PROJECT DESCRIPTION
The healthcare delivery system in the United States is cost prohibitive, inefficient, and unsustainable.\textsuperscript{1} Health care expenses in the US are continuing to rise and are expected to reach $4.0 trillion or 20\% of the GDP by 2015.\textsuperscript{2} Despite spending significantly more than any other industrialized nation on health care, outcomes within the United States fail to match those in other countries.\textsuperscript{2} This system of spending extraordinary amounts without providing superior care is flawed and creates a need for a change in healthcare delivery in the US. This change must create an environment that focuses on high-quality care at lower costs overall.\textsuperscript{1}

A study revealed that participants overall received only 54.9\% of recommended care for 30 different acute and chronic conditions. This mandates a need for improvement in the management of chronic illnesses.\textsuperscript{3} The Patient-Centered Medical Home was first introduced in 1967 by the American Academy of Pediatrics and has evolved since that time.\textsuperscript{4} In 2007 the American Academy of Family Physicians, American Academy of Pediatrics, American College of Physicians, and American Osteopathic Association joined together to issue a statement on the Joint Principles of the Patient-Centered Medical Home (PCMH). This statement focused on seven main principles which were aimed to improve the landscape of disease management in the primary care setting.\textsuperscript{5}

Previous studies of the PCMH consistently demonstrated reduction in cost via reduced emergency department and hospital utilization and improved perceived patient satisfaction. This data strongly supports the initial investment in cost and resources for conversion to a PCMH model clinic.\textsuperscript{6} Despite the encouraging economic gauges involving hospital and emergency department utilization discussed above, there exists a gap in the evaluation of the PCMH model’s effect on clinical outcomes for chronic disease management in the outpatient setting. Given the ultimate goal of the PCMH to provide better care at lower costs, it is imperative to assess both the economic and disease management affects of PCMH conversion.

A successful health care setting must provide improved quality care at lower costs. Therefore, it is necessary to evaluate if the PCMH improves overall outcomes for patients in addition to the reduction in overall cost previously demonstrated in order to provide objective support for or against widespread adoption of the PCMH model.

OBJECTIVES/PURPOSE
To assess the effect of Patient-Centered Medical Home conversion, in the primary care setting in Southwestern Virginia, on chronic disease management and clinical outcomes, using hypertension as the model disease.

METHODOLOGY
The design of this study was a retrospective case-control study using data maintained in the electronic medical record for hypertensive patients managed in six PCMH clinics (experimental group) and six non-PCMH clinics (control group). These groups included 7,061 patients and 6,111 patients respectively who had a diagnosis of hypertension during the time since 2008 when PCMH conversion occurred.

Considering the significant variation and the number of visits for each patient and the high variability in the time epoch between visits, traditional statistical methods for longitudinal analysis or repeated measurements would not work well. To bypass these difficulties, it was decided that the isotonic regression model adapted from Wu et al\textsuperscript{7} (see below) which is used to test for mean change would be used to elucidate trends among the blood pressure readings for each patient in the study. To accommodate for this analysis, all patients with <10 BP readings during the sample period were excluded from the study.
Specifically, the isotonic regression uses the following form:
\[
\Lambda_n = \frac{1}{\hat{\sigma}^2} \sum_{k=1}^{n} (\hat{\mu}_k - \bar{X})^2
\]
where \(\hat{\mu}_k\) is the fitted mean BP from the isotonic regression and \(\hat{\sigma}^2\) is a consistent estimator of the unknown population variance \(\sigma^2\). Naturally, the estimator \(\hat{\sigma}^2\) is dependent on the sample covariances and their weights. The BP of a patient is considered significantly decreasing if the test statistic \(\Lambda_n\) for the patient is greater than the critical value \(\lambda(\alpha)\).

After it was determine whether or not each patient had a decreasing BP trend based on the isotonic regression model above, an additional test was employed to compare the proportion of patient's with improving blood pressures in each the experimental and control groups. A logistical regression model was then used to elucidate whether the PCMH model had an effect on BP trends as stated above in the presence of demographic and personal attribute differences between the groups.

**APPLICANT’S ROLE IN PROJECT**
Medical student member of a team which included a family medicine attending, statistics doctoral student, and assistant professor of statistics. Worked with study design, protocol, literature review, clinical analysis of statistical results, discussion, and manuscript compilation.

**RESULTS/EVALUATION**
First, the exclusion criterion of greater than 10 BP readings during the observation period was applied to the patient population in both groups. Of the total number of PCMH patients with a diagnosis of hypertension, 901 patients (12.7%) met this criterion. For the non-PCMH control group 371 patients (6%) met the criterion. The difference in the number of patients with at least 10 separate blood pressure readings between the PCMH and non-PCMH group is highly statistically significant with a p-value <0.001.

The isotonic regression model was used to assess mean change of BP for each patient to determine if a decreasing trend in blood pressures was present. The results of the two-sample proportion test show that there is a significant difference in the proportion of patients in the PCMH group that had a decrease in SBP versus the non-PCMH group (p-value = 0.023). There was no significant difference in the proportion of patients with decreasing DBP between the two groups. Additionally, the chi-square test shows a statistically significant association between SBP and PCMH (p-value = 0.046) but again reveals no association between DBP and PCMH modeled care.

The logistical regression modeling of the data was completed for both SBP and DBP models using the following predictors: age group, race, payment status, gender, and site (PCMH vs non-PCMH). Age groups were classified in two groups, ≥ 65 years old or <65 years old. For SBP, clinical site and gender were significant while the other factors did not show significance. Using coefficient estimates, the odds ratio for reducing SBP for the PCMH site group was found to be 31% better than the non-PCMH group (odds(\text{PCMH})/odds(\text{non-PCMH})) = \exp(0.2698) = 1.31). Additionally, the odds ratio for reducing SBP for males was 33% better than females (odds(\text{males})/odds(\text{females}) = \exp(0.2864) = 1.33). If these two attributes are combined, the best odds for SBP reduction are for men managed in a PCMH clinic (\exp(-0.8806+0.2864+0.2698) = 0.72) and the corresponding proportion of decreasing SBP is 42.0%. Logistical regression modeling for DBP shows similar trends to those described above, however, no significant factors could be identified.

**CONCLUSIONS/DISCUSSION**
A large concern regarding PCMH conversion and implementation are the associated costs and whether these costs are justified in the positive impact on improved patient health and reduced overall cost of healthcare. The results of this study demonstrate a potential positive correlation between managing hypertension and the PCMH model. This observation in addition to the documented decreased emergency department utilization and hospital admissions adds strength to the continued endorsement of converting to PCMH as a method of healthcare delivery throughout the country. Additional studies are needed to deduce an exact cause and effect relationship between PCMH and chronic disease management as well as to explore the extent of any shown effect.

Moreover, the unexpected observation of a highly significant difference in the proportion of patients meeting inclusion criteria between the control and experimental groups suggests there may be a relationship between PCMH conversion and patient follow-up which also warrants additional study.