

A Strategy for Increasing Clinical Trial Diversity Using Real-World Data to Inform Patient Selection Criteria



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BACKGROUND

Clinical trials often exclude patients with select comorbidities to reduce the risk of adverse events or noise from confounding variables.¹ However, the application of narrow selection criteria has been found to reduce the eligibility of underrepresented minorities despite higher disease prevalence in these populations.^{2,3}

OBJECTIVE

The objective of this study was how electronic medical records can be used to examine the impact of selection criteria on different racial groups and demonstrate one approach for increasing the eligible patient pool

METHODS

Data source: TriNetX Dataworks USA Network

- A federated electronic medical record network of 47 Healthcare organizations across the U.S. treating 80+ million de-identified patients

Patient Selection

- Adults (≥18 years old) with a diagnosis of hypertension (ICD-10-CM: I10) at any time

Patient Stratification

- Patients were stratified by race: Asian, Black, White, Other, or Unknown
 - Other included American Indian, Alaskan Native, Native Hawaiian, and Other Pacific Islander

Measures

- For four common exclusion diagnoses, we captured the number (N) and percentage (%) of patients with the diagnosis, the N and % with a disease monitoring lab value, and the N and % whose most recent lab result indicated disease control (Table 1)

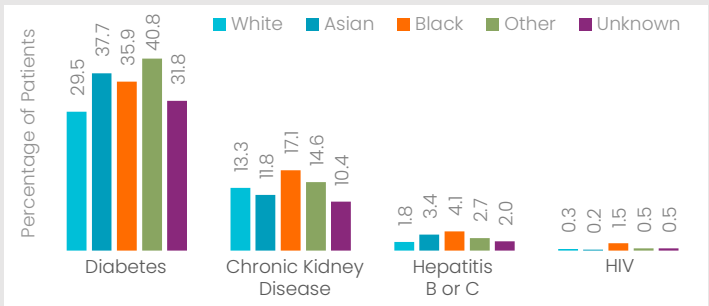
Table 1. Study Criteria

Diagnosis	ICD-10-CM	Disease monitoring labs	Lab Threshold
Diabetes (Type I or II)	E10, E11	HbA1c	6.5%
		Fasting glucose	126 mg/dL
		Glucose tolerance panel	200 units
Chronic kidney disease	N18	Urea nitrogen	60 mg/dL
		Creatinine	300 mg/dL
		Glomerular filtration rate	60 mL/min
Hepatitis B or C	B16, B17.1, B18, B19.0, B19.1, B19.2	Viral load test	10 copies/mL
HIV	B20	Viral RNA load test	200 copies/mL

Statistics

- All study analyses were conducted on the TriNetX platform using the built-in querying and analytics functions
- Patient stratification by race was performed using TriNetX Diversity Lens.

Figure 1: Percentage of hypertensive patients with a history of common diagnoses of exclusion



RESULTS

- Among the 11.8 million adults with hypertension, 8,001,487 (67.5%) were White, 233,643 (2.0%) were Asian, 2,033,014 (17.2%) were Black, and 1,582,776 (13.3%) were other/unknown

Diabetes

- Removing patients with any history of the diabetes would exclude 29.5% of White patients, 37.7% of Asian patients, and 35.9% of Black patients (Fig. 1)
- Overall, 60.7% of patients with hypertension and diabetes, including 62.2% of White patients, 53.7% of Asian patients, and 65.7% of Black patients, had a relevant lab result (Table 2)
- Among patients with a test result, 39.0% of White patients, 35.5% of Asian patients, and 40.3% of Black patients most recent test result indicated disease control

Chronic Kidney Disease

- Removing patients with any history of the chronic kidney disease would exclude 13.3% of White patients, 11.8% of Asian patients, and 17.1% of Black patients
- Overall, 88.5% of patients with hypertension and chronic kidney disease, including 89.7% of White patients, 84.8% of Asian patients, and 88.9% of Black patients, had a relevant lab result
- Among patients with a test result, 21.9% of White patients, 22.9% of Asian patients, and 22.7% of Black patients most recent test result indicated disease control

Hepatitis B or C

- Removing patients with any history of the hepatitis B or C would exclude 1.8% of White patients, 3.4% of Asian patients, and 4.1% of Black patients
- Overall, 35.7% of patients with hypertension and hepatitis B or C, including 35.0% of White patients, 37.2% of Asian patients, and 38.6% of Black patients, had a relevant lab result
- Among patients with a test result, 47.3% of White patients, 56.7% of Asian patients, and 36.3% of Black patients most recent test result indicated disease control

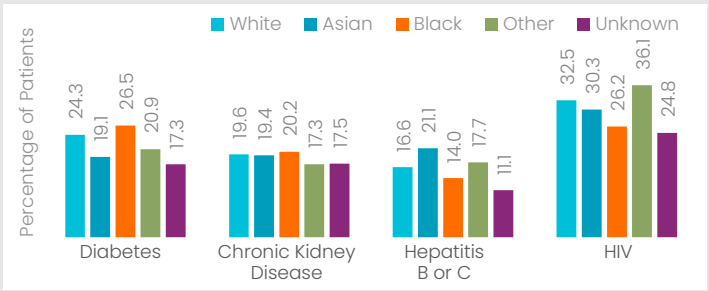
HIV

- Removing patients with any history of the HIV would exclude 0.3% of White patients, 0.2% of Asian patients, and 1.5% of Black patients

Table 2: Analysis of patient lab results

	White		Asian		Black		Other		Unknown	
Diabetes	2,361,186		88,084		730,652		20,016		487,953	
With lab	1,468,665	62.2%	47,315	53.7%	480,058	65.7%	12,465	62.3%	231,029	47.3%
With controlled disease	572,843	39.0%	16,788	35.5%	193,695	40.3%	4,185	33.6%	84,439	36.5%
Chronic kidney disease	1,067,643		27,587		347,690		7,136		159,472	
With lab	958,084	89.7%	23,397	84.8%	309,188	88.9%	6,109	85.6%	127,676	80.1%
With controlled disease	209,644	21.9%	5,351	22.9%	70,335	22.7%	1,236	20.2%	27,851	21.8%
Hepatitis B or C	147,585		7,904		83,048		1,315		30,408	
With lab	51,706	35.0%	2,943	37.2%	32,071	38.6%	481	36.6%	9,359	30.8%
With controlled disease	24,469	47.3%	1,669	56.7%	11,657	36.3%	233	48.4%	3,390	36.2%
HIV	24,720		469		31,265		230		7,365	
With lab	10,798	43.7%	191	40.7%	13,582	43.4%	133	57.8%	2,538	34.5%
With controlled disease	8,032	74.4%	142	74.3%	8,202	60.4%	83	62.4%	1,824	71.9%

Figure 2: Percentage of excluded patients with controlled disease



- Overall, 42.5% of patients with hypertension and HIV, including 43.7% of White patients, 40.7% of Asian patients, and 43.4% of Black patients, had a relevant lab result
- Among patients with a test result, 74.4% of White patients, 74.3% of Asian patients, and 60.4% of Black patients most recent test result indicated disease control

Patient Recovery

- Using these methods in patient recruitment and trial design, a sponsor could recover (Fig. 2)
 - 17.3%-26.5% of excluded patients with diabetes
 - 17.3%-20.2% of excluded patients with chronic kidney disease
 - 11.1%-21.1% of excluded patients with hepatitis B or C
 - 24.8%-36.1% of excluded patients with HIV

CONCLUSIONS

- Use of broad diagnosis-based exclusion criteria may disproportionately exclude non-White clinical trial participants.
- Electronic medical record data can be used to explore alternative exclusion strategies, such as using lab values to exclude patients based on level of disease control.
- By broadening the potential participant pool, these approaches may improve the likelihood of recruiting a trial population that better matches the real-world population.

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DISCLOSURES

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