Author's response to reviews

Title: Awareness and Management of Chronic Disease, Insurance Status, and Health Professional Shortage Areas in the REasons for Geographic and Racial Differences in Stroke (REGARDS): A Cross-Sectional Study

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Author's response to reviews: see over
Dear Dr. Ku,

Thank you for sharing yours and the reviewers’ comments and suggestions based on the review of our paper “Awareness and Management of Chronic Disease, Insurance Status, and Health Professional Shortage Areas in the REasons for Geographic And Racial Differences in Stroke (REGARDS): A Cross-Sectional Study” submitted for publication in the BMC Health Services Research. As a result of our revisions, we have now included a new “Table 2” showing the unadjusted prevalence, awareness, treatment and control for all three conditions. The former Table 2 is now labeled “Table 3”. In accord with reviewers’ suggestions, we have added some additional covariates to our models (e.g. rural vs. urban, # of target conditions present), and some of the numbers in our multivariable models have changed (Table 3). However, all numeric changes were minor and none alters the main messages of the paper. We also removed the analyses related to the predicted probabilities for the hypertension outcomes because these analyses no longer seemed to add significantly to the main message of the paper. Therefore, the Figure showing the predicted probabilities for hypertension control according to HPSA residence stratified by insurance status was removed as well.

We appreciate all of your input, and we have tried to respond to each comment below. We have organized the comments by reviewer and responded to each one immediately in bold below. Where appropriate, we also referenced corresponding changes in the text or tables.

Thank you again for your review of this revised manuscript.

Sincerely,

Raegan W. Durant, MD, MPH
1. The authors’ description of their methods is relatively thorough, but some missing details raise questions about the results. First, the article by Howard et al (2005) that the authors reference re: the sampling scheme and methods does not fully explain the information provided to participants at the time of enrollment/informed consent. Were participants informed that the study involved cardiovascular disease?

Prior to the initial telephone contact, each potential participant received a letter describing the REGARDS study. The letter included a lay-person description of the geographic variation of stroke mortality, the importance of volunteer participation in research studies and the benefits of participation (risk factor evaluations, education on stroke warning signs, etc). Therefore each potential participant was informed that the study was related to cardiovascular disease and strokes, in particular.

2. Comparing the NHANES results with the REGARDS results, individuals in REGARDS are more likely to be aware of their hypertension, hyperlipidemia and/or diabetes than the nationally representative NHANES sample. The authors do not provide any evidence/results to indicate whether the prevalence/incidence of these diseases is higher among the REGARDS population. This omission makes it hard to judge whether a sampling bias may exist.

REGARDS included participants age 45 and older with an oversampling of residents of the Stroke Belt and Buckle. This sampling strategy was intended to result in the oversampling of persons with cardiovascular risk factors such as hypertension. In this analysis cohort of REGARDS participants living in either complete HPSA or non-HPSA counties, the prevalence of hypertension is 73%. In NHANES data from 2005-2008, the prevalence of hypertension was 35.6% and 69.7% among adults aged 45-59 and 60 years or older [1], respectively. The higher prevalence among REGARDS participants could potentially be due to the sampling strategy. Despite the higher prevalences of all three conditions in REGARDS, a previous interim analysis of all REGARDS participants, regardless of HPSA status, revealed that there were no differences in awareness of hypertension according to region (Stroke Belt vs. remainder of U.S.). Similarly, the prevalence of hyperlipidemia in a separate interim analysis (n=26,122) of REGARDS yielded a prevalence 50% for hyperlipidemia [2]. Though this prevalence is significantly higher than the prevalence documented in NHANES (16.2% in adults ≥ age 20) [3], adjustment for region (Stroke Belt vs. remainder of U.S.) in multivariable models was not significantly related to awareness or treatment of hyperlipidemia. Control of hyperlipidemia was the only outcome related to region in this analysis. Therefore the impact of sampling bias on the outcome of awareness of our 3 chronic conditions may be minimal.

3. Second, I am concerned that key variables may be missing from the model, leading to omitted variable bias. The authors do not appear to control for comorbid conditions (e.g., controlling for diabetes or hyperlipidemia when running hypertension models) but these are factors affecting hypertension. The
REGARDS study collects information on family history and dietary intake, which are additional risk factors for the observed conditions, but the authors do not include in their model.

The reviewer is correct in that disease burden may have an impact on health care utilization and, thus, may influence awareness, treatment and control of chronic disease. Therefore, we have added the presence of any of the three main chronic conditions (hypertension, hyperlipidemia, or diabetes) as a covariate in our models. For example, in the models for awareness, treatment and control of hypertension, we have adjusted for the co-prevalence of hyperlipidemia and diabetes. We have adjusted for the co-prevalence of hypertension and diabetes and the co-prevalence of hyperlipidemia and hypertension in all of the hyperlipidemia and diabetes models, respectively. The addition of these covariates to the model did not substantially change our results. The family history information in REGARDS pertains mainly to strokes and coronary disease rather than our specific target conditions. Therefore, the family history information specifically for our three target conditions was unavailable.

4. But the most glaring omission, which the authors acknowledge, is the lack of any ability to control for actual use of health care services. The key conclusion to the paper is to increase staffing in HPSAs, but the authors’ findings do not justify this conclusion. They speculate in the discussion that the uninsured in HPSAs may have less continuity of care, but I have my doubts that the continuity of care is that much better for uninsured people in non-HPSA locations.

As the reviewer notes, we do acknowledge our inability to measure outpatient health care utilization in the REGARDS cohort. Therefore, we have revised our conclusions by omitting some of the recommendations for the federal government to allocate funding to health care infrastructure. Instead we have shifted our focus to recommendations for a focus on quality of care. In addition, we note that the increased prevalence of clinical and sociodemographic barriers to care among uninsured HPSA residents may warrant some consideration of patient complexity in formulas for allocating HPSA funding.

4) The X-axis in the Figure is labeled as “HPSA Residence” but the categories for the bars are insured and uninsured.

The Figure was removed because the calculation of the predicted probabilities no longer added significantly to message of the paper.

Minor Essential Revisions

5) The authors should be clear in the methods section that all information used in this study came from the baseline of the study (i.e., entrance interviews, medical exam, questionnaire, etc.).

We have added language to the Methods section to clarify that all variables were collected at baseline and that the analyses were all cross-sectional.
6) There are several extremely long paragraphs in this manuscript with many different thoughts in them. For example, the first paragraph in the background section, the third paragraph of the discussion (starting with “Among the uninsured only”), and especially the fourth paragraph of the discussion (starting with “Despite the relatively similar”). The latter paragraph goes on for about two full pages!

**We have divided some of the above-mentioned paragraphs into shorter segments to improve readability.**

7) I would prefer to see parameter estimates or impacts rather than just odds ratios, to be able to judge whether the odds ratios represent substantive differences rather than just statistically significant differences.

**We have included a new Table 2 displaying the proportions of awareness, treatment and control for each chronic condition according to HPSA residence and insurance status.**

8) I strongly prefer to see complete models and results provided for multivariate analyses, to facilitate review.

**Due to limitations of space and clarity of presentation, we did not include results for complete multivariable models for all nine outcomes stratified by insurance status and HPSA residence. This would be a total of 18 full models, each with over a dozen covariates, making it difficult to present in a succinct fashion for readers. Because our focus was the influence of insurance status and HPSA residence, we chose to show the odds ratios and confidence intervals for these factors only.**

**Discretionary Revisions**
These are recommendations for improvement which the author can choose to ignore. For example clarifications, data that would be useful but not essential.

9) I’m not sure this is possible using the baseline cross-sectional data from REGARDS, but some measure of time uninsured and how long the person has had hypertension/diabetes/hyperlipidemia would add value. People who have only been receiving treatment for a short time may be uncontrolled for a “good” reason compared to people treated more long term.

**Unfortunately, the baseline assessment of insurance status in REGARDS does not include a measure of the duration of lack of insurance. Similarly, the REGARDS baseline data used to identify those with prevalent hypertension, hyperlipidemia and diabetes does not include information on the duration of the disease.**

10) The authors note that they use the 4-item Morisky scale for medication adherence. Is it not possible to use the 8-item scale? My understanding is that it is a bit more robust.

**The adherence measure in REGARDS is a 4-item Morisky scale, Therefore, the 8-item data was not available in this cohort.**
11) I worry a bit about “control” of diabetes/hypertension/hyperlipidemia being based on a single measure at a single point in time. Is it possible to assess control for the population over a longer time frame given the longitudinal nature of the REGARDS study?

Though REGARDS is a longitudinal cohort study, the clinical exam (including blood pressure measurement) and lab studies were only done at baseline. Therefore, it is not possible to incorporate measures from different time points into our definitions of control for each of the three conditions.

Kershaw

Major Compulsory Revisions

1. Why did you decide to answer your research question by stratifying the data by insurance status instead assessing a HPSA*insurance status interaction for each outcome? Did you test for interactions before stratifying the data? The way the results are presented, it's unclear whether insurance status as an independent variable is associated with awareness, treatment, and control. It seems like it would have been more informative to start by evaluating whether HPSA and insurance status are associated with these outcomes in the entire study population, and then if there are HPSA*insurance status interactions, presenting them the way you did in the Figure for hypertension.

We did test for interactions between insurance status and HPSA residence in unified models before stratifying the data. The insurance*HPSA interactions were positive (P<0.10) in 4 of 9 models across two of the conditions. Given the frequency of this positive interaction, we decided to stratify all the models to highlight the unique intersection of HPSA residence and insurance status for these outcomes. Furthermore, in the other unified models without positive insurance*HPSA interaction terms, the respective results for the stratified analyses did not differ substantively from the unified models. We have revised the Methods section to include our testing of the interaction terms.

2. It would be helpful to know, either in Table 1 or in the text, the prevalence of awareness, treatment, and control for each outcome by insurance and HPSA. You give overall prevalences in the text, but they don't seem as informative given that you stratified all your results by insurance status.

We have added a Table 2 to include the prevalence of each target chronic condition according to insurance status and HPSA residence.

Minor Essential Revisions

3. The Allen NB citation you mention in the Discussion should be added to the end of the first paragraph in the Background section to make it clear that at least one other study has assessed whether HPSAs are associated with awareness
and management of these chronic diseases.

We have added this citation to the Allen article in the the first paragraph of the Background section.

4. In the Methods section you should indication how many times blood pressure was measured.

Blood pressure readings were based on an average of two measurements taken during the same in-home visit. We have added this information to the Methods section.

5. In the Methods section you should cite the reference for your designated hyperlipidemia cutpoint of 130 mg/dl

We chose the single cutpoint of 130 mg/dl for persons of moderate cardiovascular disease risk according to national guidelines [4]. Though we did not risk stratify patients according to 10-year Framingham risk scores, the generally older age of the REGARDS cohort and the prevalence of CVD risk factors, such as hypertension and diabetes mellitus, increases the likelihood that many in our cohort would qualify for lipid-lowering therapy at this cutpoint.

6. In the footnotes for Table 2 you should include what variables the Adjusted models are adjusted for.

We have added a footnote to what is now Table 3 to indicate the covariates that we adjusted for in the multivariable models.

7. In the third paragraph, sentence starting with "However,..." you provide a potential explanation for your seemingly paradoxical findings. Is there any literature you can cite to support this statement?

There is literature to suggest that the insured, regardless of place of residence, enjoy better access to primary care and medical specialists, supporting our argument that the absence of differences in disease awareness among the insured may be due to some buffering of the geographic barriers faced by HPSA residents. We have included the supporting citation and elaborated on this point in the Discussion.

Discretionary Revisions

8. In the Methods section of the abstract it is unclear what "complete" means. This is something that is not defined until the Methods section of the actual paper. I think you should write complete HPSAs instead.

We have revised the abstract with this clarified reference to complete HPSAs.
9. The first paragraph in the background section is too long. I think it would be better to start a new paragraph when you describe the criteria for HPSAs. Also the sentence starting with "Secondly, ..." is hard to follow. It might be best to break it into two sentences.

We have divided the aforementioned paragraph into two smaller paragraphs and divided the specified sentence into two sentences.

10. Why do you think hyperlipidemia awareness was so much lower than hypertension or diabetes awareness? I think it would be nice if you could briefly include some possible explanation in the Discussion.

Serum tests for hyperlipidemia are probably done less frequently than blood pressure measurements. Behavioral Risk Factor Surveillance System data from 2009 reveals that 77% of adults report having their blood pressure checked within the previous 5 years [5]. According to the The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, routine blood pressure check are recommended at least every 2 years following a normal reading [6]. Yet, blood pressure measurements are likely performed more frequently as part of routine assessments on vital signs at many clinic visits. The increased frequency of blood pressure assessments more than likely leads to the higher disease awareness compared to hyperlipidemia. Several other factors (e.g. guidelines suggesting immediate medical therapy for hypertension compared to some opportunity for a trial of lifestyle modification for hyperlipidemia) could potentially contribute to the relative differences between treatment and control for hypertension and diabetes with that for hyperlipidemia. Given that the overlapping influence of insurance status and HPSA residence on awareness, treatment and control was our main focus, we elected not to explore, in the Discussion, the potential underlying explanations of the differences in awareness or treatment rates between any two of the target conditions.

11. In the third paragraph of the Discussion where you compare your results to the Allen NB results, it seems worth mentioning that you only found a difference in awareness of hyperlipidemia among the uninsured. So your results were at least partially consistent with their findings.

We have added this similarity to the Allen study to our Discussion.

Allen

Access to health care can play a critical role in the health of an individual. In this cross-sectional study in the REGARDS cohort, the authors examined the impact of geographic access to primary care (living in a primary care HPSA) and financial access to care (insurance status) on the awareness, treatment, and control of cardiovascular risk factors. Their findings that uninsured individuals may achieve lower control of hypertension despite similar or higher awareness highlights the importance of access to care for chronic disease. The question under study has great public health importance, the writing is clear, and the statistics are appropriate. However, there are some questions that remain.
1) HPSAs are not primarily designated at the county level, why was that the unit of analysis? Exclusion of counties only partially covered by HPSA designation may be biasing the population being studied, please address.

The reviewer is correct that geographic primary care HPSA designations are primarily made at the census tract level. However, we were utilizing conventions from previous literature using counties as smallest geographical unit of designated HSPAs [7-10]. By utilizing county-level HPSA designations and excluding partial-county HPSAs we have taken a conservative approach to avoid classifying REGARDS participants as HPSA residents who may live in a non-HPSA portion of the county. Previous studies [9, 11] using county-level HPSA designations and excluding partial-county HPSAs, have been left with HPSA residents that are mostly white and rural. However, even after our exclusion of partial-county HPSAs, we saw a great deal of racial and residential (urban vs. rural) diversity among the HPSA residents (see Table 1). We have acknowledged, in our Discussion, the limitation of possibly missing some participants who do live in the underserved portions of the partial HPSA counties.

2) It would be interesting to have a statistical test to determine if there are truly differences in the impact of HPSA residence by insurance status, please include an interaction term for insurance*HPSA.

Please see previous response to Kershaw’s comment related to the interaction term for insurance*HPSA.

3) HPSA may simply be a marker for other county characteristics, such as urban vs rural, which may be confounding the relationship. The findings should be adjusted for these county characteristics or at least a descriptive table should be presented.

We included a measure of urbanicity in multivariable models with minor numeric changes in the results, but no overall changes in directionality of odds ratios. We have also added a description of the measure to the Methods. We had formerly included a county-level % poverty measure which did not change our results with respect to our outcomes according to HPSA residence and insurance status.

4) Although individuals live in a county, they may not be seeking primary care there, thus you may be misclassifying exposure status. Please discuss and address.

The HPSA designations take into account distance and travel times to adjacent rational areas for the delivery of primary medical care services. Therefore HPSAs designations must apply to:

A portion of a county, or an area made up of portions of more than one county, whose population, because of topography, market or transportation patterns, distinctive population characteristics or other factors, has limited access to
Using the 30-minute travel time threshold, the designations take into account distance, access to roads, type of roads and access to public transportation. Even with these considerations, it is possible that individuals could travel especially long distances (e.g. > 30 min) to seek care outside of their HPSA-designated home counties. We do not have access to information on participants’ utilization of care or their travel distance to their usual sources of care. However, even if participants were able to access care outside the HPSA-designated area, the impact of longer travel distances for outpatient care has been shown to lead to lower health care utilization for multiple medical conditions [13-16]. This lower geographic access may be intermittently mitigated by the ability to travel long distances outside of the HPSA, but the likelihood is that health care utilization may still be lower given the longer travel time required for many HPSA residents [13]. We have added this to our limitations section.

References Cited


