Title

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Journal

Journal of General Internal Medicine, 37(11)

ISSN

0884-8734

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Publication Date

2022-08-01

DOI

10.1007/s11606-021-07283-6

Peer reviewed

Warfarin Monitoring in Safety-Net Health Systems: Analysis by Race/Ethnicity and Language Preference

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BACKGROUND: Racial/ethnic disparities in anticoagulation management are well established. Differences in warfarin monitoring can contribute to these disparities and should be measured.

OBJECTIVE: We assessed for differences in international normalized ratio (INR) monitoring by race/ethnicity and language preference across safety-net care systems serving predominantly low-income, ethnically diverse populations.

DESIGN: Cross-sectional analysis of process and safety data shared from the Safety Promotion Action Research and Knowledge Network (SPARK-Net) initiative, a consortium of five California safety-net hospital systems.

PARTICIPANTS: Eligible patients were at least 18 years old, received warfarin for at least 56 days during the measurement period from July 2015 to June 2017, and had INR testing in an ambulatory care setting at a participating healthcare system.

MAIN MEASURES: We conducted a scaled Poisson regression for adjusted rate ratio of having at least one INR checked per 56-day time period for which a patient had a warfarin prescription. Adjusting for age, sex, healthcare system, and insurance status/type, we assessed for racial/ethnic and language disparities in INR monitoring.

KEY RESULTS: Of 8129 patients, 3615 (44%) were female; 1470 (18%), Black/African American; 3354 (41%), Hispanic/Latinx; 1210 (15%), Asian; 1643 (20%), White; and 452 (6%), other. Three thousand five hundred forty-nine (45%) were non-English preferring. We did not observe statistically significant disparities in the rate of appropriate INR monitoring by race/ethnicity or language; the primary source of variation was by healthcare network. Older age, female gender, and uninsured patients had a slightly higher rate of appropriate INR monitoring, but differences were not clinically significant.

CONCLUSIONS: We did not find a race/ethnicity nor language disparity in INR monitoring; safety-net site was the main source of variation.

KEYWORDS: Warfarin; anticoagulation; safety-net providers; quality indicators; health status disparities.

Prior presentations: *None*

Received April 23, 2021
Accepted November 17, 2021
Published online January 6, 2022

J Gen Intern Med 37(11):2703–10
DOI: 10.1007/s11606-021-07283-6

BACKGROUND

Despite the emergence of direct oral anticoagulants (DOAC), clinicians still commonly prescribe warfarin for atrial fibrillation, venous thromboembolism, and other coagulation disorders. 66.8% of Medicare beneficiaries[1] and 18% of patients overall with thromboembolism are prescribed warfarin.[2] Appropriate management of warfarin is key to preventing adverse outcomes related to subtherapeutic use and bleeding events related to supratherapeutic use. Racial disparities in warfarin management have been identified. Among veterans, Black patients have a decrease in time in therapeutic range (TTR) than White patients, ranging from 2.9 to 6.5%. Decreased TTR increases risk of stroke, major hemorrhage, and death.[3,4] In turn, widespread racial/ethnic disparities in stroke outcomes persist in the USA, causing disproportionate morbidity and mortality among Black/African American patients,[5] US-born Hispanic individuals,[3,6] and Asian American disaggregated groups[7] compared with non-Hispanic Whites. The delivery of warfarin management is a complex care process which may affect these observed disparities, and experts have argued that safe, effective management of warfarin requires measuring how care is delivered with a range of metrics.[8]

Safe, effective warfarin care involves engagement with a qualified warfarin clinical service in order to access regular laboratory monitoring of the international normalized ratio

(INR) and to receive therapeutic follow-up and adjustment of medication dosage, in order to achieve appropriate INR levels. Structural racism, interpersonal racism, and literacy and language-related barriers may affect how well health systems operationalize INR management for racial/ethnic minorities and non-English-preferring patients. Limited English proficiency (LEP) has been found to be an independent risk factor for lower TTR[9]; it has also been associated with an incorrect understanding of warfarin's mechanism and rate of monitoring.[10] Thus, ensuring equitable care at safety-net sites should be a priority for sites serving predominantly Black, Indigenous and People of Color (BIPOC) and LEP patients. However, few studies have evaluated warfarin care processes across race/ethnic and language proficiency at multi-site safety-net healthcare systems apart from above cited studies from the VA.

Due to differences in opportunity and healthcare access caused by structural racism and language barriers affecting housing, income, insurance coverage, and other factors, many patients identifying as BIPOC and LEP receive care at safety-net healthcare systems. We define "safety-net" systems as healthcare systems that care for predominantly publicly insured, uninsured, low-income, and ethnic minority patients.[11–13] We sought to leverage a data-sharing initiative to describe INR monitoring rates across five safety-net healthcare systems serving predominantly publicly insured patients and contrast monitoring among race/ethnic groups and non-English-preferring patients.

METHODS

Study Design and Setting

This study was a cross-sectional analysis of data from the Safety Promotion Action Research and Knowledge Network (SPARK Net) initiative. SPARK Net is a consortium of five California public hospital systems participating in performance reporting and data sharing.[14] The data were gathered for performance improvement, funded by the Public Hospital Redesign and Incentives in Medi-Cal (PRIME) Program; "Medi-Cal" is the joint Federal-State Medicaid program in California.[15] Participating hospital systems provided individual-level data in the first 2 years of the PRIME program (year 1: July 1, 2015, to June 30, 2016; year 2: July 1, 2016, to June 30, 2017). Participating hospital systems collected and reported INR monitoring data; the PRIME program reimbursed sites for reporting the proportion of patients on warfarin having an INR value checked at least once every 56 days.[16] In addition, PRIME incentivized hospital systems to capture standardized race/ethnicity and language data from all patients. Thus, this program provided a unique opportunity to more deeply examine predictors of disparities in INR monitoring at the patient level. Study staff reviewed data validation procedures with each hospital system and standardized reporting of race/ethnicity, language, and insurance type/coverage. Participants in the SparkNet collaborative shared demographic data including patient age, sex, race/ethnicity, insurance status, preferred language, hospital system, warfarin prescription start and end dates, and INR testing dates.

Participants

Eligible patients were at least 18 years old, were receiving warfarin therapy for at least 56 days during the measurement period, and had INR testing in an ambulatory care setting at one of the five participating healthcare networks. The indication for warfarin did not affect inclusion.

Variables

We grouped patient age into five groups (50 and younger, 50–59, 60–69, 70 and older). Each health system leader reviewed and categorized insurance types in their data into Medicaid, Medicare, uninsured, and other sources of payment within their respective systems. We considered government programs that were not part of Medicaid or Medicare as other. Participating healthcare systems categorized gender as a binary male/female across systems. Each system collected race and ethnicity data separately, enabling us to identify patients who reported Hispanic/Latino ethnicity. We then categorized race/ethnicity as non-Hispanic White, non-Hispanic Black, non-Hispanic Asian, other race with no Hispanic/Latino ethnicity, and Hispanic/Latino of all races. We did not have access to the clinical indication for warfarin, nor the goal INR level, based on the nature of the data-sharing initiative.

The primary outcome was the rate of "appropriate INR monitoring"; we defined this as having at least one INR lab test collected per 56-day interval. This INR metric is a National Quality Forum–endorsed process metric[17]; data has shown an association between two or more gaps of at least 56 days and a 10% lower TTR.[18] Moreover, clinical guidelines have recommended checking an INR every 4 weeks for the indication of atrial fibrillation,[19] up to 6 to 12 weeks for stable patients on warfarin for venous thromboembolism;[20] 56 days is a midpoint given the variety of indications in a network for prescribing warfarin. We calculated the appropriate INR monitoring rate as the number of 56-day testing intervals that had at least one lab completed, per the number of INR testing intervals for which the patient was eligible, based on the number of 56-day intervals during their time on the medication. We defined the first day of the first 56-day interval for each patient as the start date of the first warfarin prescription. Each subsequent 56-day interval started on the day after the former 56-day interval had ended, as long as the end date occurred within the warfarin therapy time frame on record. We used only full 56-day intervals to calculate the outcome. We could not assess TTR because we lacked the relevant individual-level data; TTR was not a PRIME performance metric.

Analysis

In the primary analysis, we used a scaled Poisson regression model with a log-link function. We chose Poisson regression because the outcome is a count of intervals in which INR testing occurred. We used the logarithm of the total number of 56-day intervals as an offset variable to account for the difference in measurement times across patients. We obtained an estimate for the INR monitoring rate ratios and a corresponding 95% CI for race/ethnicity, adjusting for age, sex, insurance status, and hospital system.

In subgroup analyses, we used the same methods described above for assessing disparities based on language preference. We compared estimated rate ratios in appropriate INR monitoring rate within race/ethnic groups for which at least 50% of the sample reported non-English preference, comparing non-English preferring to English preferring. This included the Hispanic/Latinx and Asian groups, as the prevalence of non-English-preferring patients identified as White or Black was under 50% in this sample and did not enable comparison.

The study was approved by the UCSF institutional review board (Approval number 15-18136).

RESULTS

We excluded 257 patients with private health insurance (3% of the study population) from the analysis, given the small proportion seen in this sample, and the fact that publicly insured patients are primarily served by safety-net systems. We also excluded 154 patients (2%) with missing values from the analysis. Our final analysis included a total of 8129 patients (Table 1). Of these, 3615 (44%) were female; 1470 (18%) were Black/African American, 3354 (41%) were Hispanic/Latinx, 1210 (15%) were Asian, 1643 (20%) were White, and 452 (6%) were other. The median age was 61 (IQR: 14). The median INR value was 2.6 (IQR: 1.00). Patients had a median of 7 total INR checks per year in year 1 (IQR 12) and 10 checks in year 2 (IQR 10) (counting all lab checks regardless of time interval between labs).

In Poisson regression multivariable analysis, hospital system or network was statistically significantly associated with INR monitoring, with wide variations in extent of monitoring. Adjusted for covariates, hospital systems had appropriate INR monitoring rate ratios ranging from 0.53 (95% CI 0.48–0.57) to 1.50 (95% CI 1.45–1.55) compared to the referent health system.

We found small statistically significant differences in appropriate INR monitoring among patients of older age, female gender, and "uninsured" or "other" insurance status. Age groups above 50 had higher rate ratios (ranging 1.04–1.07) of appropriate INR monitoring compared to patients aged 50 or younger. Females had a rate of 1.02 (95% CI 1.01–1.04) compared to males. Those with the "other" insurance category had slightly lower rates (0.93, 95% CI 0.88–0.98) and those with the "uninsured" insurance category had slightly higher rates (1.04, 95% CI 1.00–1.08), compared to patients insured with Medicare.

Table 1 Demographics of Included Patients

Demographics	Sample (n = 8129)	
	n	%
Preferred language		
English	4467	(54.9)
Spanish	2560	(33.0)
Other	979	(12.0)
Sex		
Female	3615	(44.5)
Male	4514	(55.5)
Age		
Median age = 61		
IQR = 15		
< 50 years	1504	(18.5)
50–59 years	2078	(25.6)
60–69 years	2720	(33.5)
70+ years	1827	(22.5)
Race/ethnicity		
White	1643	(20.2)
Black/African American	1470	(18.1)
Hispanic	3354	(41.3)
Asian	1210	(14.9)
Other	452	(5.6)
Insurance status		
Medicare	2362	(29.1)
Medicaid	4684	(57.6)
Uninsured	519	(6.4)
Other	564	(6.9)
INR values		
Mean	2.4	
Median	2.3	
Mode	2.0	
IQR	1.0	
# of INRs checked in each 1-year period	Year 1	Year 2
Median	10	7
IQR	12	10

In contrast, we did not observe statistically significant differences in rate of appropriate INR monitoring by race/ethnicity nor language (Table 2). In subgroup analysis of race/ethnic groups, non-English-preferring Latinx patients did not have different rates of appropriate INR monitoring compared to English-preferring Latinx patients (rate ratio = 1.01, 95% CI: [0.98, 1.05]). Similarly, we did not observe differences in appropriate INR monitoring between non-English-preferring Asian patients compared to English-preferring Asian patients (1.04 [0.99, 1.10]), as seen in Tables 3 and 4.

DISCUSSION

Our primary analysis of multi-site data did not find a racial/ethnic nor language-based disparity in rate of appropriate INR monitoring. Age, gender, and insurance status had a minor but statistically significant impact on proper monitoring intervals. However, there was statistically significant variation between sites with respect to INR monitoring rates.

While we did not systematically observe or survey each site's anticoagulation monitoring workflow, the sites vary in

Table 2 Association of Demographic Characteristics with Rate of Appropriate INR Monitoring for Patients in Safety-Net System

Parameter	Mean ± SD	Estimate	Standard error	Rate ratio	95% confidence limits	
Preferred language						
English preferring	2.11 ± 1.31	Reference				
Non-English preferring	2.00 ± 1.58	0.00	0.01	1.00	0.98	1.03
Age						
< 50 years	2.41 ± 0.86	Reference				
50–59 years	2.45 ± 1.89	0.06	0.01	1.07*	1.04	1.09
60–69 years	1.43 ± 1.35	0.05	0.01	1.05*	1.02	1.08
70+ years	2.28 ± 0.97	0.04	0.01	1.04*	1.01	1.07
Gender						
Male	2.26 ± 1.57	Reference				
Female	1.84 ± 1.26	0.02	0.01	1.02*	1.01	1.04
Insurance coverage						
Medicare	2.41 ± 0.86	Reference				
Medicaid	1.76 ± 1.29	− 0.01	0.01	0.99	0.97	1.02
Other	2.14 ± 1.10	− 0.08	0.03	0.93*	0.88	0.98
Uninsured	2.51 ± 2.54	0.04	0.02	1.04*	1.00	1.08
Race/ethnicity						
White	2.21 ± 1.04	Reference				
Black/African American	2.10 ± 1.65	− 0.02	0.02	0.98	0.95	1.01
Hispanic	1.94 ± 1.61	0.02	0.02	1.02	0.99	1.05
Asian	2.21 ± 1.10	0.03	0.02	1.03	1.00	1.06
Other	2.12 ± 1.09	− 0.02	0.02	0.98	0.94	1.02
Safety-net system/network						
A	2.35 ± 1.11	Reference				
B	2.41 ± 0.84	− 0.64	0.04	0.53*	0.48	0.57
C	2.40 ± 1.01	0.40	0.02	1.50*	1.45	1.55
D	1.84 ± 1.72	0.29	0.05	1.33*	1.22	1.46
E	2.28 ± 0.97	0.31	0.02	1.37*	1.32	1.42

Note: Statistically significant differences $p < 0.05$ marked with asterisks

the extent to which warfarin management occurs in dedicated anticoagulation clinics versus as part of primary care. Some sites employ population management tools such as electronic registry data and in-reach and outreach to patients who have missed recommended INR monitoring while others conduct visit-based monitoring only. This is consistent with prior studies of anticoagulation management that suggest that care processes such as a dedicated, multi-disciplinary clinic, standardized protocols to address out-of-range values, and follow-up procedures for appointment or monitoring non-adherence are critical to manage warfarin effectively and safely.[21]

Our finding from multiple safety-net systems suggesting that variation by healthcare system is the main driver in INR monitoring has several implications. First, it suggests that in a safety-net system, lapses or shortfalls in site-specific processes of warfarin management are not disproportionately impacting racial/ethnic minorities nor LEP patients but rather are relatively consistent within each site. This may reflect the mission of safety-net hospitals to maintain an open-door policy for their services, as well as the recent emphasis on standard work in the general health care setting.[22,23] Second, the overall lack of a racial/ethnic or language disparity in this analysis suggests that safety-net sites, which are specifically tailored to meet the needs of vulnerable populations, may be prepared to meet the diverse language needs for Hispanic and Asian patients compared to non-safety-net health centers. This difference may be due to higher racial/ethnic/linguistic concordance by clinicians and staff,[24–26] as well as programmatic support to ensure equity based on state- or county-driven policies. Due to existing processes in place that are culturally and literacy appropriate, safety-net systems have significant knowledge to offer in how to best engage with vulnerable populations in quality improvement activities.

While the focus of this analysis was racial/ethnic and language disparities, we did see differences by insurance coverage. Due to the mission of safety-net hospitals to care for patients regardless of their insurance status or their ability to pay, these institutions frequently rely on an array of public funding coming from federal, state, and local sources. As such, the majority of resources received may be directed towards overcoming the cost of medical expenses not paid for by patients. Therefore, the higher rates of INR monitoring for those with "uninsured" coverage category may have been eligible for local city- or county-based wraparound services or navigation support for vulnerable patients, depending on network. Those with "other" insurance category may have included patients eligible for local general relief or general assistance programs, as well as patients with insurance plans that did not support additional services. However, this group was too heterogenous to enable any meaningful interpretation of this group having slightly less monitoring.

The participating institutions conducted INR monitoring as part of PRIME, the first Medicaid waiver in California requiring performance reporting and improvement.[15] As the first large-scale performance measurement effort for safety-net health systems, the results reflect early-stage results on an innovative metric that is not widely used in US pay-for-performance programs. It is common for data management challenges to surface in early stages of performance measurement,[16] though this patient-level data was carefully validated

Table 3 Subgroup Analysis of Asian Patients (n = 1283) and Demographic Characteristics Associated with Rate of Appropriate INR Monitoring

	Mean ± SD	Estimate	Standard Error	Rate Ratio	95% Confidence Limits	
Language Preference						
English preferring	2.18 ± 1.13	Reference				
Non-English preferring	2.23 ± 1.08	0.04	0.03	1.04	0.99	1.10
Age						
Less than 50	2.46 ± 0.92	Reference				
50-59 years	2.40 ± 0.73	0.10	0.05	1.11*	1.00	1.22
60-69 years	1.95 ± 1.29	0.09	0.05	1.10*	1.00	1.20
70+years	2.35 ± 0.98	0.05	0.05	1.05	0.95	1.15
Gender						
Male	2.21 ± 1.10	Reference				
Female	2.20 ± 1.10	0.01	0.02	1.01	0.97	1.06
Insurance Coverage						
Medicare	1.86 ± 1.31	Reference				
Medicaid	2.42 ± 1.89	-0.05	0.04	0.95	0.89	1.02
Other	2.47 ± 1.12	-0.06	0.05	0.94	0.85	1.03
Uninsured	2.27 ± 0.84	0.05	0.04	1.05	0.97	1.14
Site						
A	2.48 ± 1.03	Reference				
B	2.42 ± 0.80	-0.72	0.09	0.48*	0.41	0.58
C	2.28 ± 0.68	0.32	0.03	1.38*	1.29	1.47
D	1.88 ± 1.33	0.00	0.00			
E	2.36 ± 0.96	0.29	0.04	1.34*	1.23	1.46

Notes

: $statistically significant differences p < 0.05 marked with asterisks; green$

: $higher than the reference group, holding all other explanatory variables constant; orange$

: $lower than the reference group, holding all other explanatory variables constant; blanks$

: $due to a small sample size, no valid estimates were computed$

because of the research context. Moreover, because INR monitoring is not widely measured, it is challenging to benchmark the performance of these health systems.

Consistent INR monitoring is a key care process and safety metric; gaps in monitoring may increase the risk of an embolic or bleeding event. In addition, there are many factors involved in calculating a TTR that can limit comparisons between organizations.[27] While maximizing the time in therapeutic range (TTR) provides the best assessment of how well patients are being monitored on warfarin therapy, many healthcare systems may have difficulty calculating TTR based on electronic health record data. INR monitoring rates per 56-day interval in aggregate may be easier to calculate than TTRs as a process metric. Although useful when calculating individual patients based on therapeutic target range, TTR calculations fall short when applied to a group of patients due to a lack of uniformity in INR measurement rate, temporary discontinuations of warfarin (i.e., surgery), and premature values measured before the effect of warfarin is stabilized.[27] Other quality measures that are provider or process focused include response time to out-of-range laboratory values and compliance with guideline recommendations.[8] Examination of gaps in INR monitoring as a process metric may provide insights into who may be "left behind."[18]

Prior studies in the Veterans Health Administration[3,4] and a study at a single public hospital site found lower TTR among Black patients compared to White, English-speaking patients, and lower TTR for Spanish-speaking Hispanic patients compared to English-speaking Hispanic patients.[28] A non-safety-net study at a healthcare maintenance organization found

Table 4 Subgroup Analysis of Hispanic/Latinx Patients and Demographic Characteristics Associated with Rate of Appropriate INR Monitoring

Parameter	Mean ± SD	Estimate	Standard Error	Rate Ratio	95% Confidence Limits	
Language Preference						
English preferring	2.44 ± 0.88	Reference				
Non-English preferring	1.83 ± 1.71	0.01	0.02	1.01	0.98	1.05
Age						
Less than 50	2.46 ± 2.35	Reference				
50-59 years	2.21 ± 1.15	0.04	0.02	1.05*	1.01	1.08
60-69 years	1.41 ± 1.35	0.02	0.02	1.02	0.98	1.05
70+years	1.92 ± 1.27	0.03	0.02	1.03	0.99	1.07
Gender						
Male	2.40 ± 1.80	Reference				
Female	1.59 ± 1.34	0.03	0.01	1.03*	1.01	1.06
Insurance Coverage						
Medicare	156 ± 1.36	Reference				
Medicaid	1.99 ± 1.72	0.01	0.02	1.01	0.98	1.05
Other	2.35 ± 1.03	-0.05	0.05	0.95	0.86	1.05
Uninsured	2.25 ± 0.98	0.02	0.04	1.02	0.95	1.09
Site						
A	2.51 ± 1.23	Reference				
B	2.43 ± 0.83	-0.76	0.08	0.47	0.40	0.54
C	2.50 ± 1.14	0.31	0.03	1.36*	1.28	1.45
D	1.84 ± 1.72	0.26	0.07	1.30*	1.15	1.48
E	2.28 ± 0.99	0.24	0.03	1.28	1.20	1.35

Notes

: $statistically significant differences p < 0.05 marked with asterisks; green$

: $higher than the reference group, holding all other explanatory variables constant; orange$

: $lower than the reference group, holding all other explanatory variables constant$

Black patients with atrial fibrillation had lower percent time of an INR within a range of 2–3.[29] There needs to be standard and robust outreach processes for patients who have missed scheduled follow-ups for INR monitoring, and implementation of strategies to address etiologies of those not well engaged in care. By engaging in quality improvement activities, anticoagulation providers have an opportunity to identify areas of improvement and potential interventions.[8]

Limitations of this analysis include inability to adjust for patient co-morbidities, clinician panel, clinician demographics, or clinic-level factors within the five participating healthcare systems. In addition, we were not able to calculate time in therapeutic range. We acknowledge that INR values outside the therapeutic range lead to changes in monitoring frequency, and our analysis did not account for this. There is also potential selection bias in which we could not account for patients leaving and then re-entering these healthcare networks. We did not have access to the clinical indication for warfarin, which prevented us from ascertaining goal INR and therefore TTR. While we could not adjust for patient income, most patients within the sampled networks typically have low income in order to qualify for care at these healthcare systems. There may be other unmeasured confounders to explain system-level differences by site; however, all sites served ethnically diverse, publicly insured or uninsured patient populations in California. Strengths include the racial/ethnic and linguistic diversity of the sample; the large sample size of aggregated, real-world quality improvement data that are generalizable to other safety-net healthcare systems; and the use of a relatively straightforward metric to capture a proxy for TTR which otherwise might be difficult to calculate in lower-resourced healthcare networks.

CONCLUSIONS

Safety-net systems had system-specific variations in rate of appropriate INR monitoring, rather than disparities by

race/ethnicity or language preference. Other health systems, regardless of safety-net status, can employ this metric to determine the extent of INR monitoring among patients prescribed warfarin and examine this complex care process by race/ethnicity and language proficiency. Examining care processes stratified according to race/ethnicity as well as language proficiency provides a key strategy to promote accountability and equity in anticoagulation management across safety-net systems.

Acknowledgements: *Thanks to the SparkNet Collaborators and data managers for generously sharing data and time. Thanks to David Lown, MD, of the California Healthcare Safety Network Institute and Palav Babaria, MD, of Alameda Health Systems for their role in guiding the SparkNet collaborative. Thanks to Christina Yong for proofreading this manuscript.*

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Funding *Research reported in this publication was supported in part by the National Center for Advancing Translational Sciences of the NIH under Award Number KL2TR001870 (AES and ECK), National Institute for Health's National Research Service Award under Award Number T32HP19025 (ECK), National Heart Lung and Blood Institute of the NIH under Award Number K12HL138046 (ECK), National Heart, Lung, And Blood Institute under Award Number K24HL141354 (MCF), and Agency for Healthcare Research and Quality under Award Number R01HS024426-03 (US). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.*

Data availability The datasets collected and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations:

Conflict of interest: *The authors declare that they do not have a conflict of interest.*

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