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TITLE: Development and Validation of a Risk Score for Predicting Cardiovascular Events in Women Military Service Members

PRINCIPAL INVESTIGATOR: Haekyung Jeon-Slaughter

CONTRACTING ORGANIZATION: University of Texas Southwestern Medical Center
Dallas, TX 75390

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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**6. AUTHOR(S)**

**Haekyung Jeon-Slaughter**

**email:**

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**University of Texas Southwestern Medical Center**
**Dallas, TX 75390**

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**14. ABSTRACT**

**The current study proposes a retrospective study to develop a 10-year risk score that predicts the first cardiovascular (CV) incident in women active-duty service members and veterans using Veterans Affairs (VA) Electronic Health Records of women service members.**

**15. SUBJECT TERMS**-

| 16. SECURITY CLASSIFICATION OF: | | | 17. LIMITATION OF ABSTRACT | 18. NUMBER OF PAGES | 19a. NAME OF RESPONSIBLE PERSON |
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## Table of Contents

**Page**

1. **INTRODUCTION:**

The current study proposes a retrospective study to develop a 10-year risk score that predicts the first cardiovascular (CV) incident in women active-duty service members and veterans using Veterans Affairs (VA) Electronic Health Records of women service members.

2. **KEYWORDS:**

1. Women
2. Women service members
3. Cardiovascular disease risk
4. Atherosclerosis
5. VA
6. Electronic Health Records
7. Predictive model

3. **ACCOMPLISHMENTS:**

**Overall project summary**

**The project has achieved specific aims 1 and 2.** The study completed data extraction from veterans affairs (VA) electronic health system (EHR), yielding 76,559 women active-duty service members and veterans who aged 30-79 and received healthcare from VA hospitals from 2007 to 2017. Of these, 52% were Whites (n=39,994), 42% African Americans (AA, n=31,990) and 6% Hispanics (n=4,575). CV risk factors (Table 1) and events (non-fatal myocardial infarction, non-fatal and fatal stroke, heart failure, Arrhythmia, atrial fibrillation flutter, Angina, and cardiac deaths) were created using ICD diagnoses and procedure codes, pharmacy and vital sign visit records and lab results from EHR. The study finalized a set of predictors and their transformations. The study conducted a comparison a model performance against existing AHA/ACC model. The study re-estimated risk coefficients of the ACC/AHA model and traditional risk factors and its calibration using VA women data. The study found that a different aging trajectory for CV risk from ACC/AHA white women model. Our study with inclusion of younger women, age 30-40, which was excluded from ACC/AHA CV risk model development cohort, found a log linear aging trajectory for increased CV risk at 10 years. Figure 1 describes a partial aging effect on increased CV risk. Using VA women data VA white women were estimated CV risk to increase exponentially with age from age 30, while the current ACC/AHA ASCVD risk assessment model estimated a suboptimal quadratic relationship between CV risk and age, with a rapid increase in CV risk only after age 44 (Figure 1.A). For African American women, the VA women CV risk model found that risk increased linearly with age, in contrast to an escalated aging effect only after age 50 in the ACC/AHA model (Figure 1.B). Overall model fit for the VA women CV risk model was moderate (Whites C statistics 0.66; AA 0.63).

**What were the major goals of the project?**

| Specific Aim 1 (specified in proposal) | Timeline | Percentage of completion |
|---|---|---|
| **Data extraction** | dates | |
| Write SQL to extract data from VA CDW | 7/1/2018-12/31/2018 | 100% |
| Extract death records | 7/1/2018-12/31//2018 | 100% |
| Data preparation for analysis: transformation, missing data imputation, and coding of predictors | 01/01/2019-/06/30/2019 | 80% |
| Milestone(s) Achieved | | |
| Local IRB Approval | 05/21/2016; 05/17/2019 | 100% |
| Finished data extraction | 02/14/2019 | 100% |
| **Data analysis** | | |
| Estimation Cox regression analysis; model specification, estimation, and performance | 01/01/2019-06/30/2019 | 100% |
| Identify risk factors and confounders for cardiovascular events/candidate predictors | 01/01/2019-06/30/2019 | 100% |
| Finalizing predictors for cardiovascular events in women service members | 03/01/2019-06/30/2019 | 100% |
| Milestone(s) Achieved: | 12 | |
| Final set of predictors | 12 month | 100% |
| **Specific Aim 2** | | |
| **Create predictive score** | | |
| Estimation/calibration/discrimination analyses | 02/01/2019-06/30/2019 | 50% |
| Risk coefficients and risk score calculation / predictive model | 02/01/2019-06/30/2019 | 50% |
| Milestone(s) Achieved: | 14 | |
| Predictive score per each White/African American/Hispanic women service members | 02/01/2019-06/30/2019 | 50% |

**What was accomplished under these goals?**

We have accomplished specific aims 1 and 2. **Specific *Aim 1*:** Elucidate predictors of CV events and confounders in female service members using VA national electronic health records. ***Aim 2***: Propose a 10-year CV incident risk score for women service members based on CV event predictors identified in Aim 1. This study proposed a new 10-year CV event risk score algorithms. The state-of-the-art statistical methods proposed in the study enables to develop a predictive model with >70% accuracy for the CV event at 10 years. Major activities of the project were a) data extraction, b) extract death records, c) data preparation for analysis: transformation, missing data imputation, and coding of predictors, d) CV events were dichotomized using visit dates, e) local IRB approval, and f) data analysis and results.

A. Data extraction,

All visits for each women service member who received a medical care from VA healthcare system between January 1, 2007 and December 31, 2017 were extracted. Data on traditional CV event risk factors age, systolic blood pressure, anti-hypertensive treatment, diabetes, current smoking, total cholesterol, and HDL. In addition, non-traditional CV risk factors such as Body Mass Index, hemoglobin A1C levels, triglyceride, LDL, Troponin, major depression, and hypertensive and cholesterol medication use.

The study personnel, PI and a PhD student wrote SQL to extract data from VA CDW and used both SAS (SAS Institute, Cary NC) and R (cran-r.project.org) to manage, create variables, analyze data and conduct graphic analyses.

B. Extract death records

CDW vital records and National Death Index (NDI) cause of death data to validate and identify cardiac death events. The study obtained newly released national death index 2016. The study is currently updating results with the newly obtained 2016 NDI data.

C. Data preparation for analysis: transformation, missing data imputation, and coding of predictors

The study prepared data by creating cardiovascular (CV) events and risk factors of interest. We transformed all continuous risk factors, age, systolic blood pressure (SBP), total cholesterol, and High Density Lipoprotein (HDL) and these risk factors were interacted with natural log transformed age (ln age). We set a visit interval as 6 months and averaged continuous factors if there were multiple visits within 6 months. When there were missing data on binary risk factors at some visits we selected a maximum value (1 = yes; 0 = no) such as diabetes and current smoking status. For antihypertensive treatment and lipid lowering treatment, we used prescription dispense dates to create treatment variables. If there was no prescription filled dates available, we then assumed no medication treatment.

D.CV events were dichotomized using visit dates.

Six months were set as a minimum length between visits. We imputed as no diagnoses if there were no records. Log transformed continuous predictors such as age, systolic blood pressure, total cholesterol, HDL. Dichotomized of chronic conditions such as current smoking status, diabetes, ad hypertension treatment. Inclusion of Interactions of log transformed age in the

model were tested by: Akaike Information Criteria (AIC), Likelihood test, and C statistics. The current study conducted penalized estimation (shrinkage models), a stepwise selection with high p-values and Lasso to determine an optimal number of predictors.

E. Local IRB Approval:

Dallas VA medical center IRB exempted the study in May 2018 and VA Research and Development committee approved the study in May 2018, and approved a study continuation in May 2019.

UT southwestern IRB reviewed and approved the study in May 2018 and continuing review was conducted, and approved in May 2019.

F. Data analysis and Results

We extracted 76,559 women active-duty service members and veterans aged 30-79. About a half of the study data were whites, 42% African Americans (AA), and 6% Hispanic women (see Table 1). The average age was about 44 years old at the baseline. Systolic Blood Pressure, prevalence of diabetes, and HDL level in AA were significantly higher than either whites and Hispanic women (Table 1).

There were 3,233 death events, of these, 442 were identified as cardiac deaths. Table 2 depicts cardiovascular events stratified by race. Myocardial Infarction (MI) was the most common CV event, followed by cardiac deaths, Arrhythmia, and stroke. A rate of stroke was significantly higher in AA than other race VA women.

Table 1. Baseline risk factors stratified by race and ethnic group (total n=76,559)

| | **Whites (n=39,994, 52%)** | **African Americans (n=31,990, 42%)** | **Hispanics (n=4,575, 6%)** |
|---|---|---|---|
| Age (mean±SD), year | 45.60±8.63 | 44.04±7.75 | 42.85±8.26 |
| SBP* (mean±SD), mmHg | 123.89±14.96 | 127.15±15.88 | 122.28±14.70 |
| Diabetes, n (%) | 9,091 (22.73%) | 10,288 (32.16%) | 1,133 (24.77%) |
| Current smoking, n (%) | 12,293 (30.74%) | 6,721 (21.01%) | 934 (20.42%) |
| Major depression, n (%) | 19,190 (47.98%) | 13,771 (43.05%) | 2,269 (49.60%) |

| | | | |
|---|---|---|---|
| Total cholesterol (mean±SD), mg/dL | 200.17±40.76 | 192.51±38.77 | 195.87±38.31 |
| HDL* (mean±SD), mg/dL | 53.44±16.30 | 56.37±16.41 | 53.66±15.26 |

Note. SBP= Systolic Blood Pressure; HDL = High Density Lipoprotein; SD = Standard deviation

**Table 2. Cardiovascular events by race (n)**

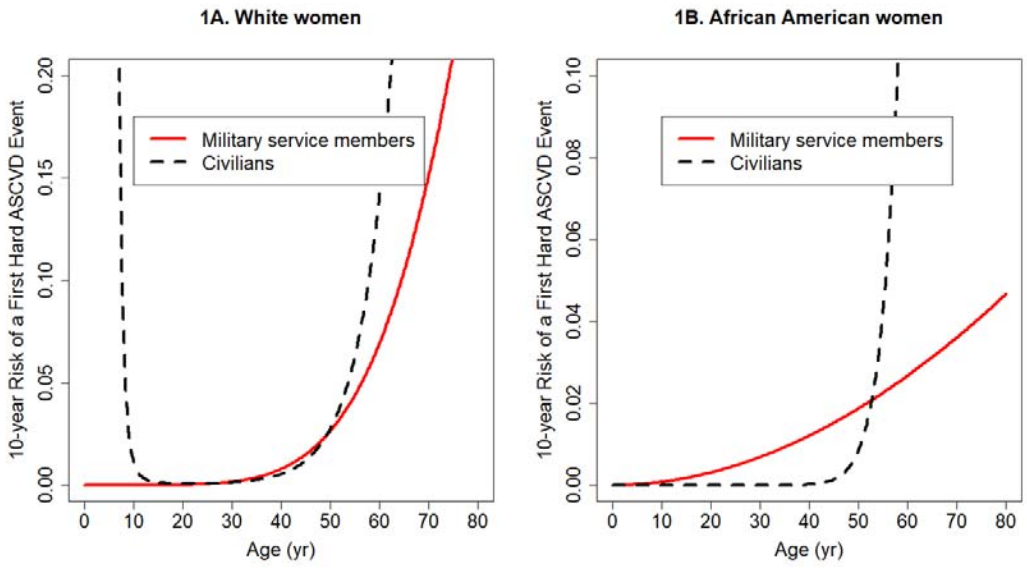
| **ASCVD** | **WHITE** | **AA** | **HISPANIC** |
|---|---|---|---|
| Myocardial Infarction (MI) | 561 | 538 | 68 |
| Stroke | 175 | 187 | 21 |
| **Other CV events** | **White** | **AA** | **Hispanic** |
| Heart failure | 79 | 77 | 6 |
| Arrhythmia | 327 | 281 | 35 |
| Fatal MI | 36 | 36 | 3 |
| Fatal stroke | 27 | 16 | 2 |
| Unstable angina | 56 | 40 | 15 |
| Cardiac arrest | 9 | 3 | 0 |

Note. The same patient can experience multiple CV events.

We performed calibration and tested log transformation fit of age, SBP, total cholesterol, and HDL. When there were missing data per visit we used single (Last observation move forward) and multiple imputation techniques to deal with missing data of predictors. We tested extensively inclusion of interaction term of log age via p-values, Akaike Information Criteria (AIC), log likelihood test and residual plots. We found that aging trajectory of increased risk of CV was following a log linear pattern.

Figure 1 shows that age effect on increased CV risk is log linear for both Whites and African American VA women. For the proposed VA women CV risk assessment model, age effect was suggested to be log linear and same across both race groups. This suggests that CV risk in VA women increase linearly starting from age 30, which differs from the current guideline for CV risk screening recommended at age 45.

Figure 1. Aging effect on increased 10-year cardiovascular risk stratified by race




between civilian women and women military service members

Our finding suggests lowering CV risk screen age to < 40 years old for VA women. After extensive sensitivity tests we concluded that factors included in the new VA women model are: age (log transformed, Ln age), treated/untreated systolic blood pressure (log transform and its interactions with Ln age), total cholesterol and HDL (natural log transform and its interaction with Ln age interaction), current smoking status (its interaction with Ln age interaction), and presence of major depressive symptoms and diabetes mellitus. Our new VA women CV risk assessment model estimated CVD risk to increase exponentially with age from age 30 in women service members for all race and ethnic groups (Figure 1).

In addition to linear aging trajectory of increased CV risk, the study identified new risk factors and confounders for cardiovascular events/candidate predictors such as major depression. The study found a significant major depression effect on increased CV risk.

The VA women CV risk assessment model includes traditional risk factors in American College of Cardiologists/American Heart Association (ACC/AHA) model but also included a non traditional CV risk factor such as major depression. Candidates of non traditional factors considered but not included in the final model are: BMI, menopause, triglyceride/HDL ratio, diastolic blood pressure (DBP), and statin medication. Estimation, discrimination and calibration were performed to determine inclusion and exclusion of traditional and non traditional risk factors.

Risk coefficients were reestimated using VA women EHR data and the following time to event model. CV risk coefficients were estimated stratified by race/ethnic group, Whites, African American and Hispanics using Cox baseline covariate model (Table 3).

The final set of predictors and their calibrated transform are: age (log transformed, Ln age), treated/untreated systolic blood pressure (log transform and its interactions with Ln age), total cholesterol and HDL (natural log transform and its interaction with Ln age interaction), current smoking status (its interaction with Ln age interaction), and presence of major depressive symptoms and diabetes mellitus.

Model fit was tested using Harrell C statistics, Homer-Lemeshaw statistics, Uno statistics, Receiving Operation Curve Area under the curve, AUC (t). We conducted proportional hazard assumptions for all covariates using residual tests. Explained Variance was 51% for White women military members and 50% for AA women military members. Residuals, Martingale residuals and Schoenfeld residuals and Proportional hazard (PH) assumption was tested (Figure 3). Calibration plots (Figure 4) showed observed and predicted probability of CV events (45 degree line represents observed and predicted probabilities are identical.).

Age and current smoking did not meet PH assumption. Thus, HR (t) HR was not constant over time.

Survival 10 year CV risk among women service members based on VA National EHR data using Cox baseline risk model were 1.8% and 2.0% for white and AA Women, respectively at age 50 years; total cholesterol 203 mg/dL; HDL 50 mg/dL;  SBP 120 mmHg; No diabetes; No current smoking.

Table 3. Baseline covariate Cox model using VA women data

| | ***White*** | ***African American*** |
|---|---|---|
| Ln Age | 6.456 | 0.2743 |
| Ln Age, squared | -0.131 | --- |
| SBP untreated | 0.119 | -1.49518 |
| SBP untreated x Ln age | --- | 0.19497 |
| SBP treated | 0.022 | -0.05712 |
| SBP treated X Ln age | --- | 0.32974 |
| Diabetes | 0.129 | 0.41774 |
| Current smoking | 2.248 | -0.43353 |
| Current smoking X Ln age | -0.394 | --- |
| Total cholesterol | -2.900 | -0.25855 |
| Total cholesterol X Ln age | 0.406 | --- |
| HDL | 8.555 | 1.15504 |
| HDL X Ln age | -1.432 | -0.20812 |

Note: Abbreviations. SBP = systolic Blood Pressure; HDL = High Density Lipoprotein

Figure 2. Martingale residual plots: Cigarette smoking

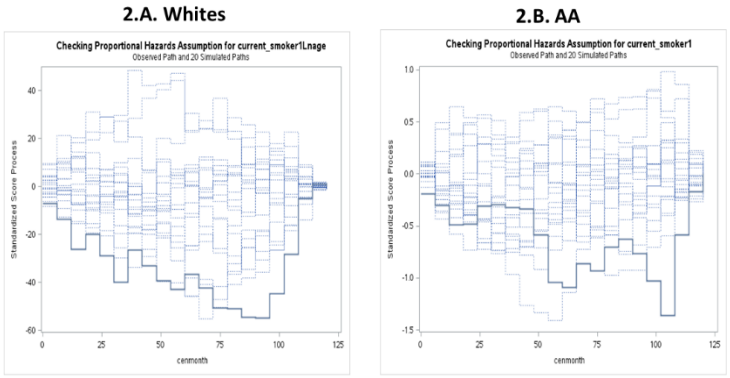



Figure 3. Martingale residual plots: Aging

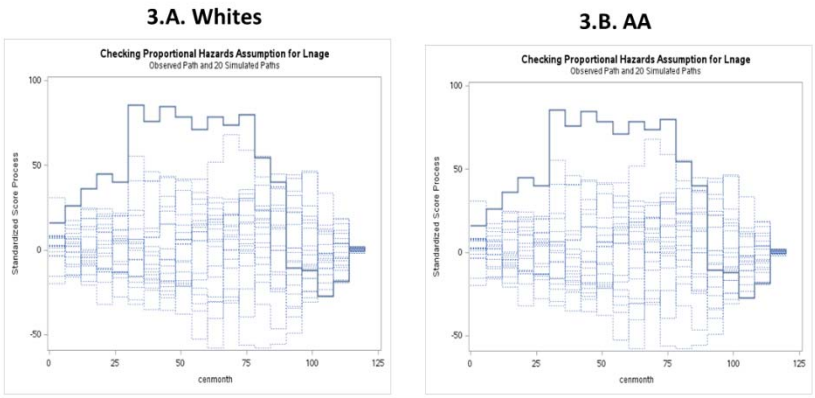



Figure 4. Calibration plots for Cox baseline risk model by race

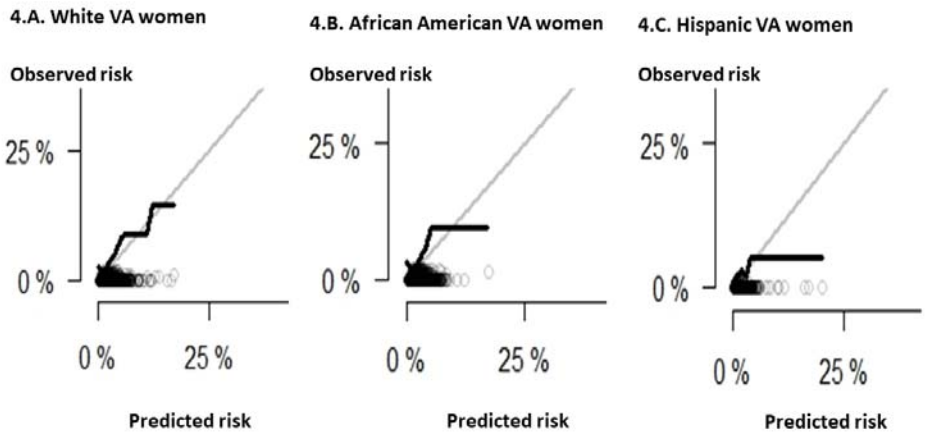


Table 4. 10-year cardiovascular event risk in white and African American VA women

| | White | African American |
|---|---|---|
| $S(10)^1$ | 0.9836 | 0.9812 |
| 10-year CV risk (%)[2] | 1.8% | 2.0% |

Notes. CV = cardiovascular 1. S(10) 10-year CV event free survival probability 2. 1- S(10) ^ $e^{(x\beta - \bar{x}\beta)}$, where x a vector of covariates in the model and $\bar{x}$ mean values of corresponding covariates, and β is a vector of risk coefficients corresponding covariates, x. Specific values of x are age 50 years, total cholesterol 203 mg/dL, HDL 50 mg/dL, SBP 120 mmHg, no diabetes, and no current smoking status.

## Conclusions

Our study found that, contrary to the currently accepted ACC/AHA ASCVD risk model, aging was linearly associated with increased 10-year CV risk in women military service members starting at ages as young as 30 years old for White women and possibly younger for AA women. The discrepancies identified in this study demonstrate the need to develop a new validated CV risk assessment model for all women, including minority groups, in military services. We proposes a single, consistent model specification that fits for all race and ethnic groups, Whites, African Americans, and Hispanics VA women using VA electronic health records data.

In the new VA women CV risk assessment model included all standard risk factors and added a new risk factor, major depression, with log linear age effect. We concluded that time varying covariate is a better fit for a predictive model following PH and residuals tests.

Furthermore, the study finding suggests lowering age for CV risk screening for women from 45 years to <40 years old.

**What opportunities for training and professional development has the project provided?**

- *"Nothing to Report."*

**How were the results disseminated to communities of interest?**

Study results were presented at a seminar of Department of Economics at the University of North Texas and the Association of VA Surgeons 2019 meeting. The PI communicated a predictive modeling methods with health economists on a model selection for cardiovascular risk prediction and implication of health services and policies, and disseminated the study findings to VA surgeons who were potential beneficiaries of the study findings.

Results are currently under review for a publication in JAMA Surgery.

**What do you plan to do during the next reporting period to accomplish the goals?**

*The study plans to conduct an internal validation of the proposed CV risk assessment model under the new time varying Cox model using cross-validation method specified in Aim 3.*

Aim 3: Internally validate the new 10-year CV event risk score for women service members. The newly proposed 10-year CV risk score for women military service members will be tested. *After finalizing the model, the study team will develop a nomogram for CV risk assessment with applications at both website and EHR*

4. **IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

- *The proposed CV assessment model will predict CV risk in age groups younger as well as older women. Either underestimation of CV risk in young population and over estimation of age group >65 age will be corrected using large-, representative EHR.*

**What was the impact on other disciplines?**

- *The proposed VA women CV model will be used in primary care settings to prevent CV events and identify patients at risk early for a treatment.*
- *The proposed VA women CV model can also be used for the pre-op work up before surgery to minimize risk of CV adverse events.*
- *New c*alibration methods developed to assess goodness of fit for time dependent Cox model will be used for predictive models in other disciplines.

**What was the impact on technology transfer?**

- *"Nothing to Report."*

**What was the impact on society beyond science and technology?**

- *The study result, cross-validated 10-year Cardiovascular Risk model, will improve a delivery of the best care for women military service members at VA health care system.*

5. **CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

- *Haekyung Jeon-Slaughter has become PI at both UT southwestern Medical Center and Dallas VA Medical Center. The change enables the PI carry out a full responsibility as a PI as Dallas VA Medical Center and to continue the effort level at 3.7 months.*
- *Bala Ramanan, MD, will continue to contribute her effort as a Co-I at Dallas VA medical center.*

- *The PI requests to remove Subhash Banerjee, MD from the study. Dr. Banerjee assumed more responsibilities at Dallas VA medical center, maintaining his contribution to the current study at 0.6 calendar year is no longer feasible.*

**Actual or anticipated problems or delays and actions or plans to resolve them**

- *The study team requested newly available cause of death data up to 2016 to define specific causes of death, cardiac death and obtained the data on June 21, 2019. With newly obtained death data the study is currently updating and re-estimating risk coefficients model and a fit of goodness of the model.*

**Changes that had a significant impact on expenditures**

- *None*

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

- *None*

**Significant changes in use or care of human subjects**

- **None**

**Significant changes in use or care of vertebrate animals.**

- **None**

**Significant changes in use of biohazards and/or select agents**

- **None**

6. **PRODUCTS:**

***"Nothing to Report"***

**Publications, conference papers, and presentations**

- **Journal publications.**

  Jeon-Slaughter, H*; Chen, X; Ramanan, B.; Modrall, J.G.; Tsai, S. "Differential impact of aging on cardiovascular risk in women military service members," JAMA Surgery, Under review

*All presentations and a publication acknowledgement of federal support was explicitly included.*

**Books or other non-periodical, one-time publications. Other publications, conference papers, and presentations.**

**Presentations**

- Jeon-Slaughter, H*; Chen, X; Ramanan, B.; Modrall, J.G.; Tsai, S. "Differential impact of aging on cardiovascular risk in women military service members," presented at Association of VA Surgeons Annual meeting April 27-30, 2019 Seattle, WA.
- Jeon-Slaughter, H*; Chen, X; Ramanan, B.; Tsai, S. "Developing a Veterans Affairs (VA) Women Atherosclerotic Cardiovascular Risk Assessment Model from VA National Electronic Health Records Data," Abstract Submitted to the American Heart Association Scientific meeting, November 16-18, 2019, Philadelphia, PA
- **Website(s) or other Internet site(s)**
  *None*

**Technologies or techniques**
*None*

**Inventions, patent applications, and/or licenses**
*None*

**Other Products**
*None*

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

**What individuals have worked on the project?**

*Haekyung Jeon-Slaughter, PhD. PI at both UT Southwestern Medical Center and Dallas VA medical center, Dallas Texas (Since May 2015);*

*Xiaofei Chen, MS, Graduate student, UT Southwestern, Dallas Texas*

*Bala Ramanan, MD. Co-I, Dallas VA Medical Center, Dallas Texas (PI at Dallas VA medical center July, 2018- May 2018)*

*Shirling Tsai, MD. Co-I, Dallas VA Medical Center, Dallas Texas*

*Robin B. Jarrett, PhD. Co-I, Dallas VA Medical Center, Dallas Texas*

*Subhash Banerjee, MD. Co-I, Dallas VA Medical Center, Dallas Texas (request to remove Dr. Banerjee from the study from July 1, 2019).*

| | |
|---|---|
| Name: | *Haekyung Jeon-Slaughter* |
| Project Role: | *PI at UT Southwestern and PI at Dallas VA since May 2019* |
| Researcher Identifier (e.g. ORCID ID): | 0000-0002-5753-2935 |
| Nearest person month worked: | *3.7* |
| Contribution to Project: | *Dr. Jeon-Slaughter has performed data extraction, management, and analysis from VA CDW. The PI obtained IRB approvals from both Dallas VA and UT Southwestern and daily project management. The PI conducted model estimation, accuracy, calibration, and section of a final set of predictors. The PI has presented study results at a national meeting and an invited talk. The PI was responsible for abstract submissions to both AVAS and AHA meetings and a manuscript, and its submission to JAMA surgery.* |
| Funding Support: | ----- |
| Name: | *Xiaofei Chen* |
| Project Role: | *Graduate Student* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *12* |
| Contribution to Project: | *Mr. Chen has performed data extraction, management, and analysis.* |
| Funding Support: | |
| Name: | *Bala Ramanan* |
| Project Role: | *PI at Dallas VA until May 5, 2019 and will serve as a Co-I at since May 2019* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *0.6* |
| Contribution to Project: | *Bala Ramanan has performed tasks that identify risk factors and confounders for cardiovascular events/candidate predictors; Finalize predictors for cardiovascular events in women service members; Calculate and interpret risk coefficients and risk score calculation / predictive model.* |
| Funding Support: | |
| Name: | *Shirling Tsai* |
| Project Role: | *Co-I at Dallas VA* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *0.6* |
| Contribution to Project: | *Dr. Tsai has performed tasks that identify risk factors and confounders for cardiovascular events/candidate predictors; Finalize predictors for cardiovascular events in women service members; Calculate and interpret risk coefficients and risk score calculation / predictive model.* |
| Funding Support: | |
| Name: | *Robin B. Jarrett* |
| Project Role: | *Co-I at UT Southwestern* |

| | |
|---|---|
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *0.6* |
| Contribution to Project: | *Dr. Jarrett has performed tasks that identify risk factors and confounders for cardiovascular events/candidate predictors; Finalize predictors for cardiovascular events in women service members; Calculate and interpret risk coefficients and risk score calculation / predictive model..* |
| Funding Support: | |
| Name: | *Subhash Banerjee* |
| Project Role: | *Co-I at Dallas VA* |
| Researcher Identifier (e.g. ORCID ID): | |
| Nearest person month worked: | *0.6* |
| Contribution to Project: | *Dr. Banerjee has assisted the study team to perform tasks that identify risk factors and confounders for cardiovascular events/candidate predictors; Finalize predictors for cardiovascular events in women service members.* |
| Funding Support: | |

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

- *"Nothing to Report."*

**What other organizations were involved as partners?**

- *"Nothing to Report."*

8. **SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:**

- *"Nothing to Report."*

**QUAD CHARTS:**

- *"Nothing to Report."*

9. **APPENDICES:**

None