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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-022623
Article Type:	Protocol
Date Submitted by the Author:	27-Feb-2018
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Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Physician implicit racial bias, Patient-physician communication, Black/African American patients, PRIMARY CARE, PUBLIC HEALTH

A STUDY PROTOCOL FOR INVESTIGATING PHYSICIAN COMMUNICATION BEHAVIORS THAT LINK PHYSICIAN IMPLICIT RACIAL BIAS AND PATIENT CLINICAL OUTCOMES IN BLACK PATIENTS WITH TYPE 2 DIABETES USING AN EXPLORATORY SEQUENTIAL MIXED METHODS DESIGN

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Disclaimers: The views expressed in the submitted article are the authors' own and not an official position of the institutions or the funder.

Word count: 4,957 words

Number of figures and tables: 3 figures, 1 table

ABSTRACT

Introduction: Patient-physician racial discordance is associated with Black patient reports of dissatisfaction and mistrust, which in turn are associated with poor adherence to treatment recommendations and underutilization of healthcare. Research further has shown patient dissatisfaction and mistrust are magnified particularly when physicians hold high levels of implicit racial bias. This suggests physician implicit racial bias manifests in their communication behaviors during medical interactions. The overall goal of this research is to identify physician communication behaviors that link physician implicit racial bias and Black patient immediate (satisfaction, trust) and long-term clinical outcomes (mediation adherence, self-management, healthcare utilization).

Methods and analysis: Using an exploratory sequential mixed methods research design, we will collect data from approximately 30 family medicine physicians and 300 Black patients with Type 2 diabetes mellitus (T2DM). The data sources will include one physician survey, three patient surveys, medical interaction videos, video elicitation interviews, and medical chart reviews. Physician implicit racial bias will be assessed with the physician survey, and patient clinical outcomes will be assessed with the patient surveys and medical chart reviews. In video elicitation interviews, a subset of patients (approximately 20-40) will watch their own interactions while being monitored physiologically to identify evocative physician behaviors. Information from the interview will determine which physician communication behaviors will be coded from medical interactions videos. Coding will be done independently by two trained coders. A series of statistical analyses (zero-order correlations, partial correlations, regressions) will be conducted to identify physician behaviors that are associated significantly with both physician implicit racial bias and patient clinical outcomes.

Ethics and dissemination: Ethics approval was obtained from the Virginia Commonwealth University IRB. Study results will be disseminated through publications in peer-reviewed journals and presentations at conferences. A novel *Medical Interaction involving Black Patients Coding System* (*MIBPCS*) from this project will be made publicly available.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Use of an exploratory sequential mixed methods research design will incorporate Black patients' perspectives into patient-physician communication research, an approach crucial for advancing understanding of the impact of physician communication behaviors on patient clinical outcomes.
- The study combines physiological assessment and in-depth qualitative video elicitation interviews in a unique way for methodological innovation.
- This research will produce a novel, culturally tailored *Medical Interaction involving Black Patients Coding System* (*MIBPCS*) that will be designed to assess physician communication behaviors that can negatively or positively impact patient clinical outcomes.
- One study limitation is that physician implicit racial bias is only one of several factors that determine patient clinical outcomes.
- The generalizability of findings from this research to Black patients with other diseases (e.g., hypertension, asthma, cancer) will need to be tested empirically.

INTRODUCTION

Patient-physician racial discordance is associated strongly with patient reports of dissatisfaction with and mistrust in physicians,[1-7] which in turn are associated with poor patient adherence to treatment recommendations and underutilization of healthcare.[8-10] This poses serious public health concerns because approximately 80-90% of Black patients see physicians from different racial groups.[5-7; 11; 12] Recent research has shown further that patient dissatisfaction and mistrust are magnified particularly when physicians hold high levels of implicit bias toward Black Americans (Figure 1A).[13-16] This negative association between physician implicit racial bias and Black patient reports of satisfaction/trust suggests that physician implicit racial bias impacts their communication behaviors during medical interactions and ultimately contributes to poorer clinical outcomes in Black patients (Figure 1B).

Social psychology research provides strong evidence that an individual's implicit bias often is reflected in their nonverbal (e.g., body posture, eye contact, nodding) and paraverbal (e.g., the amount, speed, and pitch of the speech) behaviors, as opposed to verbal behaviors (i.e., the content of the speech), during inter-racial interactions.[17-19] Drawing on this literature, several recent studies have successfully identified specific physician communication behaviors during racially discordant medical interactions that are associated with physician implicit racial bias. Specifically, physicians with higher levels of implicit racial bias had a greater ratio of physician to patient statements in a given medical interaction, reflecting their verbal dominance, as compared to physicians with lower levels of implicit racial bias.[15] Similarly, higher levels of implicit racial bias was associated with a greater ratio of physician to patient talk time.[20] Finally, physicians with higher levels of implicit racial bias were more likely to use first person plural pronouns (e.g., we, us, our) and anxiety-related words (e.g., worried, afraid, nervous).[21] However,

none of the physician communication behaviors identified and tested in the previous studies have been directly associated with patient clinical outcomes.

We posit that one major reason why previous studies have failed to identify physician communication behaviors linking physician implicit racial bias and patient clinical outcomes is due to a lack of Black patients' perspectives in the assessments. Specifically, the identification of physician communication behaviors associated with physician implicit racial bias was based on the researchers' perspectives on or assumptions about what positive patient-physician communication *should* look like. Although this theory-driven approach is one strength of the previous studies, it is not sufficient for two reasons. First, research has consistently shown that patient clinical outcomes are better predicted by *patient reports* of patient-physician communication than *observer-rated* patient-physician communication.[22-25] This suggests the conceptualization of positive patient-physician communication is likely to be different between patients and researchers. Second, social psychology demonstrates that the same behaviors can be viewed in different ways in intra- vs. inter-racial interactions.[26] This suggests how Black and White patients conceptualize positive patient-physician communication may be different.

Hence, little is known about how physician implicit racial bias manifests behaviorally during medical interactions (Path A in Figure 1B) and how Black patients react to such behaviors (Path B in Figure 1B). To illuminate these processes, an innovative methodological approach that integrates Black patients' perspectives in patient-physician communication research is crucial. The overall goal of this research is to identify physician communication behaviors during medical interactions that are associated with both physician implicit racial bias and Black patient immediate (satisfaction, trust) and long-term clinical outcomes (mediation adherence, self-management, healthcare utilization). This investigation uses an exploratory sequential mixed

methods research design, a design characterized by initial qualitative exploration and subsequent quantitative assessment of a phenomenon of interest.

To address this study goal, we will focus on Black patients with Type 2 diabetes mellitus (T2DM) for both theoretical and methodological reasons. The focus on T2DM is *theoretically* important because evidence shows an overwhelmingly low rate of diabetes medication adherence in Black patients.[27-36] Physician communication behaviors stemming from implicit racial bias are likely to explain at least partially why medication adherence is particularly low in Black patients with T2DM. This assertion is based on evidence showing that patient reports of patient-physician communication quality are associated with diabetes medication adherence in general.[37-43] Focusing on Black patients with T2DM is also *methodologically* important as it increases the homogeneity of patient encounters and thus provides greater precision in estimating the role of physician implicit racial bias in patient clinical outcomes.

OBJECTIVES

To achieve the study goal, we will address four objectives:

Objective 1: To explore what physician communication behaviors during medical interactions are perceived as negative and what behaviors are perceived as positive by Black patients and why

Objective 2: To identify which physician communication behaviors identified in Objective 1 are associated with physician implicit racial bias

Objective 3: To examine how physician implicit racial bias impacts Black patient satisfaction, trust, adherence, and healthcare utilization through physician communication behaviors

Objective 4: To develop the *Medical Interaction involving Black Patients Coding System* (*MIBPCS*), a novel culturally tailored coding system that will identify physician communication behaviors that are perceived as negative and behaviors that are perceived as positive by Black patients.

METHODS AND ANALYSIS

The overview of the study

We will use an exploratory sequential mixed methods research design that integrates the strengths of inductive and deductive reasoning, thus allowing us to explore Black patient narratives on physician communication behaviors and to identify theoretically meaningful behaviors (Figure 2).[44] In Stage 1, to address Objective 1, we explore what physician communication behaviors during medical interactions are perceived as negative and what behaviors are perceived as positive by Black patients and why. In Stage 2, we will develop and refine a novel instrument designed to quantify negative and positive physician communication behaviors. In Stage 3, we will address Objectives 2-4 by conducting a series of statistical analyses. The summary of chronological study flow and the research design are presented in Figure 3 and Table 1, respectively.

Table 1. Summary of research design: Data sources, analyses, and goals of each specific aim

Objectives	Data sources	Analyses	Goals
1	• Video elicitation interviews (Step E)	Qualitative analysis of transcribed interviews for themes regarding negative and positive physician communication behaviors	Identify physician communication behaviors perceived as negative and behaviors perceived as positive by Black patients
2	• Physician survey (Step A) • Video-recorded medical interactions (Step C) • Scales quantifying behaviors (Step F) • Coding of the video-recorded medical interactions (Step G)	Quantitative analysis of: (1) physician communication behaviors (e.g., amount, degree, frequency, length) in all video-recorded medical interactions; and (2) the association between physician implicit racial bias and communication behaviors	Identify coded physician communication behaviors that are statistically significantly associated with physician implicit racial bias
3 & 4	• Physician survey (Step A) • Patient baseline survey (Step B) • Patient post-interaction survey (Step D) • Coding of the video-recorded medical interactions (Step G) • Patient follow-up survey (Step H) • Medical chart reviews (Step I)	Quantitative analysis of associations among physician implicit racial bias, physician communication behaviors during the medical interactions, patient reports of satisfaction/trust, patient reports of subsequent T2DM medication adherence, and healthcare utilization	Identify physician communication behaviors that mediate the association between physician implicit racial bias and Black patient clinical outcomes Develop the MIBPCS

Surveys, video-recorded medical interactions, and medical chart reviews

Participants

We will recruit approximately 30 physicians and 300 patients from multiple Family Medicine clinics affiliated with Virginia Commonwealth University that serve patients from diverse racial/ethnic backgrounds. The only eligibility criterion for physicians is that they have to be either 2nd-3rd year medical residents or faculty physicians at the participating clinics. In order to be eligible for the study, patients must: (1) self-identify as Black or African American; (2) be at least 21 years old; (3) have a diagnosis of T2DM; and (4) be able to comprehend all documents in English, written at a 6th grade reading level. A Monte Carlo Simulation with 1000 simulated datasets revealed that we can achieve adequate power (.80) to detect a small to moderate effect of physician implicit racial bias on physician communication behaviors (with 8 physician factors and 11 patient factors included in the model) with a total of 15 physicians and 150 patients. An additional simulation showed a total of 15 residents, 15 attending physicians, and 300 patients will further enable testing for a moderating effect of physician status (resident vs. attending) on the association between physician implicit racial bias and communication behaviors.

Procedure

Physicians who meet the eligibility criterion and agree to participate will provide written consent and complete a one-time survey either on a laptop or desktop computer prior to meeting with participating patients. The physician survey is designed to assess basic demographic and professional information, prior training and experiences, and implicit and explicit racial bias.

Eligible patients will complete a total of three surveys: the baseline, post-interaction, and 6-month follow-up. First, the patients will complete the baseline survey over the phone

immediately after they provide verbal consent and HIPAA authorization, and before the scheduled appointment with their participating physician. The patient baseline survey is designed to assess potential covariates such as basic demographic information, perceived discrimination, general satisfaction, trust, and adherence.

On the day of the scheduled appointment, the patients will first be asked to sign a consent form and HIPAA authorization. Then, the patient and the physician will participate in a previously scheduled routine or follow-up office visit interaction while being video-recorded. The exam room will be equipped with two cameras: one focusing on the physician, and the other focusing on the patient. Immediately after the video-recorded medical interaction, the patient will complete the post-interaction survey on a laptop computer. The post-interaction survey is designed to assess patient immediate clinical outcomes—satisfaction with the care they have just received and trust in the physician they have just seen.

Patients will also complete a follow-up phone survey six months after the video-recorded medical interactions. The follow-up survey is designed to assess patient long-term clinical outcomes (i.e., medical adherence, self-management, healthcare utilization). The long-term outcomes also will be assessed with medical chart reviews. Specifically, we will code: (1) the number of healthcare visits within 12 months of the video-recorded medical interaction, and (2) history of diabetes complications (e.g., retinopathy, neuropathy, kidney disease, cardiovascular disease, amputation) and laboratory values (e.g., BMI, blood pressure, HbA1c, cholesterol, etc.). The medical chart reviews will be conducted 12 months after the video-recorded medical interactions in order to ensure that each patient had at least one required follow-up visit as periodic clinic visits are part of recommended T2DM treatment regimens. The American Diabetes Association treatment guidelines state that patients with T2DM should have their

hemoglobin A1c (a measure of glycemic control over the past 30-90 days) checked by a physician (a) every 3 months if glycemic control goals are not being met or if they have diabetes complications, or (b) every 6 months of their control is adequate and they do not have diabetes complications.[45]

Video elicitation interviews

Participants

Upon completion of the post-interaction survey, a subset of the patients will be recruited to participate in the subsequent video elicitation interviews. For the patients to be eligible for the video elicitation interviews, they have to: (1) have interacted with a physician with either one of the five highest or the five lowest IAT scores; and (2) be able to commit to a 3-hour interview within a few weeks of their video-recorded medical interactions. The first criterion ensures securing patient narratives for both groups of physicians, those with high and those with low levels of implicit racial bias. Within these constraints, we will sample a roughly equal number of men and women. Based on prior video elicitation work on "tacit clues" (subtle communication that people do not notice during interactions but impact people's judgments) in primary care,[46; 47] we expect to reach data saturation with $n = 40$. However, we will terminate data collection once we reach data saturation, the point when no substantively new information is being found.

Procedure

Video elicitation interviewing is a qualitative technique that has patients: (1) recall the thoughts and emotions they experienced during the interactions; (2) re-experience the thoughts and emotions or relive the interactions; and (3) reflect on their thoughts, emotions, and actions or those of their physicians.[46; 48] This technique is particularly suitable to the proposed research for two reasons. First, we cannot ask patients about their reactions to their physician communication

behaviors during the actual medical interactions. Second, research provides strong evidence that people's *recall* of their emotions is often inaccurate.[49-51]

Before each video elicitation interview, the research team (NH, JEL, MF, and a trained female Black interviewer) will meet and create a set of interview questions that is personally-tailored for each patient by going through five steps. In Step 1, we will watch the entire video-recorded medical interaction. Each research member will note: (1) moments she/he got the impression that the patient was either negatively or positively reacting to the physician, and (2) physician communication behaviors that she/he perceived to be either negative or positive even if the patient reaction to the behaviors was neutral. In Step 2, we will share notes and discuss each point raised by the research members by replaying the video-recorded interaction. In Step 3, we will create a set of interview questions for the patient based on the discussion in Step 2. In Step 4, the interviewer will simulate the interview with the questions. During the simulation, the other members will jot down any concerns. In Step 5, we will share noted concerns and modify the question set as necessary. We will repeat Steps 4 and 5 until we have no more concerns with the question set. A key purpose is to identify points in the video as possible feeling-provocative events where the interviewer will stop the video (if the patient does not her/himself), and discuss whether the event elicited any negative or positive feelings in the patient.

Each video elicitation interview will consist of three phases. In Phase 1, the patient will be connected to equipment measuring physiological parameters and rest for 5 minutes to stabilize baseline physiological activity. Specifically, we will use electrodermal activity (EDA) to assess arousal of the sympathetic nervous system. We will also use a facial expression analysis program to determine whether the arousal recorded with EDA is associated with positive or negative facial expression. In Phase 2, the patient will watch her/his entire video-recorded

medical interaction without any interruption. The patient will be instructed to pay attention to physician communication behaviors that cause her/him to feel negatively or feel positively. While the patient is watching her/his video-recorded interaction, the research assistant will monitor the patient's physiological activity, identify any emotional reactivity, and record the nature of physiological reactivity and when the activity occurred. In Phase 3, the patient will re-watch the entire video-recorded interactions and be instructed to stop the video to elaborate on thoughts and feelings whenever she/he observes physician communication behaviors that are negative and behaviors that are positive. In this phase, the interviewer will also stop the video at predetermined points. The stopping frequency and the timing of stopping of the video by the interviewer is determined by both (1) the set of interview questions about possibly feeling evocative as developed by the research team prior to the interview, and (2) changes in the patient's physiological activity recorded by the research assistant when the patient watched the encounter in Phase 2. At each predetermined point, the patient will be asked to report how a physician communication behavior that she/he has just observed makes her/him feel and if possible, why it makes her/him feel that way. The interviews in Phase 3 will be video recorded and audio recorded for later analysis.

Measures

The physician survey

Demographic information. We will assess physician age, ethnicity, race, and gender.

Professional information. The professional information includes: position (2nd year resident, 3rd year resident, faculty), medical degree (M.D., D. O., Other), years in practice (faculty only), years at the current clinic (faculty only`), and location of medical school training (in the U.S., outside the U.S.).

Prior training in cultural competency. The physicians will be asked to select when they last participated in cultural competency training (within the last 6 months, 1 year, 2-3 years, 4-5 years, more than 5 years ago, never). They will also be asked to rate their own level of cultural competency (poor, adequate, good, very good, outstanding).

Prior training in communication skills. The physicians will be asked to report: (1) when they last participated in communication skills training (within the last 6 months, 1 year, 2-3 years, 4-5 years, more than 5 years ago, never); and (2) how they rate their communication skills.

Prior experiences with the target patients. The physicians will be asked to: (1) report how often they treat patients with T2DM (not much, little, somewhat, much, a great deal); (2) report how often they treat Black patients; and (3) rate their performance treating patients with T2DM (poor, adequate, good, very good, outstanding).

Implicit racial bias. Implicit racial bias will be assessed with the *Race Implicit Association Test* (IAT)[52] and *Affect Misattribution Procedure* (AMP).[53] In the *IAT*, the physicians respond to items that are to be classified into four categories: two representing racial groups (White vs. Black) and two representing valence (negative vs. positive), which are presented in pairs (Appendix A). The premise is that individuals respond more quickly when the social group and valence mapped onto the same response are strongly associated than when they are weakly associated. The well-validated[54-58] IAT will be scored by computing a *D* score that ranges from -2.0 to 2.0 (the average αs = .78).[54] In the *AMP*, the physicians rate unfamiliar images (e.g., foreign alphabets) that come up on a computer screen immediately after the priming images (White vs. Black faces; Appendix B). The premise is that unfamiliar images are rated more negatively or positively following the prime to which the individuals feel negatively

or positively, respectively. The AMP will be scored by subtracting the proportion of positive responses on trials with Black faces from that on trials with White faces (αs > .85).[53]

Explicit racial bias. Explicit racial bias will be assessed with the *Symbolic Racism 2000 Scale* (*SR2K*).[59]. The SR2K is a well-validated 8-item scale that is designed to measure people's belief systems based on the ideas that racial discrimination is no longer an issue in the U.S. and that Black Americans' demands for fairness are unjustified.[60-63]

The patient baseline survey

*Sociodemographic information***.** Patient age, gender, marital status, education, income, BMI (computed with weight and height), and health insurance will be assessed.

Perceived racial discrimination. Perceived discrimination will be assessed with the *Brief Perceived Ethnic Discrimination Questionnaire-Community Version* (α = .87) designed to assess both daily and lifetime experience of multiple forms of discrimination (e.g., exclusion, stigmatization, threat) in multiple domains (e.g., work, public places).[64] We will also use a measure that is designed to assess the perceptions of racial discrimination at both personal and group level (α = .77).[65]

Perceived competence in T2DM management. Patient competency in T2DM management will be assessed with the 4-item *Perceived Competence Scale (PCS).* The PCS has good internal consistency (α > .80) and has been found to predict diabetes self-care.[66; 67]

General trust in physicians. Baseline trust in physicians will be assessed with the 10-item *Wake Forest Physician Trust Scale* which has been found to have better internal consistency (α = .93, test-retest reliability = .75), validity, discriminability, and scale distribution as compared to other trust scales.[68; 69]

General satisfaction. Baseline patient satisfaction will be assessed with the *Patient Satisfaction Questionnaire Form III* (PSQ-III).[70] The PSQ-III is highly reliable and captures patient satisfaction with seven specific domains of medical care nested within an overall general domain.[71] We focus on three subscales: General (6 items, $\alpha = .88$), Interpersonal Aspects (7 items, $\alpha = .82$), and Communication (5 items, $\alpha = .82$).[70]

General T2DM adherence. The modified version of the *Summary of Diabetes Self-Care Activities Questionnaire* (SDSCA) will be used to assess baseline T2DM adherence in five domains: diet, exercise, self-monitoring of blood glucose, foot care, and medication.[72]

The patient post-interaction survey

Trust in/satisfaction with the physician the patient has just met. The Wake Forest Physician Trust Scale and PSQ-III will be modified to reflect the specific physician each patient saw during study appointments (as opposed to physicians in general).

Prior interaction with the physician the patient has just met. Patients will be asked to indicate whether they have ever seen the physician before (Yes, No, Don't remember). If they answer affirmatively, they will be asked further to report: (1) how frequently they see the physician (not much, little, somewhat, much, a great deal); and (2) how well they think the physician knows them.

The patient 6-month follow-up survey

T2DM adherence in the past 6 month. The same modified version of SDSCA as the patient baseline survey will be used to assess T2DM adherence except that the patients will be instructed to think about the past six months specifically.

Additional interactions with the physician they met. Patients will be asked to indicate whether they have had any additional interaction with the physician they met during the video-

recorded medical interaction in the last six months (Yes, No, Don't remember). If they answer affirmatively, they will be asked to indicate further whether the additional medical interactions were related to their T2DM management (Yes, No, Don't remember).

Assessment of emotions during the video elicitation interviews

Emotional reactivity. EDA is one of the most commonly used tools for assessing emotional arousal.[73-79] It monitors sweat gland activity of the skin, an indicator of increased activity of the sympathetic nervous system.[80-83] EDA does not differentiate different types of positive and negative emotions. To assess specific emotions associated with arousal recorded with EDA, we will use a non-intrusive facial expression analysis method (iMotions Affectiva).

Analysis of data from the video elicitation interviews

Objective 1: To explore what physician communication behaviors during medical interactions are perceived as negative and what behaviors are perceived as positive by Black patients and why

The audio-recorded interviews will be professionally transcribed verbatim using a transcription protocol and analyzed in four steps. Step 1 involves unitization of thought units (i.e., identifying appropriate blocks of text that represent discrete units of meaning rather than predefined blocks of text such as sentences and paragraphs) using de-identified transcripts. Two research assistants will be trained to unitize a sample of 10 transcript pages until they achieve consensus. After the training period, the research assistants will complete the unitizing of the remaining transcripts. They will meet with the PI after coding every five transcripts in order to discuss any discrepancy and achieve consensus. Unitization of thought units allows logical partitioning of the transcripts into discrete categories.[84-86] Step 2 involves development of a *transcript codebook*. The research team (NH, JEL, MF) will examine about 40% of the

transcripts to create a comprehensive list of themes. The data will be analyzed inductively: transcripts will be read and themes identified, refined, collapsed, and organized into higher-level categories. The transcript codebook provides coding procedures, rules for coding, and descriptions and examples of the codes. Step 3 involves the coding of all transcripts. Two research assistants will be trained on coding a few transcripts until they achieve consensus. The transcript codebook will be fine-tuned during this training period. After the training period, the research assistants will analyze the remaining transcripts. They will meet with the PI every third transcript to avoid coding drift by comparing results, discussing any discrepancies, and reaching consensus. Step 4 involves the identification of potentially evocative negative and positive physician communication behaviors that are endorsed by multiple patients. Identification of a clear pattern will be a major criteria for saturation. The research team members will first independently identify evocative physician communication behaviors by reviewing the data. Then, they will discuss and select the final set of physician communication behaviors that are going to be further coded using the video-recorded medical interactions.

Analysis of data from the video-recorded medical interactions

The research team members will first discuss an appropriate measurement unit (e.g., amount, degree, frequency, duration) and coding procedure for each discrete physician communication behavior identified by analyzing the interview transcripts (see above) and then creating a *video codebook*. The video codebook will provide coding rules, describe procedures for each physician communication behavior that need to be identified, provide examples for each, describe parameters for exclusion, and note related-code cross-referencing. For each discrete behavior, three research assistants will be first trained in the coding procedure using a set of 10 video-recorded medical interactions that will be randomly chosen until they reach consensus.

The video codebook will be refined iteratively as necessary during this training period. After the training period, two of the three research assistants will continue analyzing the rest of the approximately 300 video-recorded medical interactions independently. Every 10 will be double-coded to prevent coding drift. Upon completion of the coding, the PI will identify any substantive discrepancies in two coders' ratings, that will be resolved by the third research assistant and if necessary the PI. Finally, values provided by the two coders (or the two closest values if there was a third coder) are averaged to compute a single score representing the quantity (e.g., amount, degree, frequency, duration) of a particular discrete behavior. Some behaviors are not discrete and cannot be easily identified, such as speech characteristics (e.g., pitch, tone, amplitude) and facial expression of emotion (e.g., neutral, surprise, happy). These behaviors will be quantified with computer software widely-used in academic research, rather than by using coders (e.g., Praat to quantify speech characteristics, iMotions Affectiva to quantify facial expression of emotion).

Statistical analysis

Objective 2: To identify which physician communication behaviors identified in Objective 1 are associated with physician implicit racial bias

First, basic descriptive statistics will be conducted to identify any non-normal distributions of continuous variables that may require data transformation. Next, the main analyses will be carried out in three steps in order to identify physician communication behaviors that are associated with physician implicit racial bias. In Step 1, we will identify covariates that may impact physician communication behaviors by computing bivariate correlations among all quantified physician communication behaviors and factors that were assessed in the baseline surveys (e.g., physician and patient demographics, physician professional characteristics, patient

perceived discrimination, etc.). In Step 2, we will compute partial correlations between physician implicit racial bias and all quantified physician communication behaviors while controlling for covariates that were associated significantly with any of the physician behaviors. In Step 3, in order to correct for biased estimates due to nonindependence in data (i.e., patients nested within physicians), we will conduct regression analysis using a Generalized Estimating Equations (GEE) framework for each of the physician communication behaviors that were found to be associated significantly with physician implicit racial bias in Step 2. The regression modeling will also include the same set of covariates as in Step 2. We will correct family-wise error rate due to conducting multiple regression tests with the Bonferroni correction procedure.[87; 88] The physician communication behaviors that remain statistically significant in Step 3 are considered as behaviors that reflect physician implicit racial bias.

Objective 3: To examine how physician implicit racial bias impacts Black patient satisfaction, trust, adherence, and healthcare utilization through physician communication behaviors

To identify physician communication behaviors that are associated with both physician implicit racial bias and Black patient clinical outcomes (i.e., satisfaction, trust, adherence, and healthcare utilization), the analysis will be conducted in three steps similar to Objective 2. The physician communication behaviors that remain statistically significant after all steps will be considered as important behaviors that link physician implicit racial bias and patient clinical outcomes.

Objective 4: To develop the MIBPCS

The MIBPCS will be designed to assess physician communication behaviors that negatively or positively impact patient clinical outcomes and will not be constrained to physician communication behaviors associated with physician implicit racial bias. To create the MIBPCS,

we first conduct partial correlations among all quantified physician communication behaviors and patient clinical outcomes while controlling for potential covariates that might impact patient clinical outcomes. Then, the significant correlations will be further tested with regression analysis using GEE. Physician communication behaviors that remain significant in the regression analysis will be compiled into the MIBPCS, which also will include detailed coding instructions as to how to quantify each behavior (i.e., the instructions used by the research assistants who coded the behaviors using the video-recorded medical interactions).

Patient and Public Involvement

Patients and public were not involved in the development of the research question or the design of this study.

DISCUSSION

Findings from this research will advance knowledge about the impact of physician implicit racial bias on Black patient outcomes by using novel approaches and methods. Understanding how physician implicit racial bias is manifested behaviorally during medical interactions, and how Black patients react to these behaviors, is critical to designing effective communication skills training for physicians and interventions to facilitate improved outcomes among Black patients. Additionally, the MIBPCS that will be developed in this study will be superior to prior patient-physician communication coding systems in that it will: (1) focus on physician communication behaviors during medical interactions involving Black patients that predict patient outcomes; and (2) place an unprecedented importance on the patient point of view. The MIBPCS could play an invaluable role in future intervention research and ultimately in medical training as it will enable researchers to pinpoint negative and positive physician

communication behaviors and provide them personally-tailored communication skills training that targets those behaviors.

ETHICS AND DISSEMINATION

Research ethics approval for the present study protocol was obtained from the Virginia Commonwealth University IRB. Certificate of Confidentiality for both participating physicians and patients was also obtained from the National Institute of Health. Signed informed consent will be obtained from all participating physicians and patients, and signed HIPAA authorization will be obtained from all participating patients prior to any data collection. Study results will be disseminated through publications in peer-reviewed journals and presentations at national and international professional conferences. A novel culturally tailored MIBPCS from this project will be made publicly available.

FIGURE LEGENDS

Figure 1. A conceptual model summarizing findings from the previous research on physician implicit racial bias (1A), and our conceptual mediation model of the role of physician implicit racial bias in Black patient clinical outcomes (1B).

Figure 2. An overview of an exploratory sequential mixed methods research design in the proposed research

Figure 3. Chronological order of data collection

AUTHORS' CONTRIBUIONS

Nao Hagiwara is the PI of the study and wrote the first draft of the study protocol. She also edited every draft.

Jennifer Elston Lafata is the Co-I of the study and edited the study protocol with the PI.

Brian Mezuk is the Co-I of the study edited the study protocol with the PI.

Scott Vrana is the Co-I of the study edited the study protocol with the PI.

Michael Fetters is the Co-I of the study. As a senior mentor on the team, he edited the study protocol with the PI.

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FUNDING STATEMENT

This work is funded by the National Institute of Health/the National Institute of Diabetes and Digestive and Kidney Diseases (R01 DK112009).

COMPETING INTERESTS STATEMENT

None to declare

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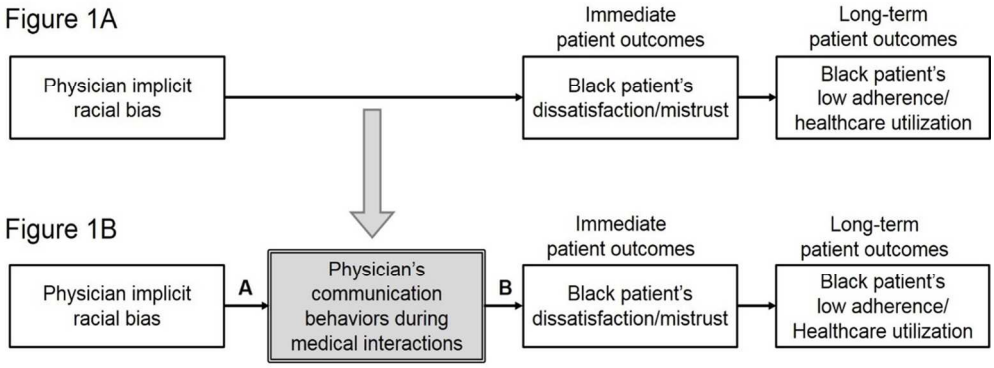


Figure 1. A conceptual model summarizing findings from the previous research on physician implicit racial bias (1A), and our conceptual mediation model of the role of physician implicit racial bias in Black patient clinical outcomes (1B).

444x166mm (300 x 300 DPI)

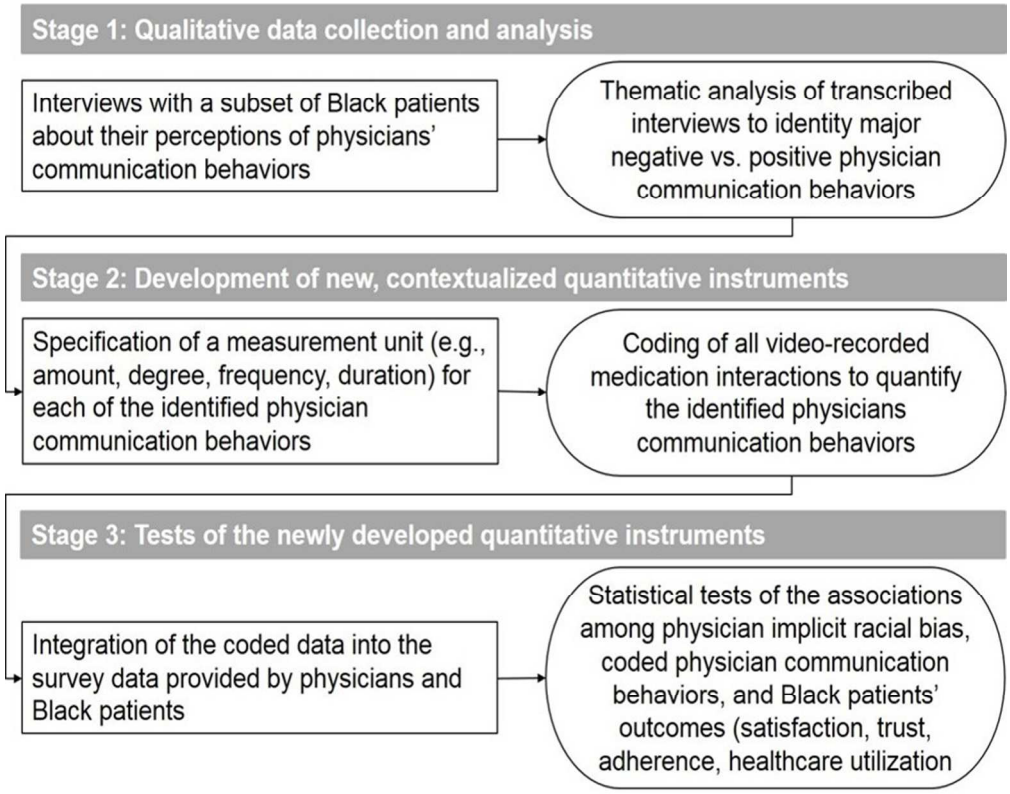


Figure 2. An overview of an exploratory sequential mixed methods research design in the proposed research

348x276mm (300 x 300 DPI)

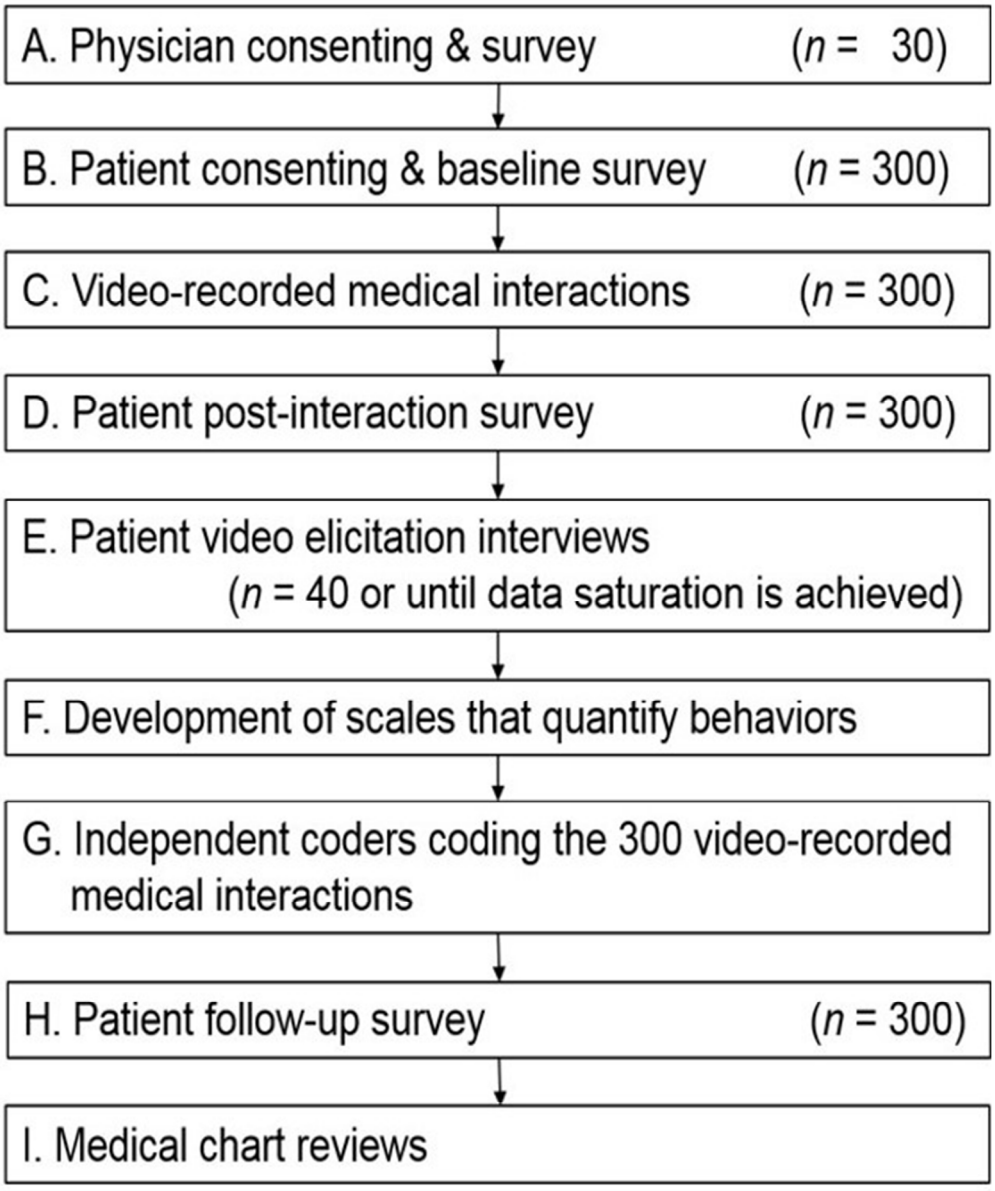


Figure 3. Chronological order of data collection

315x381mm (300 x 300 DPI)

APPENDIX A

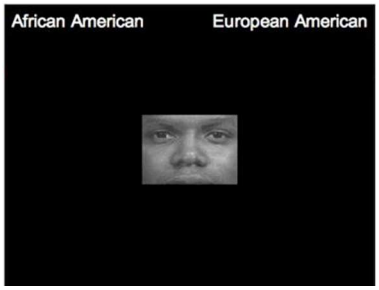
Implicit Association Task (IAT)

Stimuli used in two categories representing racial groups (African American vs. European American):

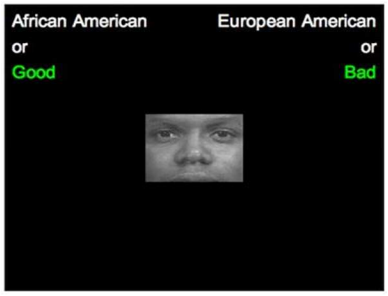
Stimuli used in two categories representing valence (positive vs. negative):
Positive words: *Wonderful, Best, Superb, Excellent*
Negative words: *Terrible, Horrible, Awful, Worst*

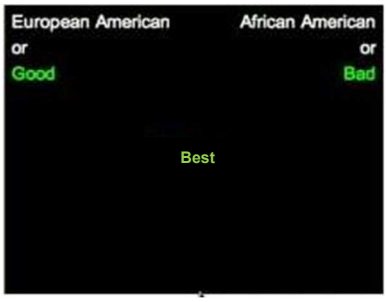
Example trials:

Practice trials



Test trials





For test trials, participants classify items that appear on the center of the computer screen into four categories which are presented in pairs. The premise is that participants respond more quickly when the racial group and valence mapped onto the same response are strongly associated than when they are weakly associated.

APPENDIX B

Affect Misattribution Procedure (AMP)

Example priming images representing racial groups (white vs. black):

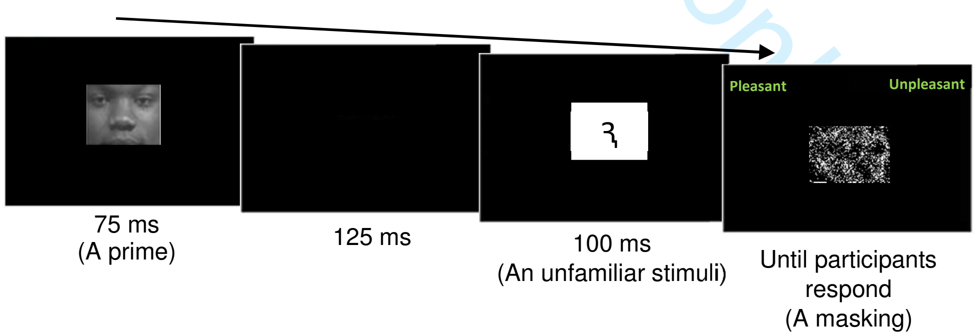
Note. We will use a total of 12 White faces and 12 Black faces.

Example images representing emotionally neutral unfamiliar stimuli:

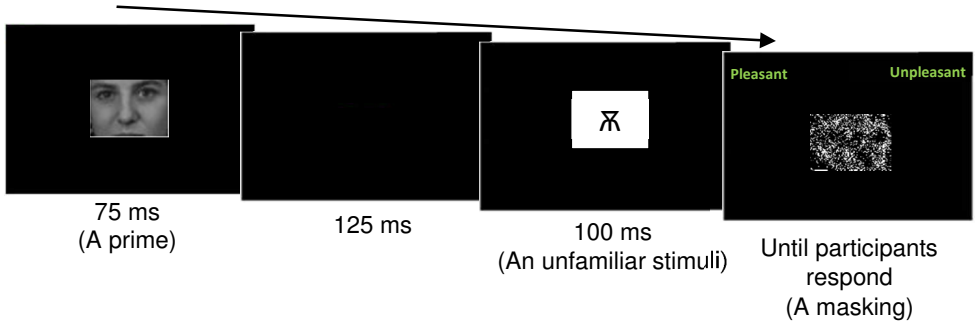
Note. We will use a total of 36 different foreign alphabets.

Sequence of trials:

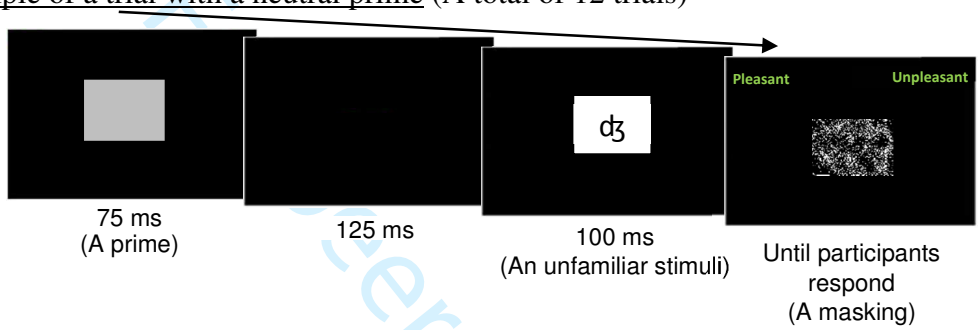
An example of a trial with a Back face prime (A total of 12 trials)



An example of a trial with a White face prime (A total of 12 trials)



An example of a trial with a neutral prime (A total of 12 trials)



Participants are instructed to indicate whether foreign alphabets that come up on a computer screen immediately after the priming images are visually pleasant or unpleasant. The premise is that unfamiliar images are rated more positively or negatively following the prime to which the participants feel positively or negatively, respectively.

BMJ Open

A STUDY PROTOCOL FOR INVESTIGATING PHYSICIAN COMMUNICATION BEHAVIORS THAT LINK PHYSICIAN IMPLICIT RACIAL BIAS AND PATIENT OUTCOMES IN BLACK PATIENTS WITH TYPE 2 DIABETES USING AN EXPLORATORY SEQUENTIAL MIXED METHODS DESIGN

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-022623.R1
Article Type:	Protocol
Date Submitted by the Author:	12-Jun-2018
Complete List of Authors:	Hagiwara, Nao; Virginia Commonwealth University, Psychology Mezuk, B.; Department of Epidemiology, University of Michigan, Epidemiology Elston Lafata, Jennifer; University of North Carolina at Chapel Hill Eshelman School of Pharmacy, Pharmaceutical Outcomes and Policy Vrana, Scott; Virginia Commonwealth University, Psychology Fetters, MD; University of Michigan, Family Medicine
Primary Subject Heading:	Communication
Secondary Subject Heading:	Diabetes and endocrinology, Qualitative research, Public health
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Physician implicit racial bias, Patient-physician communication, Black/African American patients, PRIMARY CARE, PUBLIC HEALTH

A STUDY PROTOCOL FOR INVESTIGATING PHYSICIAN COMMUNICATION BEHAVIORS THAT LINK PHYSICIAN IMPLICIT RACIAL BIAS AND PATIENT OUTCOMES IN BLACK PATIENTS WITH TYPE 2 DIABETES USING AN EXPLORATORY SEQUENTIAL MIXED METHODS DESIGN

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Disclaimers: The views expressed in the submitted article are the authors' own and not an official position of the institutions or the funder.

Word count: 4,957 words

Number of figures and tables: 3 figures, 1 table

ABSTRACT

Introduction: Patient-physician racial discordance is associated with Black patient reports of dissatisfaction and mistrust, which in turn are associated with poor adherence to treatment recommendations and underutilization of healthcare. Research further has shown patient dissatisfaction and mistrust are magnified particularly when physicians hold high levels of implicit racial bias. This suggests physician implicit racial bias manifests in their communication behaviors during medical interactions. The overall goal of this research is to identify physician communication behaviors that link physician implicit racial bias and Black patient immediate (patient-reported satisfaction and trust) and long-term outcomes (e.g, medication adherence, self-management, and healthcare utilization) as well as clinical indicators of diabetes control (e.g., blood pressure, HbA1c, and history of diabetes complication).

Methods and analysis: Using an exploratory sequential mixed methods research design, we will collect data from approximately 30 family medicine physicians and 300 Black patients with Type 2 diabetes mellitus (T2DM). The data sources will include one physician survey, three patient surveys, medical interaction videos, video elicitation interviews, and medical chart reviews. Physician implicit racial bias will be assessed with the physician survey, and patient outcomes will be assessed with the patient surveys and medical chart reviews. In video elicitation interviews, a subset of patients (approximately 20-40) will watch their own interactions while being monitored physiologically to identify evocative physician behaviors. Information from the interview will determine which physician communication behaviors will be coded from medical interactions videos. Coding will be done independently by two trained coders. A series of statistical analyses (zero-order correlations, partial correlations, regressions) will be conducted to identify physician behaviors that are associated significantly with both physician implicit racial bias and patient outcomes.

Ethics and dissemination: Ethics approval was obtained from the Virginia Commonwealth University IRB. Study results will be disseminated through publications in peer-reviewed journals and presentations at conferences. A novel *Medical Interaction involving Black Patients Coding System* (*MIBPCS*) from this project will be made publicly available.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- Use of an exploratory sequential mixed methods research design will incorporate Black patients' perspectives into patient-physician communication research, an approach crucial for advancing understanding of the impact of physician communication behaviors on patient outcomes (i.e., patient perceptions, self-care, and clinical indicators of diabetes control).
- The study combines physiological assessment and in-depth qualitative video elicitation interviews in a unique way for methodological innovation.
- This research will produce a novel, culturally tailored *Medical Interaction involving Black Patients Coding System* (*MIBPCS*) that will be designed to assess physician communication behaviors that can negatively or positively impact patient outcomes.
- One study limitation is that physician implicit racial bias is only one of several factors that determine patient outcomes.
- The generalizability of findings from this research to Black patients with other diseases (e.g., hypertension, asthma, cancer) will need to be tested empirically.

INTRODUCTION

Patient-physician racial discordance is associated strongly with patient reports of dissatisfaction with and mistrust in physicians,[1-7] which in turn are associated with poor patient adherence to treatment recommendations and underutilization of healthcare.[8-10] This poses serious public health concerns because approximately 80-90% of Black patients see physicians from different racial groups.[5-7; 11; 12] Recent research has shown further that patient dissatisfaction and mistrust are magnified particularly when physicians hold high levels of implicit bias toward Black Americans (Figure 1A).[13-16] This negative association between physician implicit racial bias and Black patient reports of satisfaction/trust suggests that physician implicit racial bias impacts their communication behaviors during medical interactions and ultimately contributes to worse long-term outcomes in Black patients (Figure 1B).

Social psychology research provides strong evidence that an individual's implicit bias often is reflected in their nonverbal (e.g., body posture, eye contact, nodding) and paraverbal (e.g., the amount, speed, and pitch of the speech) behaviors, as opposed to verbal behaviors (i.e., the content of the speech), during inter-racial interactions.[17-19] Drawing on this literature, several recent studies have successfully identified specific physician communication behaviors during racially discordant medical interactions that are associated with physician implicit racial bias. Specifically, physicians with higher levels of implicit racial bias had a greater ratio of physician to patient statements in a given medical interaction, reflecting their verbal dominance, as compared to physicians with lower levels of implicit racial bias.[15] Similarly, higher levels of implicit racial bias was associated with a greater ratio of physician to patient talk time.[20] Finally, physicians with higher levels of implicit racial bias were more likely to use first person plural pronouns (e.g., we, us, our) and anxiety-related words (e.g., worried, afraid, nervous).[21] However,

none of the physician communication behaviors identified and tested in the previous studies have been directly associated with immediate patient outcomes.

We posit that one major reason why previous studies have failed to identify physician communication behaviors linking physician implicit racial bias and patient outcomes is due to a lack of Black patients' perspectives in the assessments. Specifically, the identification of physician communication behaviors associated with physician implicit racial bias was based on the researchers' perspectives on or assumptions about what positive patient-physician communication *should* look like. Although this theory-driven approach is one strength of the previous studies, it is not sufficient for two reasons. First, research has consistently shown that immediate patient outcomes are better predicted by *patient reports* of patient-physician communication than *observer-rated* patient-physician communication.[22-25] This suggests the conceptualization of positive patient-physician communication is likely to be different between patients and researchers. Second, social psychology demonstrates that the same behaviors can be viewed in different ways in intra- vs. inter-racial interactions.[26] This suggests how Black and White patients conceptualize positive patient-physician communication may be different.

Hence, little is known about how physician implicit racial bias manifests behaviorally during medical interactions (Path A in Figure 1B) and how Black patients react to such behaviors (Path B in Figure 1B). To illuminate these processes, an innovative methodological approach that integrates Black patients' perspectives in patient-physician communication research is crucial. The overall goal of this research is to identify physician communication behaviors during medical interactions that are associated with both physician implicit racial bias and Black patient immediate (satisfaction, trust) and long-term outcomes (mediation adherence, self-management, healthcare utilization). This investigation uses an exploratory sequential mixed methods research

design, a design characterized by initial qualitative exploration and subsequent quantitative assessment of a phenomenon of interest.

To address this study goal, we will focus on Black patients with Type 2 diabetes mellitus (T2DM) for both theoretical and methodological reasons. The focus on T2DM is *theoretically* important because evidence shows an overwhelmingly low rate of diabetes medication adherence in Black patients.[27-36] Physician communication behaviors stemming from implicit racial bias are likely to explain at least partially why medication adherence is particularly low in Black patients with T2DM. This assertion is based on evidence showing that patient reports of patient-physician communication quality are associated with diabetes medication adherence in general.[37-43] Focusing on Black patients with T2DM is also *methodologically* important as it increases the homogeneity of patient encounters and thus provides greater precision in estimating the role of physician implicit racial bias in patient outcomes, including immediate and long-term outcomes as well as clinical indicators of diabetes.

OBJECTIVES

To achieve the study goal, we will address four objectives:

Objective 1: To explore what physician communication behaviors during medical interactions are perceived as negative and what behaviors are perceived as positive by Black patients and why.

Objective 2: To identify which physician communication behaviors identified in Objective 1 are associated with physician implicit racial bias.

Objective 3: To examine how physician implicit racial bias is associated with Black patient satisfaction, trust, adherence, and healthcare utilization through physician communication behaviors.

Objective 4: To develop the *Medical Interaction involving Black Patients Coding System* (*MIBPCS*), a novel culturally tailored coding system that will identify physician communication behaviors that are perceived as negative and behaviors that are perceived as positive by Black patients.

METHODS AND ANALYSIS

The overview of the study

We will use an exploratory sequential mixed methods research design, initial qualitative data collection and analysis informing subsequent quantitative data collection and analysis, that integrates the strengths of inductive and deductive reasoning. This will allow us to explore Black patient narratives on physician communication behaviors and to identify theoretically meaningful behaviors (Figure 2).[44] In Stage 1, to address Objective 1, we explore what physician communication behaviors during medical interactions are perceived as negative and what behaviors are perceived as positive by Black patients and why. In Stage 2, we will develop and refine a novel instrument designed to quantify negative and positive physician communication behaviors. In Stage 3, we will address Objectives 2-4 by conducting a series of statistical analyses. The summary of chronological study flow and the research design are presented in Figure 3 and Table 1, respectively.

Table 1. Summary of research design: Data sources, analyses, and goals of each specific aim

Objectives	Data sources	Analyses	Goals
1	• Video elicitation interviews (Step E)	Qualitative analysis of transcribed interviews for themes regarding negative and positive physician communication behaviors	Identify physician communication behaviors perceived as negative and behaviors perceived as positive by Black patients
2	• Physician survey (Step A) • Video-recorded medical interactions (Step C) • Scales quantifying behaviors (Step F) • Coding of the video-recorded medical interactions (Step G)	Quantitative analysis of: (1) physician communication behaviors (e.g., amount, degree, frequency, length) in all video-recorded medical interactions; and (2) the association between physician implicit racial bias and communication behaviors	Identify coded physician communication behaviors that are statistically significantly associated with physician implicit racial bias
3 & 4	• Physician survey (Step A) • Patient baseline survey (Step B) • Patient post-interaction survey (Step D) • Coding of the video-recorded medical interactions (Step G) • Patient follow-up survey (Step H) • Medical chart reviews (Step I)	Quantitative analysis of associations among physician implicit racial bias, physician communication behaviors during the medical interactions, patient reports of satisfaction/trust, patient reports of subsequent T2DM medication adherence, and healthcare utilization	Identify physician communication behaviors that mediate the association between physician implicit racial bias and Black patient outcomes Develop the MIBPCS

Surveys, video-recorded medical interactions, and medical chart reviews

Participants

We will recruit approximately 30 physicians and 300 patients from multiple Family Medicine clinics affiliated with Virginia Commonwealth University that serve patients from diverse racial/ethnic backgrounds. The only eligibility criterion for physicians is that they have to be either 2nd-3rd year medical residents or faculty physicians at the participating clinics. The number of Black physicians will not be sufficient to conduct conclusive inferential statistics and compare racially concordant vs. discordant medical interactions. However, we will not exclude Black physicians from the present study. Rather the data from Black physicians will be used as hypothesis generating for future work to inform specifically how to interpret physician communication behaviors during racially concordant vs. discordant medical interactions.

In order to be eligible for the study, patients must: (1) self-identify as Black or African American; (2) be at least 21 years old; (3) have a diagnosis of T2DM; and (4) be able to comprehend all documents in English, written at a 6th grade reading level. A Monte Carlo Simulation with 1000 simulated datasets revealed that we can achieve adequate power (.80) to detect a small to moderate effect of physician implicit racial bias on physician communication behaviors (with 8 physician factors and 11 patient factors included in the model) with a total of 15 physicians and 150 patients. An additional simulation showed a total of 15 residents, 15 attending physicians, and 300 patients will further enable testing for a moderating effect of physician status (resident vs. attending) on the association between physician implicit racial bias and communication behaviors. Research has shown that even a small sample size at the upper-level (i.e., physicians in the context of the present research) has been found to yield accurate estimates of the regression coefficients, the variance components, and standard errors when the

lower-level sample size was greater than 50. Only when the lower-level sample size was 50 or less, the small upper-level sample size resulted in biased estimates of the standard errors.[45] Thus, 30 physicians with 300 patients are enough to obtain unbiased and accurate estimates. However, we will take a more conservative approach and use generalized estimating equations (GEE) framework to correct for potential biased estimates of the standard errors, which is a common statistical approach in the current patient-physician communication literature.[46-50]

Procedure

Physicians who meet the eligibility criterion and agree to participate will provide written consent and complete a one-time survey either on a laptop or desktop computer prior to meeting with participating patients. The physician survey is designed to assess implicit and explicit racial bias as well as covariates that are likely to be associated with patient-physician communication and/or patient outcomes, including basic demographic information,[51-54] professional information, and prior training and experiences.[55-59]

Eligible patients will complete a total of three surveys: the baseline, post-interaction, and 6-month follow-up. First, the patients will complete the baseline survey over the phone immediately after they provide verbal consent and HIPAA authorization, and before the scheduled appointment with their participating physician. The patient baseline survey is designed to assess covariates that are likely to predict patient-physician communication and/or patient outcomes, including basic demographic information,[60-64] general trust and satisfaction,[38,65-67] and perceived discrimination.[20,68-71]

On the day of the scheduled appointment, the patients will first be asked to sign a consent form and HIPAA authorization. Then, the patient and the physician will participate in a previously scheduled routine or follow-up office visit interaction while being video-recorded.

The exam room will be equipped with two cameras: one focusing on the physician, and the other focusing on the patient. Immediately after the video-recorded medical interaction, the patient will complete the post-interaction survey on a laptop computer. The post-interaction survey is designed to assess patient immediate outcomes—satisfaction with the care they have just received and trust in the physician they have just seen.

Patients will also complete a follow-up phone survey approximately six months after the video-recorded medical interactions. The follow-up survey is designed to assess patient long-term outcomes (i.e., medical adherence, self-management, healthcare utilization). The longer-term outcomes also will be assessed with medical chart reviews. Specifically, we will code: (1) the number of healthcare visits within 12 months of the video-recorded medical interaction, and (2) history of diabetes complications (e.g., retinopathy, neuropathy, kidney disease, cardiovascular disease, amputation) and laboratory values (e.g., BMI, blood pressure, HbA1c, cholesterol, etc.). The medical chart reviews will be conducted 12 months after the video-recorded medical interactions in order to ensure that each patient had at least one required follow-up visit as periodic clinic visits are part of recommended T2DM treatment regimens. The American Diabetes Association treatment guidelines state that patients with T2DM should have their hemoglobin A1c (a measure of glycemic control over the past 30-90 days) checked by a physician (a) every 3 months if glycemic control goals are not being met or if they have diabetes complications, or (b) every 6 months of their control is adequate and they do not have diabetes complications.[72]

Video elicitation interviews

Participants

Upon completion of the post-interaction survey, a subset of the patients will be recruited to participate in the subsequent video elicitation interviews. For the patients to be eligible for this subset of individuals participating in video elicitation interviews, they must: (1) have interacted with a physician with either one of the five highest or the five lowest IAT scores; and (2) be able to commit to a 3-hour interview within a few weeks of their video-recorded medical interactions. The first criterion ensures securing patient narratives for both groups of physicians, those with high and those with low levels of implicit racial bias. Within these constraints, we will sample a roughly equal number of men and women. Based on prior video elicitation work on "tacit clues" (subtle communication that people do not notice during interactions but impact people's judgments) in primary care,[73; 74] we expect to reach data saturation with $n = 40$. However, we will terminate data collection once we reach data saturation, the point when no substantively new information is being found.

Procedure

Video elicitation interviewing is a qualitative technique that has patients: (1) recall the thoughts and emotions they experienced during the interactions; (2) re-experience the thoughts and emotions or relive the interactions; and (3) reflect on their thoughts, emotions, and actions or those of their physicians.[73; 75] This technique is particularly suitable to the proposed research for two reasons. First, we cannot ask patients about their reactions to their physician communication behaviors during the actual medical interactions. Second, research provides strong evidence that people's *recall* of their emotions is often inaccurate.[76-78]

Before each video elicitation interview, the research team (NH, JEL, MF, and a trained female Black interviewer) will meet and create a set of interview questions that is personally-tailored for each patient by going through five steps. In Step 1, we will watch the entire video-

recorded medical interaction. Each research member will note: (1) moments she/he got the impression that the patient was either negatively or positively reacting to the physician, and (2) physician communication behaviors that she/he perceived to be either negative or positive even if the patient reaction to the behaviors was neutral. In Step 2, we will share notes and discuss each point raised by the research members by replaying the video-recorded interaction. In Step 3, we will create a set of interview questions for the patient based on the discussion in Step 2. In Step 4, the interviewer will simulate the interview with the questions. During the simulation, the other members will jot down any concerns. In Step 5, we will share noted concerns and modify the question set as necessary. We will repeat Steps 4 and 5 until we have no more concerns with the question set. A key purpose is to identify points in the video as possible feeling-provocative events where the interviewer will stop the video (if the patient does not her/himself), and discuss whether the event elicited any negative or positive feelings in the patient.

Each video elicitation interview will consist of three phases. In Phase 1, the patient will be connected to equipment measuring physiological parameters and rest for 5 minutes to stabilize baseline physiological activity. Specifically, we will use electrodermal activity (EDA) to assess arousal of the sympathetic nervous system. We will also use a facial expression analysis program to determine whether the arousal recorded with EDA is associated with positive or negative facial expression. In Phase 2, the patient will watch her/his entire video-recorded medical interaction without any interruption. The patient will be instructed to pay attention to physician communication behaviors that cause her/him to feel negatively or feel positively. While the patient is watching her/his video-recorded interaction, the research assistant will monitor the patient's physiological activity, identify any emotional reactivity, and record the nature of physiological reactivity and when the activity occurred. In Phase 3, the patient will re-

watch the entire video-recorded interactions and be instructed to stop the video to elaborate on thoughts and feelings whenever she/he observes physician communication behaviors that are negative and behaviors that are positive. In this phase, the interviewer will also stop the video at predetermined points. The stopping frequency and the timing of stopping of the video by the interviewer is determined by both (1) the set of interview questions about possibly feeling evocative as developed by the research team prior to the interview, and (2) changes in the patient's physiological activity recorded by the research assistant when the patient watched the encounter in Phase 2. At each predetermined point, the patient will be asked to report how a physician communication behavior that she/he has just observed makes her/him feel and if possible, why it makes her/him feel that way. The interviews in Phase 3 will be video recorded and audio recorded for later analysis.

Measures

The physician survey

Demographic information. We will assess physician age, ethnicity, race, and gender.

Professional information. The professional information includes: position (2nd year resident, 3rd year resident, faculty), medical degree (M.D., D. O., Other), years in practice (faculty only), years at the current clinic (faculty only), and location of medical school training (in the U.S., outside the U.S.).

Prior training in cultural competency. The physicians will be asked to select when they last participated in cultural competency training (within the last 6 months, 1 year, 2-3 years, 4-5 years, more than 5 years ago, never). They will also be asked to rate their own level of cultural competency (poor, adequate, good, very good, outstanding).

Prior training in communication skills. The physicians will be asked to report: (1) when they last participated in communication skills training (within the last 6 months, 1 year, 2-3 years, 4-5 years, more than 5 years ago, never); and (2) how they rate their communication skills.

Prior experiences with the target patients. The physicians will be asked to: (1) report how often they treat patients with T2DM (not much, little, somewhat, much, a great deal); (2) report how often they treat Black patients; and (3) rate their performance treating patients with T2DM (poor, adequate, good, very good, outstanding).

Implicit racial bias. Implicit racial bias will be assessed with the computer-based *Race Implicit Association Test* (IAT)[79] and computer-based *Affect Misattribution Procedure* (AMP).[80] In the *IAT*, the physicians respond to items that are to be classified into four categories: two representing racial groups (White vs. Black) and two representing valence (negative vs. positive), which are presented in pairs (Appendix A). The premise is that individuals respond more quickly when the social group and valence mapped onto the same response are strongly associated than when they are weakly associated. The well-validated[81-85] IAT will be scored by computing a *D* score that ranges from -2.0 to 2.0 (the average αs = .78).[81] In the *AMP*, the physicians rate unfamiliar images (e.g., foreign alphabets) that come up on a computer screen immediately after the priming images (White vs. Black faces; Appendix B). The premise is that unfamiliar images are rated more negatively or positively following the prime to which the individuals feel negatively or positively, respectively. The AMP will be scored by subtracting the proportion of positive responses on trials with Black faces from that on trials with White faces (αs > .85).[80]

Explicit racial bias. Explicit racial bias will be assessed with the *Symbolic Racism 2000 Scale* (*SR2K*).[86] The SR2K is a well-validated 8-item scale that is designed to measure people's belief systems based on the ideas that racial discrimination is no longer an issue in the U.S. and

that Black Americans' demands for fairness are unjustified. An example item includes "*Over the past few years, blacks have gotten more economically than they deserve*" (α = .75).[87-90]

The patient baseline survey

*Sociodemographic information***.** Patient age, gender, marital status, education, income, BMI (computed with weight and height), and health insurance will be assessed.

Perceived racial discrimination. Perceived discrimination will be assessed with the *Brief Perceived Ethnic Discrimination Questionnaire-Community Version* (α = .87) designed to assess both daily and lifetime experience of multiple forms of discrimination (e.g., exclusion, stigmatization, threat) in multiple domains (e.g., work, public places).[91] We will also use a measure that is designed to assess the perceptions of racial discrimination at both personal and group level (α = .77).[92]

Perceived competence in T2DM management. Patient competency in T2DM management will be assessed with the 4-item *Perceived Competence Scale (PCS).* The PCS has good internal consistency (α > .80) and has been found to predict diabetes self-care.[93; 94]

General trust in physicians. Baseline trust in physicians will be assessed with the 10-item *Wake Forest Physician Trust Scale* which has been found to have better internal consistency (α = .93, test-retest reliability = .75), validity, discriminability, and scale distribution as compared to other trust scales.[95;96]

General satisfaction. Baseline patient satisfaction will be assessed with the *Patient Satisfaction Questionnaire Form III* (PSQ-III).[97] The PSQ-III is highly reliable and captures patient satisfaction with seven specific domains of medical care nested within an overall general domain.[98] We focus on three subscales: General (6 items, α = .88), Interpersonal Aspects (7 items, α = .82), and Communication (5 items, α = .82).[97]

General T2DM adherence. The modified version of the *Summary of Diabetes Self-Care Activities Questionnaire* (SDSCA) will be used to assess baseline T2DM adherence in five domains: diet, exercise, self-monitoring of blood glucose, foot care, and medication.[99]

The patient post-interaction survey

Trust in/satisfaction with the physician the patient has just met. The Wake Forest Physician Trust Scale and PSQ-III will be modified to reflect the specific physician each patient saw during study appointments (as opposed to physicians in general).

Prior interaction with the physician the patient has just met. Patients will be asked to indicate whether they have ever seen the physician before (Yes, No, Don't remember). If they answer affirmatively, they will be asked further to report: (1) how frequently they see the physician (not much, little, somewhat, much, a great deal); and (2) how well they think the physician knows them.

The patient 6-month follow-up survey

T2DM adherence in the past 6 month. The same modified version of SDSCA as the patient baseline survey will be used to assess T2DM adherence except that the patients will be instructed to think about the past six months specifically.

Additional interactions with the physician they met. Patients will be asked to indicate whether they have had any additional interaction with the physician they met during the video-recorded medical interaction in the last six months (Yes, No, Don't remember). If they answer affirmatively, they will be asked to indicate further whether the additional medical interactions were related to their T2DM management (Yes, No, Don't remember).

Assessment of emotions during the video elicitation interviews

Emotional reactivity. EDA is one of the most commonly used tools for assessing emotional arousal.[100-106] It monitors sweat gland activity of the skin, an indicator of increased activity of the sympathetic nervous system.[107-110] EDA does not differentiate different types of positive and negative emotions. To assess specific emotions associated with arousal recorded with EDA, we will use a non-intrusive facial expression analysis method (iMotions Affectiva).

Analysis of data from the video elicitation interviews

Objective 1: To explore what physician communication behaviors during medical interactions are perceived as negative and what behaviors are perceived as positive by Black patients and why

The audio-recorded interviews will be professionally transcribed verbatim using a transcription protocol and analyzed in four steps. Step 1 involves unitization of thought units (i.e., identifying appropriate blocks of text that represent discrete units of meaning rather than predefined blocks of text such as sentences and paragraphs) using de-identified transcripts. Two research assistants will be trained to unitize a sample of 10 transcript pages until they achieve consensus. After the training period, the research assistants will complete the unitizing of the remaining transcripts. They will meet with the PI after coding every five transcripts in order to discuss any discrepancy and achieve consensus. Unitization of thought units allows logical partitioning of the transcripts into discrete categories.[111-113] Step 2 involves development of a *transcript codebook*. The research team (NH, JEL, MF) will examine about 40% of the transcripts to create a comprehensive list of themes. The data will be analyzed inductively: transcripts will be read and themes identified, refined, collapsed, and organized into higher-level categories. The transcript codebook provides coding procedures, rules for coding, and descriptions and examples of the codes. Step 3 involves the coding of all transcripts. Two

research assistants will be trained on coding a few transcripts until they achieve consensus. The transcript codebook will be fine-tuned during this training period. After the training period, the research assistants will analyze the remaining transcripts. They will meet with the PI every third transcript to avoid coding drift by comparing results, discussing any discrepancies, and reaching consensus. Step 4 involves the identification of potentially evocative negative and positive physician communication behaviors that are endorsed by multiple patients. Identification of a clear pattern will be a major criteria for saturation. The research team members will first independently identify evocative physician communication behaviors by reviewing the data. Then, they will discuss and select the final set of physician communication behaviors that are going to be further coded using the video-recorded medical interactions.

Analysis of data from the video-recorded medical interactions

The research team members will first discuss an appropriate measurement unit (e.g., amount, degree, frequency, duration) and coding procedure for each discrete physician communication behavior identified by analyzing the interview transcripts (see above) and then creating a *video codebook*. The video codebook will provide coding rules, describe procedures for each physician communication behavior that need to be identified, provide examples for each, describe parameters for exclusion, and note related-code cross-referencing. For each discrete behavior, three research assistants will be first trained in the coding procedure using a set of 10 video-recorded medical interactions that will be randomly chosen until they reach consensus. The video codebook will be refined iteratively as necessary during this training period. After the training period, two of the three research assistants will continue analyzing the rest of the approximately 300 video-recorded medical interactions independently. Every 10 will be double-coded to prevent coding drift. Upon completion of the coding, the PI will identify any

substantive discrepancies in two coders' ratings, that will be resolved by the third research assistant and if necessary the PI. Finally, values provided by the two coders (or the two closest values if there was a third coder) are averaged to compute a single score representing the quantity (e.g., amount, degree, frequency, duration) of a particular discrete behavior. Some behaviors are not discrete and cannot be easily identified, such as speech characteristics (e.g., pitch, tone, amplitude) and facial expression of emotion (e.g., neutral, surprise, happy). These behaviors will be quantified with computer software widely-used in academic research, rather than by using coders (e.g., Praat to quantify speech characteristics, iMotions Affectiva to quantify facial expression of emotion).

Statistical analysis

In general, participants enrolled in the qualitative portion of the study are not enrolled in the quantitative portion of the study in order to avoid potential data contamination. In order to address this potential concern, we will conduct the following analyses for Objectives 2-4 with and without the patients who participated in the video elicitation interviews. This approach will enable us to empirically examine whether an inclusion of the overlapping patients (n = approximately 40) can bias the results.

Objective 2: To identify which physician communication behaviors identified in Objective 1 are associated with physician implicit racial bias

First, basic descriptive statistics will be conducted to identify any non-normal distributions of continuous variables that may require data transformation. Next, the main analyses will be carried out in three steps in order to identify physician communication behaviors that are associated with physician implicit racial bias. In Step 1, we will identify covariates that may impact physician communication behaviors by computing bivariate correlations among all

quantified physician communication behaviors and factors that were assessed in the baseline surveys (e.g., physician and patient demographics, physician professional characteristics, patient perceived discrimination, etc.). In Step 2, we will compute partial correlations between physician implicit racial bias (both IAT and AMP) and all quantified physician communication behaviors while controlling for covariates that were associated significantly with any of the physician behaviors. In Step 3, in order to correct for biased estimates due to nonindependence in data (i.e., patients nested within physicians), we will conduct regression analysis using a Generalized Estimating Equations (GEE) framework for each of the physician communication behaviors that were found to be associated significantly with physician implicit racial bias in Step 2. The model will include the main effects of both IAT and AMP to control for the effect of one another. The regression modeling will also include the same set of covariates as in Step 2. We will correct family-wise error rate due to conducting multiple regression tests with the Bonferroni correction procedure.[114;115] The physician communication behaviors that remain statistically significant in Step 3 are considered as behaviors that reflect physician implicit racial bias.

Objective 3: To examine how physician implicit racial bias is associated with Black patient satisfaction, trust, adherence, and healthcare utilization through physician communication behaviors

To identify physician communication behaviors that are associated with both physician implicit racial bias and Black patient outcomes (i.e., patient perceptions, self-management, and clinical indicators of diabetes control), the analysis will be conducted in three steps similar to Objective 2. The physician communication behaviors that remain statistically significant after all steps will be considered as important behaviors that link physician implicit racial bias and patient outcomes.

Objective 4: To develop the MIBPCS

The MIBPCS will be designed to assess physician communication behaviors that negatively or positively impact patient outcomes and will not be constrained to physician communication behaviors associated with physician implicit racial bias. To create the MIBPCS, we first conduct partial correlations among all quantified physician communication behaviors and patient outcomes while controlling for potential covariates that might impact patient outcomes. Then, the significant correlations will be further tested with regression analysis using GEE. Physician communication behaviors that remain significant in the regression analysis will be compiled into the MIBPCS, which also will include detailed coding instructions as to how to quantify each behavior (i.e., the instructions used by the research assistants who coded the behaviors using the video-recorded medical interactions).

Patient and Public Involvement

Patients and public were not involved in the development of the research question or the design of this study.

DISCUSSION

Findings from this research will advance knowledge about the impact of physician implicit racial bias on Black patient outcomes by using novel approaches and methods. Understanding how physician implicit racial bias is manifested behaviorally during medical interactions, and how Black patients react to these behaviors, is critical to designing effective communication skills training for physicians and interventions to facilitate improved outcomes among Black patients. Additionally, the MIBPCS that will be developed in this study will be superior to prior patient-physician communication coding systems in that it will: (1) focus on physician communication behaviors during medical interactions involving Black patients that are

associated with patient outcomes; and (2) place an unprecedented importance on the patient point of view. The MIBPCS could play an invaluable role in future intervention research and ultimately in medical training as it will enable researchers to pinpoint negative and positive physician communication behaviors and provide them personally-tailored communication skills training that targets those behaviors. Subsequent research should compare the predictive validity of the MIBPCS to that of the existing patient-physician communication coding systems for patient outcomes.

This is the first study to integrate physiological assessment of emotion into video elicitation interviews. One limitation with the video elicitation interviews is that emotion experienced during the video elicitation interviews could be different from that experienced during the actual interactions. However, we believe that video elicitation interviews that integrate physiological assessment are superior to either the live assessment of physiological reactivity or the reporting of emotions immediately after the interaction because they adequately address the major limitations of the two approaches: limited bodily movement and recall inaccuracy. Another potential limitation of this study is that it assumes a single visit with one specific physician is reflective of the overall office visit care received and as such can be associated with self-management and clinical indicators of diabetes control subsequently. We also assume the ability to evaluate the contribution of a given physician's office-based care to a patient's outcomes by controlling for characteristics of that patient's relationship with that physician before and after their participation in the video-recorded medical interaction. However, future research should consider the advantages that may be afforded by a longitudinal research design.

ETHICS AND DISSEMINATION

Research ethics approval for the present study protocol was obtained from the Virginia Commonwealth University IRB. Certificate of Confidentiality for both participating physicians and patients was also obtained from the National Institute of Health. Signed informed consent will be obtained from all participating physicians and patients, and signed HIPAA authorization will be obtained from all participating patients prior to any data collection. Study results will be disseminated through publications in peer-reviewed journals and presentations at national and international professional conferences. The results will be also made available to those engaged in communication skills training. Finally, a novel culturally tailored MIBPCS from this project will be made publicly available.

FIGURE LEGENDS

Figure 1. A conceptual model summarizing findings from the previous research on physician implicit racial bias (1A), and our conceptual mediation model of the role of physician implicit racial bias in Black patient immediate and longer-term outcomes (1B).

Figure 2. An overview of an exploratory sequential mixed methods research design in the proposed research

Figure 3. Chronological order of data collection

AUTHORS' CONTRIBUIONS

Nao Hagiwara is the PI of the study and wrote the first draft of the study protocol. She also edited every draft.

Jennifer Elston Lafata is a Co-I on the study and edited the study protocol with the PI.

Briana Mezuk is a Co-I on the study edited the study protocol with the PI.

Scott Vrana is a Co-I on the study edited the study protocol with the PI.

Michael D. Fetters is a Co-I on the study. As a senior mentor on the team, he edited the study protocol with the PI.

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FUNDING STATEMENT

This work is funded by the National Institute of Health/the National Institute of Diabetes and Digestive and Kidney Diseases (R01 DK112009).

COMPETING INTERESTS STATEMENT

None to declare

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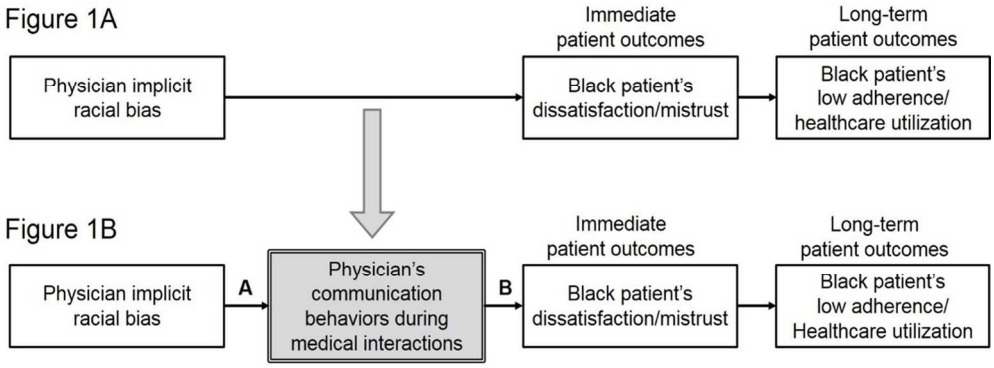

Figure 1. A conceptual model summarizing findings from the previous research on physician implicit racial bias (1A), and our conceptual mediation model of the role of physician implicit racial bias in Black patient clinical outcomes (1B).

444x166mm (300 x 300 DPI)

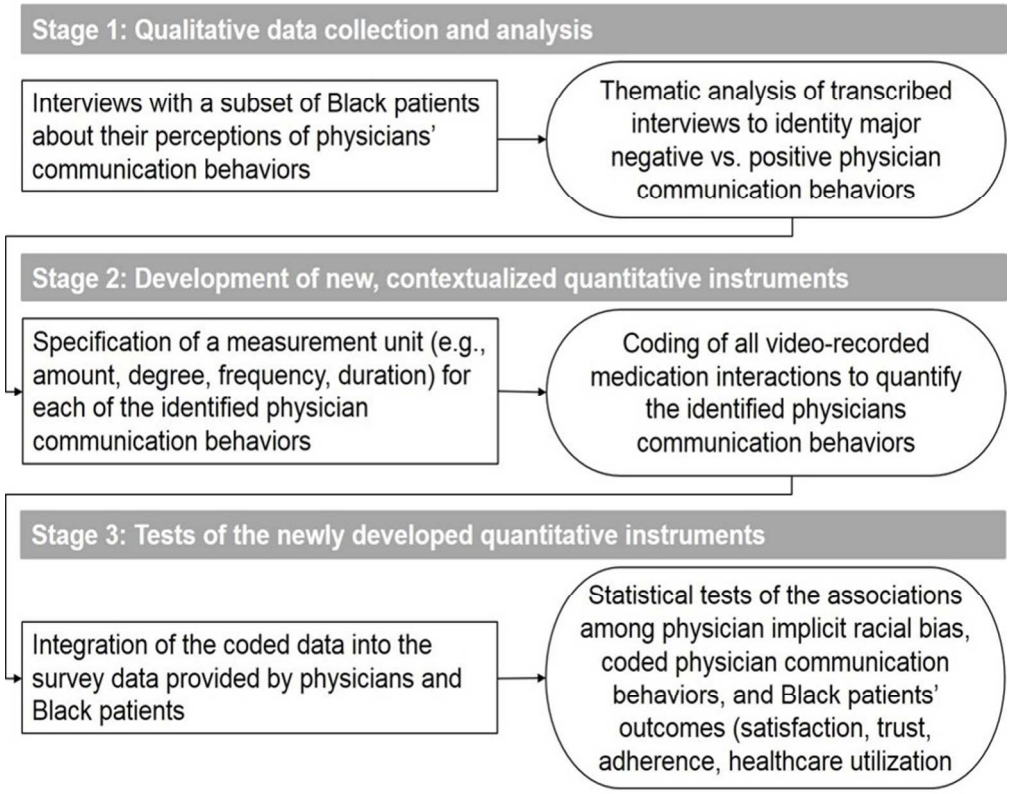

Figure 2. An overview of an exploratory sequential mixed methods research design in the proposed research

348x276mm (300 x 300 DPI)

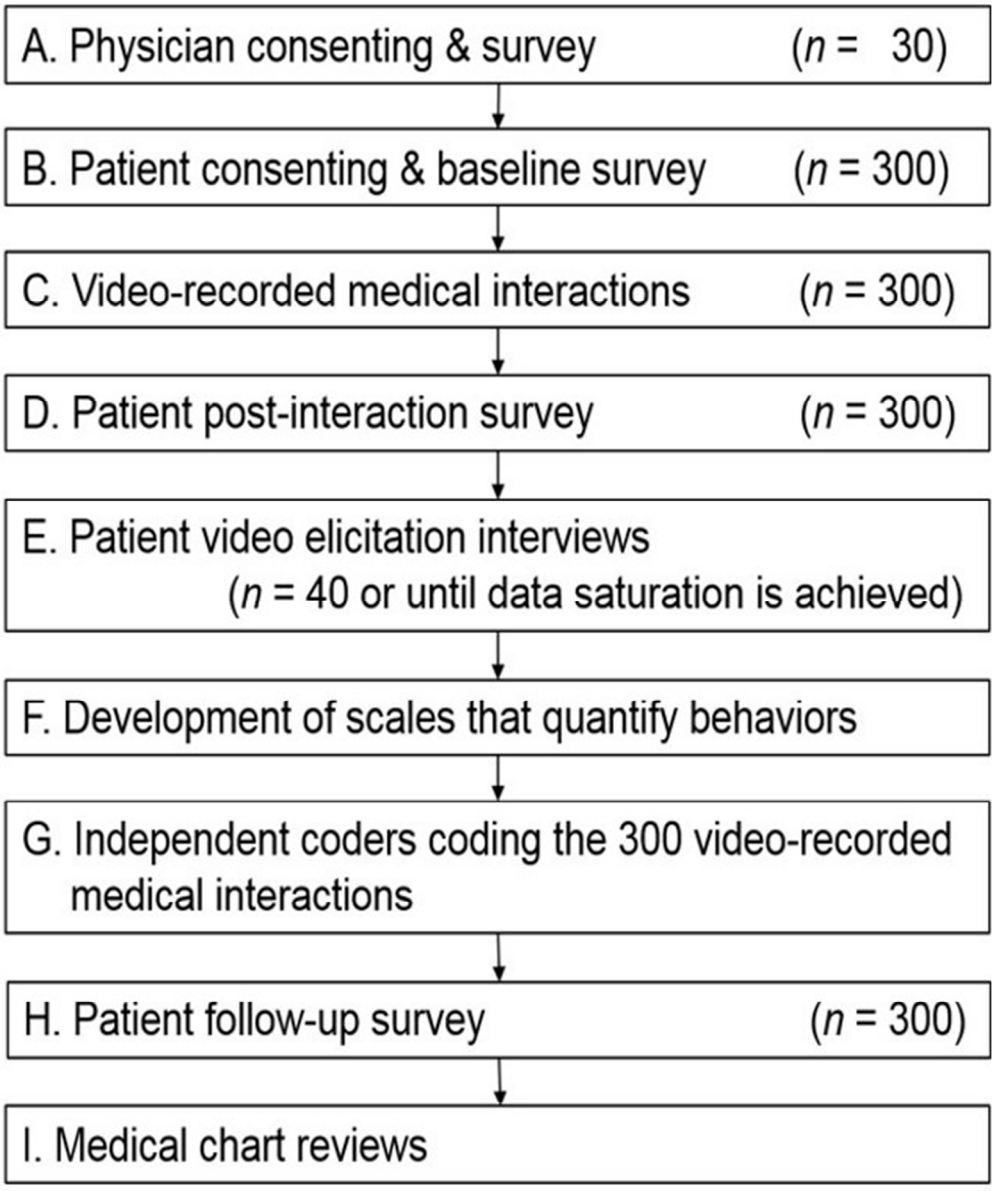

Figure 3. Chronological order of data collection

315x381mm (300 x 300 DPI)

APPENDIX A

Implicit Association Task (IAT)

Stimuli used in two categories representing racial groups (6 white faces vs. 6 black faces) are obtained from https://www.projectimplicit.net/nosek/iat/

IAT script (Brief IAT with Pictures) is obtained from the Millisecond Test Library (https://www.millisecond.com/download/library/)

References:

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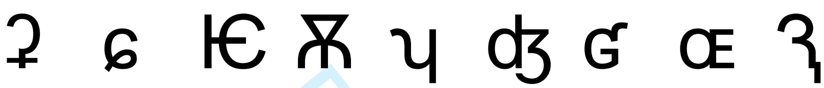
APPENDIX B

Affect Misattribution Procedure (AMP)

Priming images representing racial groups (12 white faces and 12 black faces) are obtained from http://faculty.chicagobooth.edu/bernd.wittenbrink/cfd/index.html

AMP script (Affect Misattribution Procedure) obtained from the Millisecond Test Library is modified to use 36 novel symbols (examples provided below):



Refecens:

Ma, Correll, & Wittenbrink (2015). The Chicago Face Database: A Free Stimulus Set of Faces and Norming Data. *Behavior Research Methods, 47*, 1122-1135.

Payne, B. K., Cheng, C. M., Govorun, O., Stewart, B. D. (2005). An Inkblot for Attitudes: Affect Misattribution as Implicit Measurement. *Journal of Personality and Social Psychology, 89*, 277-293.