## 2. Pilot Test of the DEGREE Protocol, CKDu Module, and Point-of-care Device Measurements in Outdoor Hispanic Workers

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## **Abstract:**

Introduction: Comparison studies of estimated glomerular filtration rate (eGFR) are limited by lack of protocols using standardized creatinine measurements. Use of Point-of-Care (POC) measurements that require a smaller amount of blood, no transporting of specimens, and can be immediately analyzed in the field is attractive, but their accuracy outside of healthcare settings has been questioned. There is also little standardization on questionnaires designed to gather information on risk factors for "CKD of unknown origin" (CKDu).

Objective: To field test the Disadvantaged Populations eGFR Epidemiology Study (DEGREE) protocol, a CKDu risk factor module from the Second Central American Survey of Working Conditions and Health, and POC testing of renal function with the i-STAT (Abbott Laboratories, Abbott Park, IL)/Chem8+ in outdoor workers in different seasons.

Methods: Cross-sectional study of 55 Hispanic workers in Houston. Inclusion criteria were: 1) ≥18 years; 2) working outdoors ≥20 hours/week; 3) no prior diagnosis or medications for diabetes, renal or cardiovascular disease. Interviewer-administered DEGREE and CKDu module questionnaires and a urine sample were completed indoors; anthropometrics, blood pressure and paired blood samples for POC and isotope dilution mass spectrometry (IDMS) were completed outdoors during November-December (winter) 2017 and April-May (spring) 2018. Correlations between POC and IDMS were compared between coldest/hottest temperatures, lowest/highest humidity, and lowest/highest heat index.

Results: Outdoor temperatures ranged from 60°F to 90°F, relative humidity from 25% to 99%, and heat index from 34°F to 106°F. Administration of the DEGREE protocol and CKDu module averaged 10 and 5 minutes, respectively; questions were easily understood. Average eGFR was 114.07 ml/min/1.73m2 (SD = 15.18) in the winter and 105.81 ml/min/1.73m2 (SD = 18.21) in the spring. Hemoglobin measurements were strongly correlated during the coldest temperatures (60°F to 70°F) and lowest heat index reported (34°F to 69°F) (r=0.97); in the hottest temperatures (80°F to 90°F) and the highest heat index (90°F to 106°F), this correlation was lower (r=0.84). The Bland-Altman plots for hemoglobin showed that, on average, the POC i-STAT results were 3.58% higher than with IDMS. Serum creatinine measurements correlated well (r=0.93) and blood urea nitrogen (BUN) (r=0.96) across the range of temperatures, humidity levels, and heat index. On average, POC-derived creatinine and BUN values were 0.18% and 0.72% higher than IDMS, respectively. Technical limitations with the POC included "out of range" readings and disabled cartridge testing when temperatures were above 85°F or below 65°F, but these resolved when the instrument was brought indoors for a few minutes.

Limitations with the IDMS method included hemolyzed specimens, which affected glucose, sodium and potassium levels, but minimally affected BUN and creatinine.

Conclusion: Implementation of the DEGREE protocol and CKDu module was straightforward, well understood and conducted in a reasonable period of time. The POC device performed adequately in the field insofar as renal function measurements, but required some adjustment in methods when temperature readings were out of range. Acknowledgement to Grant No. 5T42OH00842109 from the National Institute for Occupational Safety and Health (NIOSH) / Centers for Disease Control and Prevention (CDC) to the Southwest Center for Occupational and Environmental Health (SWCOEH)

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