA errors. We linked 91% of prescriptions evaluated to a diagnosis, with 89% of those linked to diagnoses ≤ 7 days before to the dispensing dates. When we could not link to diagnosis, we counted that script as NOT having support in the diagnoses. Because most frequencies of potential errors were $< 1\%$, we present frequencies per 1,000 prescriptions.

D-5. Determining drugs to evaluate for narcotic overdosing. We first determined the frequencies of all drugs in the dataset, identifying those with narcotics (e.g. codeine, hydrocodone, morphine). We identified the top five codeine-containing products and the top five hydrocodone-containing products, as morphine-containing products were much less prevalent in the dataset.

D-6. Determining frequencies of narcotic overdosing. For each of the 10 drugs, we obtained the maximum recommended daily dose (per kg) from Micromedex. Utilizing the drug name, we identified the concentration of either codeine or hydrocodone in the preparation. Using the "days supply" and "volume dispensed," we were able to calculate the total drug dispensed per day. Utilizing age and gender-specific 95th percentile weights (from CDC growth charts), we determined the frequency of children 0-3 years old who were dispensed a total daily dose of either codeine or hydrocodone that exceeded the amount that should have been dispensed for a child at the 95th percentile weight.

D-7. Limitations. The most significant limitation of the LASA study is that we examined only 11 drug pairs, comprising 16% of all the dispensing available in our Medicaid data, so we do not know how representative these 11 pairs are of all pediatric LASA pairs. The limitations of reviewing prescriptions as dispensed rather than as written and the fact that we missed errors that might have occurred when patients do not have a pattern of drug dispensing to rely upon have been discussed previously.

For the dosing error estimations, another limitation is that we do not know how much of the medication dispensed the child actually took, so the errors represent potential overdoses. In addition, we are not able to determine whether any individual prescription was for "PRN" use, meaning that the intention may not have ever been for the child to take the entire daily dispensed amount.

Overall limitations include that these data are from one state's Medicaid prescriptions, so they may not be representative of the Medicaid population of other states nor the non-Medicaid population of our own state. Because of the limitations of the administrative dataset used for this study, we are unable to attribute any individual error to the providers (prescribing error) or pharmacists (dispensing errors). Such attribution would require a prospective study of individual alerts and prescriptions.

E. Results

1. Principle Findings and Outcomes:

E-1a. LASA Error Results: Among the 22 test drugs, there were 1,420,091 prescriptions to 173,005 subjects. We identified 395 screening alerts, for a screening alert rate of 0.28 screening alerts per 1,000 prescriptions. The total number of prescriptions varied widely, from 51 total prescriptions for "Viagra" to 531,245 for "Adderall" and its generics. The number of patients who triggered a screening alert was greatest for Adderall, with 115 patients who received Adderall as a usual drug triggering a screening alert for receiving at least one Inderal. The frequency of screening alerts per prescription was highest for methadone at 23.3 alerts per 1,000 methadone prescriptions.

In total, 95 screening alerts met the criteria for review of diagnoses, and 88 were linked to a diagnosis (91%). The raw agreement of the two reviewers for whether the diagnostic data supported a prescription was 94.1% (kappa statistic 0.88, $p < 0.001$). After review of diagnostic data, we identified 43 true errors (0.00003% of all prescriptions of the 22 drugs, or 0.03 errors per 1,000 prescriptions). The positive predictive values of the screening alerts was "0" for nine of the drugs, meaning that all subjects who were on those drugs and triggered a screening alert had diagnoses supporting the use of the paired drug that triggered the alert. However, the PPV for 7/17 (41%) drugs that triggered an alert remained $\geq 10\%$.

E-1b. Dosing Error Results: We are still conducting these analyses. However, we have completed preliminary analyses on codeine-containing products. Among children 0-3 years old in the dataset, 17,164 received 20,475 prescriptions. The per-prescription 2x overdose (patient dispensed \geq two times the upper limit of total recommended dose per day) frequency was 1.23%, corresponding to 251 prescriptions. The per-patient 2x overdose frequency was 1.36%, or 233 patients. We will calculate similar rates for hydrocodone-containing preparations and additional formulations of codeine-containing preparations. These data will be submitted for the Southern Regional Meetings and Pediatric Academic Societies Meeting for 2011.

E-1c. Factors associated with receipt of error, answering Aim 3.

In the LASA error study, no patient characteristic was predictive of receipt of an error. With only 43 total subjects receiving a LASA error among the drugs studied, the low number made it difficult to show associations with gender, race/ethnicity, or rural habitation.

In the preliminary dosing evaluations, male subjects were more likely to receive a 2x overdose of codeine (1.6% vs 1.2% of females, $p < 0.01$), and African American children also appeared more likely to receive a 2x overdose of codeine (1.6% vs 1.2% of non-AA, $p < 0.04$). In addition, frequency of overdose was associated with age. The mean age of all subjects who received any codeine-containing preparation was 9.3 months, and the mean age of those receiving a 2x overdose was only 1.8 months ($p < 0.0001$). Rural habitation was not associated with 2x overdose in the preliminary analyses.

2. Discussion and Conclusions:

E-2a. We believe that the LASA study demonstrates the feasibility of real-time pharmacy screening for LASA errors, and the frequency of those errors appears to be generally low in the 22 drugs studied. The study appears to be the first to publish frequencies of LASA errors in pediatric care. Comparison of the LASA error frequency to frequencies of other types of pediatric medication errors in outpatient settings suggests that the frequencies of LASA errors may be much lower than dosing errors and other error types. (7;12;13) McPhillips et al. evaluated almost 2,000 outpatient pediatric prescriptions and found a dosing error frequency of 15%. (7) Kozer demonstrated that 10% of pediatric emergency department patients experienced a medication error. (13)

E-2b. The difference in the magnitude of the frequencies of dosing prescribing error in other studies and our frequencies of potential LASA error may be explained in part by the fact that all pediatric drugs represent the potential for a dosing error, but not every pediatric drug has LASA potential. The LASA error frequencies suggested by these data are undoubtedly underestimates of the true LASA error rate for several significant reasons. First, the McPhillips and Kozer studies reviewed prescriptions and charts, so their rates represent prescriptions that had not yet been evaluated by a pharmacist, whereas ours are only after pharmacy review and dispensing. Pharmacists identify approximately 75-80% of prescription errors before dispensing in inpatient studies. (14;15) Assuming that pharmacists would identify LASA errors in outpatient prescriptions at similar rates, multiplying the estimates of LASA error frequencies in this study by a factor of 5 still would still result in screening alert frequencies of $< 0.01\%$ of prescriptions and error rates of $< 0.001\%$ for these drug pairs. Second, we only estimated LASA error rates among patients who were able to demonstrate a pattern of receiving one drug first, making it likely that we missed patients who received only one dispensing or very sporadic dispensing of these drugs. Even with these differences, the published rates of dosing errors appear to be many times more common than LASA errors based on our estimates. Additional studies with more comprehensive drug pairs could further clarify the relative frequency of LASA errors.

The preliminary analyses for dosing errors does not allow specific conclusions at this time. However, even though the frequency of 2x dosing errors in our preliminary analyses is also low ($< 5\%$), 2x dosing errors of narcotics are a high-risk-of-harm scenario. The study will also illustrate the relatively common use of these preparations in outpatient pediatric practice, despite the fact that dosing for children under 2 years of age is difficult.

3. Significance: Both of these studies are the only existing (published, in the case of LASA study) studies of either LASA or dosing errors in children using such a large, population-based data set. As such, they provide LASA and dosing error frequencies that have not previously been available.

4. Implications: Identifying either LASA substitution errors or dosing errors may be akin to "finding a needle in a haystack" and possibly not workable without automation. Use of Health Information Technology, including automated screening of prescriptions for either LASA or dosing errors would be a

potential approach to decreasing the risk of pediatric medication errors. In regard to LASA screening, an automated approach relying on prescribing history would likely require a pharmacist actually evaluating < 0.001% of prescriptions (< 1/1,000). Given that pharmacists dispense an average of 27,000 prescriptions per year, (16) a pharmacist would expect to experience approximately seven such alerts per year based on these 11 drug pairs. This suggests that future implementations of alerts for LASA or dosing errors should consist of an alert very different (e.g., different alert color on screen, different alert audio tone) from existing alerts in order to help deal with the phenomenon of "alert fatigue" among pharmacists. (1)

The screening approach suggested by these studies would ideally be part of larger approaches to limiting prescribing errors. The electronic prescribing requirement by the Centers for Medicare and Medicaid Services may partially address this problem, as all future drug prescriptions for Medicaid patients will have real-time reconciliation with stored records of patient prescriptions. (17) One approach demonstrated to reduce LASA errors is the use of "Tall Man" lettering, whereby the phonemes that are different between two LASA-paired drugs are placed in all capitalized letters, forcing the reader to mentally emphasize the different portions of the drug names. (18) It is worth noting that the work of a pharmacist to identify LASA errors under our approach would be greatly aided by inclusion of an "indication" on every prescription. Computerized physician order (medication) entry (CPOE) or e-prescribing also has significant potential to reduce LASA errors by improving the clarity of a prescription, reducing the risk of confirmation bias, as could automatically include an indication on the printed prescription. (1;19) Inclusion of a patient weight and indication on every prescription would allow the pharmacy dispensing computer to quickly determine if the dose is in an acceptable range. Although such decision support is sporadically available at both the prescribing and dispensing points, their use has not yet become widespread.

Our ultimate plan is to continue work in LASA errors, devising a set of LASA pairs that can be used to implement a real-time screening effort for LASA substitutions. I have been awarded an AHRQ-sponsored R03 (in the HIT Portfolio) that will result in the list of candidate LASA pairs for the real-time screening program, and we will also determine the frequencies of LASA error in this larger sample of drugs. After the R03, we plan to seek implementation grants to devise the screening alert program, pilot test it, and then implement it.

F. List of Publications and Products:

F-1. Overall Research Productivity: As noted in past Progress Reports, this award has been very helpful to my research productivity. Both research abstract output and research manuscript output markedly increased during the years of the funding period.

F-2. Research Abstract Output: Figure 1 demonstrates my involvement in research abstracts presented at regional or national meetings over the past 6 years. The first 2 years were pre K-award. As you can see, the protected time and coursework that has come as part of the K-award has allowed me to present a great deal more research abstracts, and manuscripts have begun to follow. In fact, an increase in manuscript activity accounted in part for the slight dip in research abstract activity in year 3 of the award.

Figure 1: Research Abstract Presentations by Dr. Basco Over 6 Academic Years.
Years 1-4 = K-08 funding period.

02468102004-20052005-20062006-2007 (Yr 1)2007-2008 (Yr 2)2008-2009 (Yr 3)2009-2010 (Yr 4)Number of AbstractsResearch Abstracts atRegional or Nat'lMeetings

F-3. Research Manuscript Output: Figure 2 demonstrates the frequency of peer-reviewed manuscripts (both research and other) published over the past 6 years. Just as in the case of abstracts, I have been able to develop considerable momentum in large part due to the K award program, and 2010 will see six manuscripts (all research) appear in print – a high-water mark for my career so far.

1. Basco WT, Ebeling M, Hulse TC, Simpson K. Using Pharmacy Data to Screen for Look-Alike, Sound-Alike Substitution Errors in Pediatric Prescriptions. *Acad Pediatr* 2010;10:233-7.

2. Basco WT Jr., Hletko PJ, West L, Darden PM. Determining the Proportion of Children Too Heavy for Age Appropriate Car Seats in a Practice-Based Research Network. *Clin Pediatr* 2009;48:37-43. This manuscript utilized the weight data collected as part of Aim 1.

3. Roberts JR, Kennedy SA, Darden PM, Basco WT, Jr. Prevalence of Overweight in Children: Comparing Children from the South Carolina Pediatric Practice Research Network to a National Sample. *Clin Pediatr* 2010;49(8);750-55. This manuscript utilized the weight data collected as part of Aim 1.

F-4. Research manuscripts aligned with the goals of this award: Since approximately 2006, I have collaborated with Dr. Ron Teufel, a junior hospitalist at MUSC, on his work on computerized physician order entry (CPOE) and outcomes. He has utilized AHRQ data for his efforts. CPOE and its literature have significant overlap with the patient safety literature, so my collaboration with him has helped me gain experience in the broader field of patient safety by learning more about CPOE.

4. Teufel RJ, Basco WT Jr, Simpson KN. Cost-Effectiveness of an Inpatient Influenza Immunization Assessment and Delivery Program for Pediatric Asthmatics. *J Hosp Med* April 2008;3(2):134-141.

5. Teufel RJ, Kazley AS, Basco WT Jr. Early Adopters of Computerized Physician Order Entry in Hospitals That Care for Children: A Picture of United States Healthcare Shortly After the Institute of Medicine Reports on Quality. *Clin Pediatr* 2009;48:389-396. This manuscript looks at uptake of CPOE in the early 2000s among hospitals that care for children, using a combination of HCUP-KID and HIMMS data.

F-5. Research manuscripts aligned with Dr. Basco's career goals:

6. Basco, WT, Jr, Cull WL, O'Connor CG, Shipman SA. Assessing Trends in Practice Demographics of Underrepresented Minority Pediatricians, 1993-2007. *Pediatr* 2010; 125: 460-467. This manuscript resulted from Dr. Basco's work with the AAP Committee on Pediatric Workforce and represents continuation of Dr. Basco's career-long interest in minority physicians and their role in the general medical and pediatric workforce.

7. Sheridan MEB, Blue AV, Basco WT Jr. Promoting Students' Community Service During Medical School: The MUSC Gives Back Office. *Teach Learn Med* 2010; 22 (3):214-218. This manuscript is a result of Dr. Basco's longstanding interest in how the medical school admission process relates to workforce issues.

8. Lintzenich AE, Teufel R, Basco W. Identifying Pediatric Asthma Patients Who Don't Receive Recommended Care Prior to Hospital Discharge. *Clin Pediatr*, In press. Dr. Basco has become the research mentor for a promising health services research fellow, Dr. Annie Lintzenich, at MUSC.

F-6. Non-research manuscripts aligned with Dr. Basco's career goals:

9. American Academy of Pediatrics, Committee on Pediatric Workforce. Enhancing the Diversity of the Pediatrician Workforce. Committee members: Friedman AL, Interim Chairperson (Lead Author), Basco WT, Jr., Hotaling AJ, Pletcher BA, Rimsza ME, Shipman SA, Shugerman RP, Tellez RW. Past Committee members: Anderson MR, Gilchrist GS, Goodman DC. Liason: McGuinness GA. Staff: Jewett EA. *Pediatr* 2007;119:833-7. This manuscript and the ones below (#11, 12) represent position statements published by the AAP Committee on Pediatric Workforce while I was on the committee.

10. Hletko PJ, Basco WT Jr. Making the Most of Data Collection: Lessons from a Practice-Based Research Network. *J SC Med Assn* August 2008;104:186-7. This essay on "best practices" for successful data collections in PBRN research was published in a PBRN symposium issue of the *J* of the SC Med Assoc.

11. American Academy of Pediatrics, Committee on Pediatric Workforce. Nondiscrimination in Pediatric Healthcare. Committee members: Pletcher BA (Chairperson), Alvarado-Domenench LI, Basco WT, Hotaling AJ, Rimsza ME, Shipman S, Shugerman RP, Tellez RW, Anderson MR (Lead Author, Past Chairperson), Friedman AL (Past Interim Chairperson), Goodman DC (Past Committee Member). *Pediatr* 2007;120:922-3.

12. American Academy of Pediatrics, Committee on Pediatric Workforce. Financing Graduate Medical Education to Meet the Needs of Children and the Future Pediatrician Workforce. Committee Members: Pletcher BA (Chairperson), Alvarado-Domenench LI, Basco WT, Hotaling AJ, Rimsza ME, Shipman S (Lead Author), Shugerman RP, Tellez RW, Pan RJD (Contributor). *Pediatr* 2008;121:855-61.

Figure 2: Research and Non-Research Manuscripts by Dr. Basco over 6 Academic Years. Yrs 1-4 = K-08 funding period.

02468, 2004-2005, 2005-2006, 2006-2007 (Yr 1)2007-2008 (Yr 2)2008-2009 (Yr 3)2009-2010 (Yr 4)Number of Publications, Research Manuscripts, Other manuscripts

F-7. Grant productivity:

In Year 3 and into Year 4 of this award, I successfully prepared and was awarded an R03 from AHRQ: R03 HS018841. "Assessment of Pediatric Look-alike, Sound-alike (LASA) Substitution Errors." This study will develop and evaluate a list of 200+ pediatric Look-Alike, Sound-Alike drug pairs used in outpatient pediatric care and thought to be problematic for patients should a substitution occur at the time of drug dispensing.

G: Summary: In short, the K award funding period has been extremely helpful to my career development, and I believe that I have been very productive with my time. I have published three papers using data from the project, and I expect to submit the fourth paper (on dosing errors) this fall. Completing the MSCR helped me advance my research methodology skills, such that I can properly mentor other

investigators and improve my contributions as a co-investigator, and that fact is evidenced by the numerous other manuscripts I authored or co-authored over the 4 years of funding. Finally, I have directly applied my skills to the methods used for the large dataset studies that comprise the core of the research plan.

I sincerely thank the Agency for Healthcare Research and Quality for allowing me this opportunity!

Sincerely,

William T. Basco, Jr., MD, MS
Associate Professor of Pediatrics
Director, Division of General Pediatrics
Medical University of South Carolina
135 Rutledge Avenue, MSC 561
Charleston, SC 29425
(843) 876-8512

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