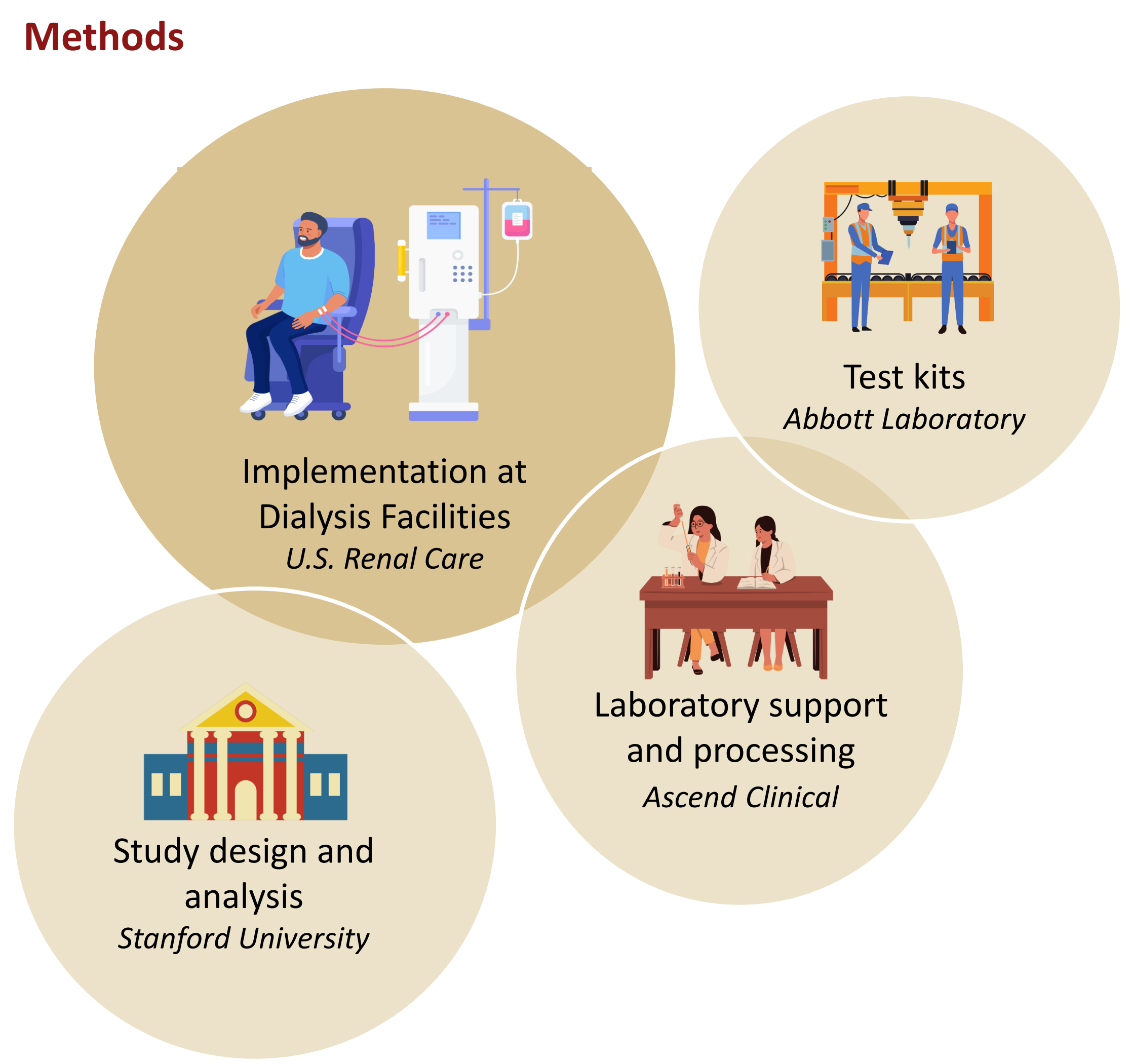


# SARS-CoV-2 TESTING DURING ROUTINE HEMODIALYSIS CARE: A NATIONWIDE PRAGMATIC CLINICAL TRIAL

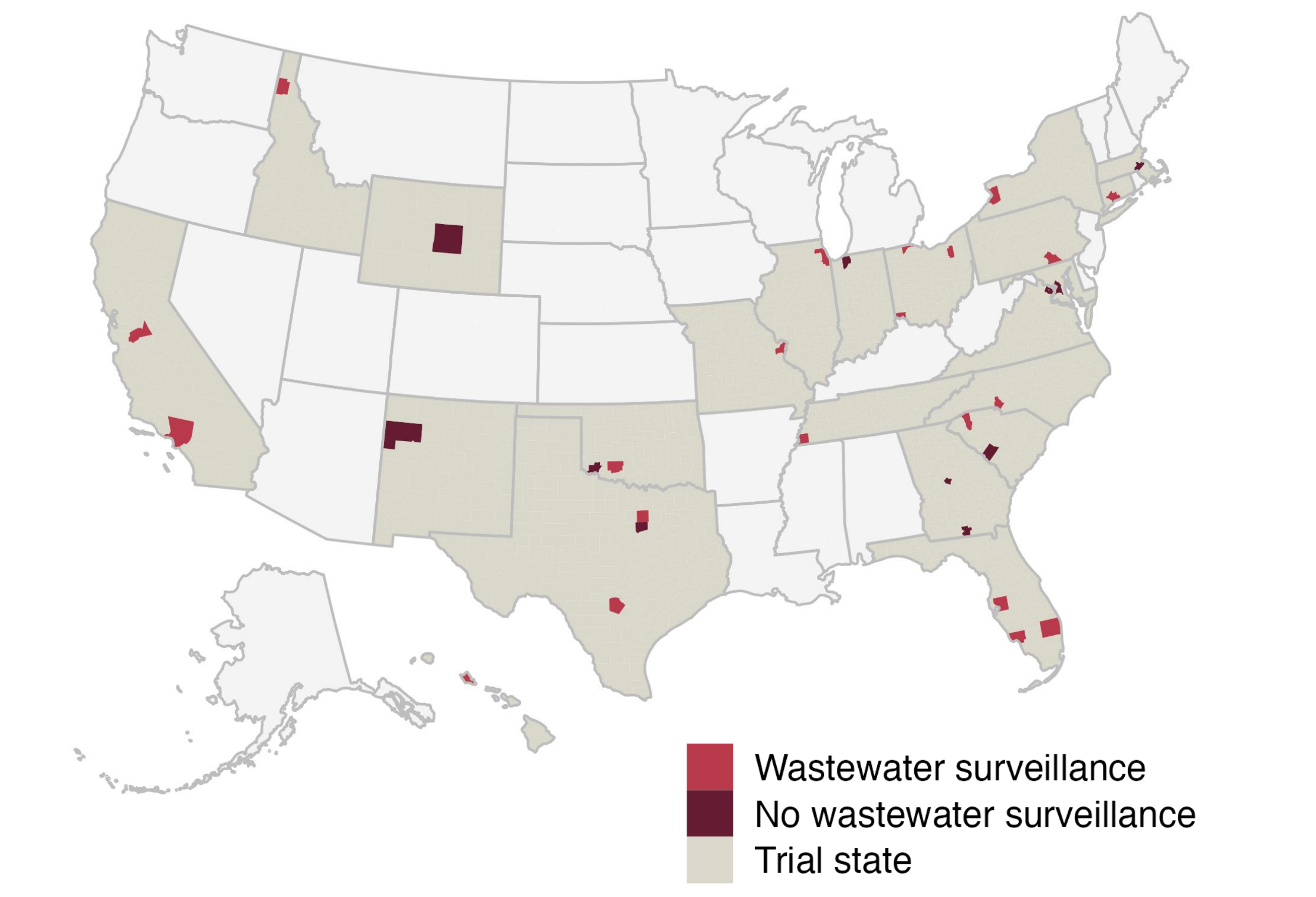
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**Introduction**  
 Screening for infections in dialysis facilities could:  
 1. Facilitate early detection & treatment  
 2. Reduce transmission  
 3. Strengthen public health surveillance in a future pandemic

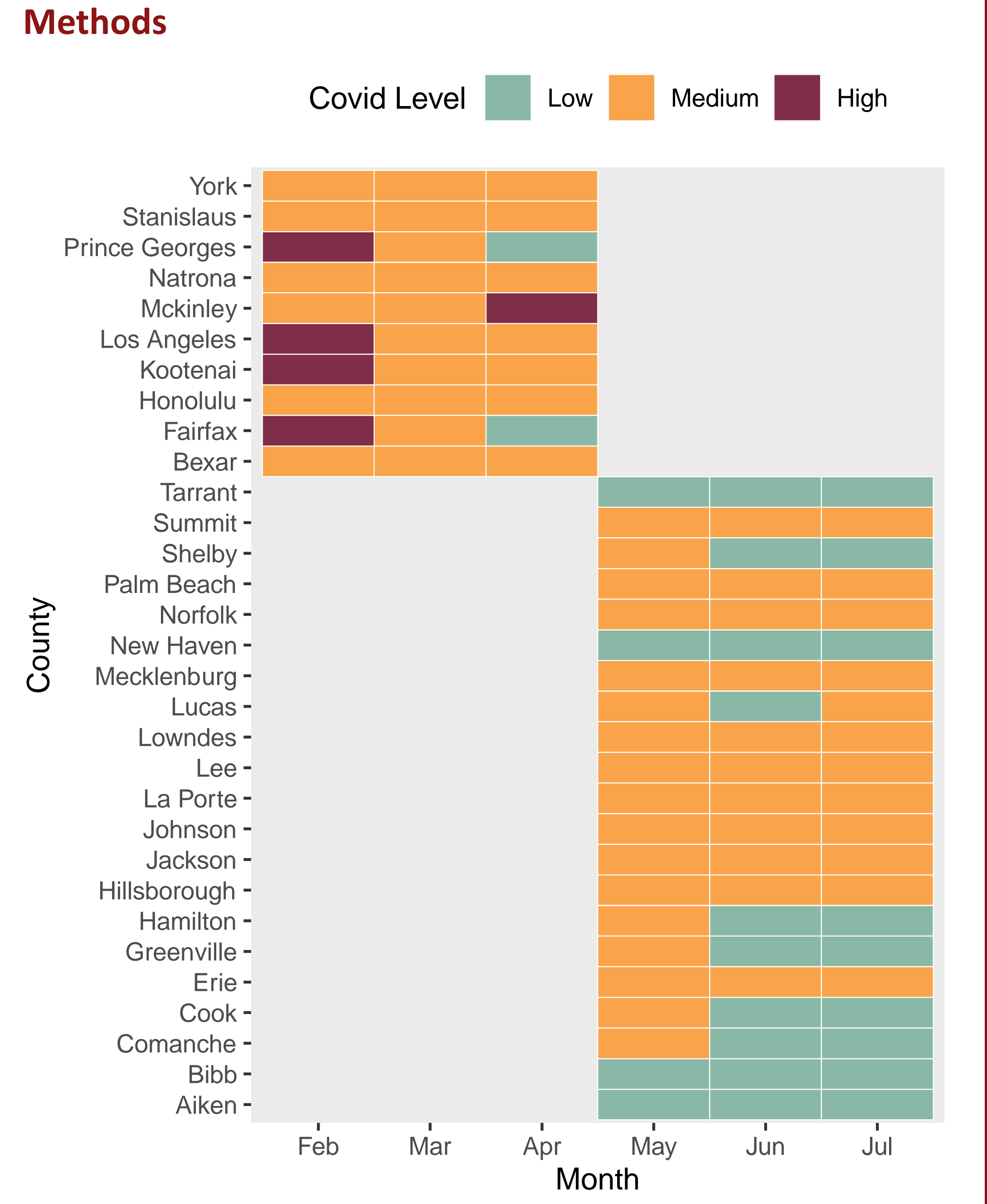
We evaluated the acceptability of routine SARS-CoV-2 screening among asymptomatic patients in dialysis facilities.



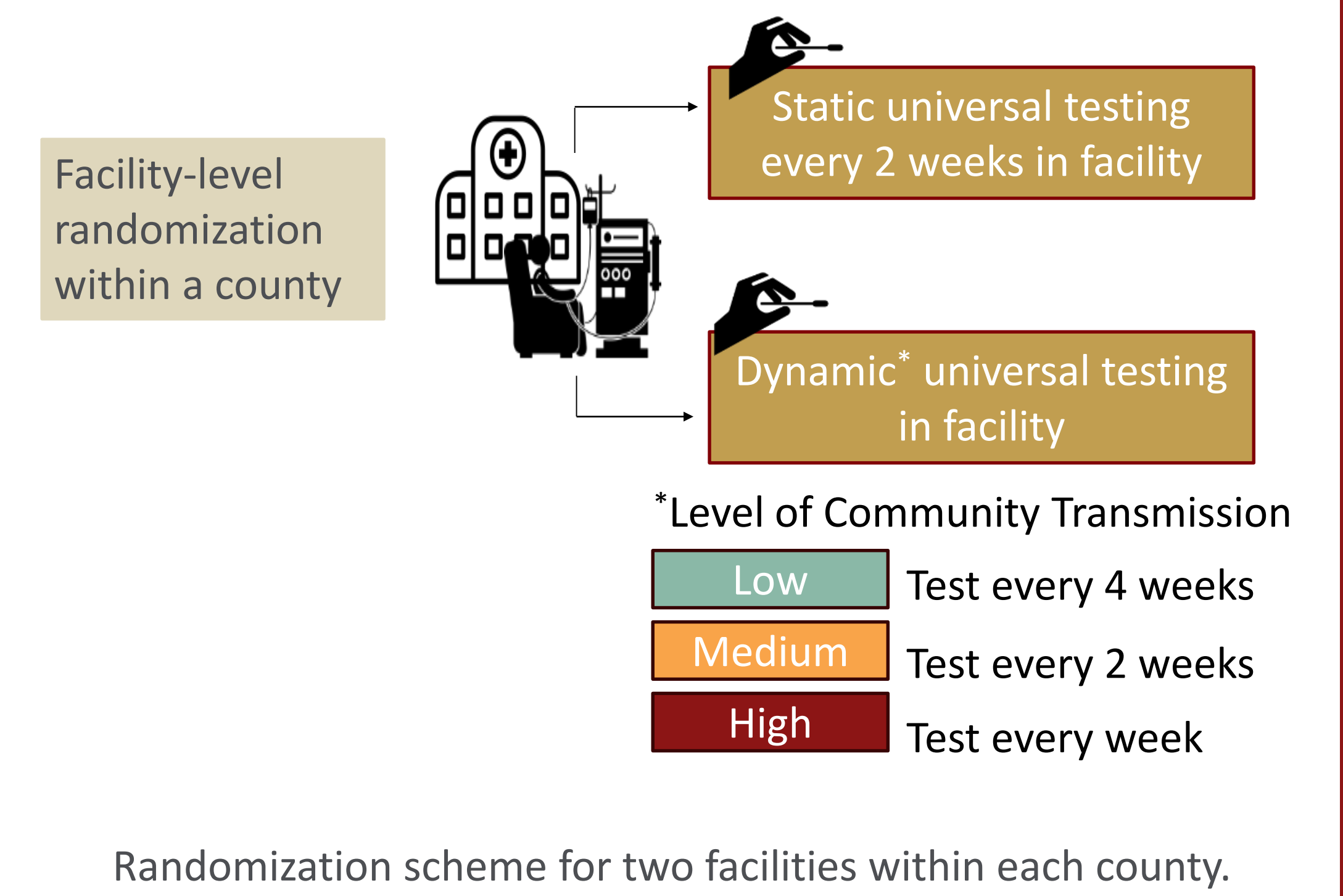
Pragmatic, cluster randomized trial across 31 counties in the U.S., under the Rapid Acceleration of Diagnostics for Underserved Population (RADxUP) Consortium through the NIH (NCT05225298).



County COVID-19 levels assessed using wastewater surveillance if available (■) or else CDC case and hospitalization rates (■)



The trial ran in two separate periods for a length of three months. For each county, we assigned the COVID-19 level based on wastewater or county CDC case or hospitalization rates, determined two weeks prior to the beginning of each month. Wastewater surveillance was available for 21 counties.



Randomization scheme for two facilities within each county.

Primary Outcome: Test acceptability  
 Secondary Outcome: Positivity rate

**Results**

	Static	Dynamic	P-value <sup>^</sup>
<b>Facility level</b>			
Facilities, n	28	29	
Participating patients per facility <sup>#</sup>	37 (25-45)	43 (34-59)	0.07
<b>Region</b>			
Northeast	4 (4.3%)	4 (13.8%)	0.99
Midwest	5 (17.9%)	5 (17.2%)	
South	13 (46.4%)	14 (48.3%)	
West	6 (21.4%)	6 (20.7%)	
<b>Patient level</b>			
Patients, n	1069	1320	
Age <sup>5</sup>	63 (54-73)	65 (54-74)	0.04
Female sex	478 (44.7%)	570 (43.2%)	0.48
<b>Race/Ethnicity</b>			
White	381 (35.6%)	495 (37.5%)	0.11
Black	395 (37.0%)	490 (37.1%)	
Asian	26 (2.4%)	34 (2.6%)	
Hispanic	165 (15.4%)	173 (13.1%)	
Native Hawaiian or Pacific Islander	26 (2.4%)	49 (3.7%)	
American Indian	72 (6.7%)	66 (5.0%)	
Missing	4 (0.4%)	13 (1.0%)	
Accepted at least 1 test	276 (25.8%)	227 (17.2%)	<0.01

<sup>#</sup>median (p25-p75); <sup>^</sup>Exact/Pearson chi-square test or Wilcoxon rank-sum (Mann-Whitney) test for the difference, as appropriate

- 57 facilities across 29 counties participated and contributed data to the trial
- 2389 patients participated and 12,553 tests were offered
- More patients accepted at least one test in facilities in the static arm in comparison to facilities in the dynamic arm (25.8% vs 17.2%, respectively; p<0.01)

	Static	Dynamic	P-value <sup>^</sup>
Total tests offered, n	6347	6206	
Tests offered per patient <sup>#</sup>	6 (6-6)	4 (3-6)	<0.01
Total tests accepted	509 (8.0%)	475 (7.7%)	0.45
Positive (among accepted tests)	10 (2.0%)	9 (1.9%)	0.56

<sup>#</sup>median (p25-p75); <sup>^</sup>Exact/Pearson chi-square test or Wilcoxon rank-sum (Mann-Whitney) test for the difference, as appropriate

- More tests were offered in facilities in the static arm versus facilities in the dynamic arm (median of 6 versus 4, respectively; p<0.01)
- Test acceptability: 8.0% vs 7.7% (p=0.45) in facilities in the static arm versus facilities in the dynamic arm
- Positivity rate: 2.0% vs. 1.9% (p=0.56) in facilities in the static arm versus facilities in the dynamic arm

**Strengths**

- We were able to reach a diverse population nationwide
- Following the precedence of TIME trial, the study was conducted using Opt-out consent, facilitated by research information sheets
- Tests were offered and results were ascertained without any research staff present at the facilities

**Limitations**

- The timing of the study (early-mid 2023) limited its clinical relevance, as tests were widely available, county COVID-19 rates were low, and risk for hospitalization or death among those infected was lower
- Facility staff attitudes toward COVID19 may have affected quality of test offer

**Conclusions**

- We demonstrated that dialysis facilities can participate in public health surveillance for underserved populations during future pandemics
- In this national trial integrating routine SARS-CoV-2 test offer in dialysis care and in which a diverse group of patients participated, we found test acceptability was poor and did not vary by testing strategy
- As might be expected during a period of low SARS-CoV2 transmission, a dynamic testing strategy anchored to community transmission rates, resulted in fewer test offers per patient than a static one
- Positivity rates among those tested indicate continued risk for facility transmission even during a time of low COVID-19 incidence

**Future Directions**

- Pragmatic studies including clinical trials and public health surveillance in dialysis facilities could reach a disadvantaged, underserved population
- Any future infection screening strategies in dialysis facilities will need significant buy in from patients and staff

**Acknowledgements**

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