How do Clinical Trial Exclusion Criteria Impact the Inclusivity of Clinical Trials?

- The GCNKSS is a population-1.3 million people living in a 5-county area of southern Ohio/ Northern Kentucky.
- 7/1/14-12/31/15 for blacks, and 2015 for whites, we captured all hospitalized ischemic strokes by screening ICD-9 codes 430-436 and ICD10 codes I60-I68, and G45-46.
- Commonly used exclusion criteria from stroke clinical trials were applied to the GCNKSS IS population, and were compared by sex and race.
  - Age, Disability, NIHSS, Time from sx onset to arrival, CKD, SBP
- All comparisons for race and sex were evaluated with chi-square test and corrected for multiple comparisons, as necessary.

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Exclusion Criteria^	Women Excluded	Men Excluded	p-value	White Excluded	Black Excluded	p-value
Chronic Kidney Disease (serum Creatinine >2.0 mg/dL)	7.01%	9.48%	0.0232*	6.00%	13.20%	<0.001*
Chronic Kidney Disease D) (serum Creatinine >3.0 mg/dL)	3.47%	4.28%	0.2890	2.29%	7.50%	<.0001*
Age > 80 (years)	33.43%	16.61%	<.0001*	30.91%	13.71%	<.0001*
Age > 90 (years)	9.67%	3.10%	<.0001*	8.06%	3.36%	<.0001*
NIHSS < 10	80.00%	88.00%	<.0001*	83.71%	83.96%	0.8216
NIHSS < 6	67.97%	75.50%	<.0001*	72.80%	68.82%	0.0412
Time From Sx Onset to Arrival in ED > 12hrs	53.73%	51.34%	0.2291	50.51%	57.05%	0.0024*
Time From Sx Onset to Arrival in ED > 6hrs	66.86%	65.18%	0.3719	64.63%	69.21%	0.0251*
Pre-stroke Disability mRS > 2	75.79%	61.83%	<.0001*	68.86%	70.38%	0.4459
Pre-stroke Disability mRS > 3	40.74%	29.03%	<.0001*	34.97%	35.71%	0.7221
SBP > 180 mmHg	23.03%	19.97%	0.0612	20.06%	25.10%	0.0046*
SBP > 200 mmHg	9.23%	7.05%	0.0457	6.86%	11.13%	0.0003*

How do Clinical Trial Criteria Impact the Inclusivity of Clinical Trials?

- Every trial exclusion criteria evaluated had significant differences by sex, race, or both.
  - commonly-used age and disability clinical trial exclusion criteria exclude more women than men, and exclusion of milder strokes affects more men than women.
  - Blood pressure, renal function, and early arrival time criteria exclude more blacks than whites, while older age exclude more whites than blacks.
- Optimal clinical trial design should be informed by epidemiology data to help ensure adequate representation of underrepresented populations in clinical trials in the future.