Title: Targeting Bias to Reduce Disparities in End of Life Care

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Protocol

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Targeting Bias to Reduce Disparities in End of Life Care: Clinician Communication Behavior in Simulated Patient Encounters (BRiDgE-Sim)

Significance

Scope of the problem:

US adults over 65 are more racially diverse than ever, and this trend will continue. The number of older Black Americans is projected to reach 12 million or 12% of older adults by 2060.[1] Although the growth of palliative care has improved the quality of end-of-life care over the past two decades,[2] racial and ethnic minority patients have not fully benefitted from these advances. There are well-documented disparities in access and uptake of palliative care and in the quality and intensity of end-of-life care.[3-5] These inequalities affect many minority groups, each with its unique history, language and culture that may influence the underlying mechanisms of disparities. The current proposal focuses on Black Americans who experience disparities that are deeply rooted in complex historical and present-day interactions with the health care system.[6,7] Black patients receive more intensive care and are less likely to use hospice at the end of life.[8-15] Their family members are more likely to report poor quality care and decisional regret.[3,4,16,17]

Mechanisms underlying disparities in quality of end-of-life care

Patient and family factors:

Behavioral, attitudinal, cultural and knowledge differences between Black and White patients and family members have been proposed as explanatory mechanisms. Black patients have lower rates of completion of advance directives, which *only partially* explains differences in end-of-life treatments that they receive.[13,18-28] Studies suggest that there may be differences in preferences for life-sustaining treatment between racial groups.[20,25,29-33] However, the absolute differences in these studies were small, and the majority of Black patients preferred comfort care at end-of-life.[20,21,27,33-37] When Black patients are presented with adequate information, their choices do not differ from those of White patients.[38] While some studies found racial differences in patient and family factors such as religiosity, discomfort discussing death, preferences, health literacy and distrust,[18,21,39-41] studies were often inconclusive and sometimes contradictory.[22,24,27,35,42-46] In qualitative studies, Black Americans were open to discussing end-of-life treatment options and limiting life-sustaining treatment in terminal illness.[42,47] These proposed cultural and attitudinal barriers may be stereotypes, rather than true impediments to quality end-of-life care.[48] Regardless of population variations in preferences, clear presentation of options is the standard of care and essential for providing goal-concordant care tailored to the values and beliefs held by individuals.[49]

Healthcare systems factors:

Patient race is not only a marker of shared social identity and beliefs. It is also a proxy for unequal access to resources and systemic racism.[50,51] Systems factors including geographic distribution of resources play a role in quality of end of life care.[15,52]

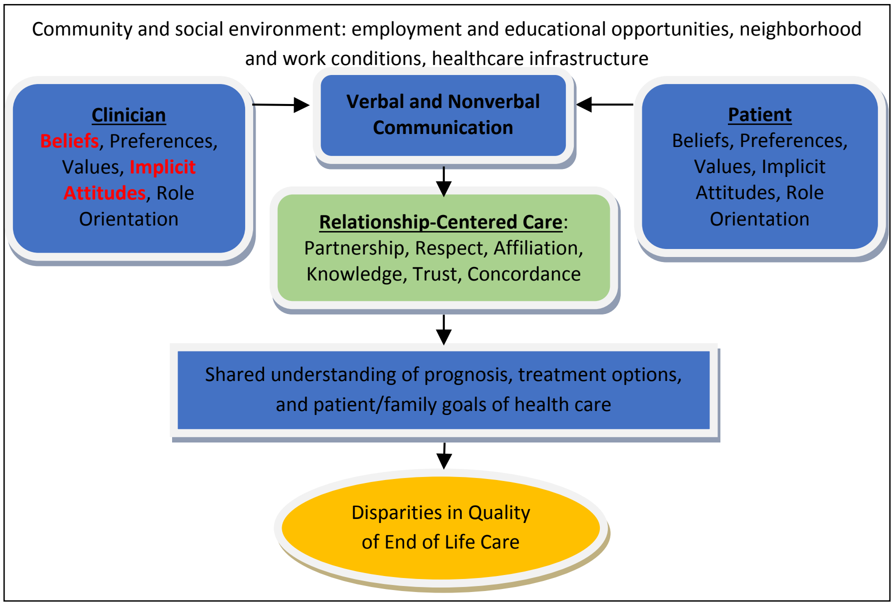
Clinician factors:

There is a major gap in knowledge regarding clinicians' contributions to end-of-life disparities**.**[4,32,45] *The National Institute on Minority Health and Health Disparities has identified a key research priority of exploring health care systems factors at the interpersonal level of the patient-clinician relationship*.[53,54] The majority of physicians are White, and only 4% are Black.[55] Patient-physician racial discordance is associated with decreased quality of communication.[56] Quality of communication explained a significant portion of the variance in decisional regret among Black family members.[17] Clinician communication during racially discordant encounters is an important and modifiable factor in end-of-life care disparities.[5,44,57-65]

The wide dissemination of studies indicating that Black patients and their families prefer more aggressive end-of-life care may result in stereotyping Black patients as less receptive to discussing other end-of-life options.[66-69] These beliefs may increase clinician anxiety when suggesting more comfort-oriented options to Black patients and families. However, given that the literature is equivocal and absolute differences are small, the assumption that a Black patient will prefer aggressive care will most often be false. My research has shown that in an urban medical center, Black patients were more likely to be referred for specialty-level palliative care (Figure 1), but less likely to have a documented goals-of-care discussion initiated by the primary team (Figure 2).[70] This finding suggests that clinicians perceive goals of care discussions to be more complex for Black patients, necessitating specialty referral. Other studies have shown that even when these conversations occur, clinicians are less likely to share prognostic information with Black patients,[71] and are more likely to include inflated survival estimates when speaking with Black compared to White patients.[72] End-of-life conversations are less likely to result in goal-concordant care for Black compared with White patients.[36] Possible explanations for these differences include implicit bias,[73] as well as explicit beliefs.[68,74] Cooper et al. have developed a theoretical model outlining the contribution of relationship-centered care to health disparities.[75] Figure 3 shows the importance of implicit associations and explicit stereotypes in a version of this model modified to highlight the centrality of communication to relationship-centered care and its relation to quality of end-of-life care. Stereotypical beliefs hinder development of true knowledge of the patient by shortcutting around knowledge-gathering communication. Implicit attitudes decrease the quality of communication affecting partnership, respect, affiliation and trust.

Patients who are acutely deteriorating in the inpatient setting are particularly vulnerable to clinician bias because high cognitive load, stress, little prior knowledge of the patient, clinical uncertainty and time constraints accentuate the effects of bias.[76-80] Clinicians who lack specific end-of-life communication training may have more stress when engaged in these challenging discussions. Given current and projected severe shortfalls in the palliative care workforce,[81,82] it is critical to address bias in *all* clinicians caring for the seriously ill to avoid widening disparities over time. Reduced access to quality communication could explain some of the increased use of aggressive care and reduced quality of end-of-life care for Black patients.[83]

Bias and Communication:



Implicit bias refers to unconscious, automatic positive or negative attitudes. Clinicians rarely mention race and ethnicity as barriers to communication, suggesting that they are unable to name these barriers due either to the implicit nature of the bias or to social desirability bias in reporting.[63,84,85] The Implicit Association Test (IAT) demonstrates unconscious racial bias among clinicians.[86-95] Implicit bias predicts patient ratings in domains critical to quality end-of-life care including interpersonal treatment, communication and trust.[96] Physician implicit bias results in poor communication patterns, and poor patient-doctor relationships.[73,89,97-102] Implicit racial bias has been linked to more verbal dominance, less positive affect, visit length and patient-centeredness.[99] A single study showed unconscious differences in nonverbal communication with Black patients while communicating bad news regarding terminal illness.[73] Some physicians *do* express explicit beliefs regarding Black patients' "resistance" to hospice care.[66] It is unknown whether explicit stereotypes about end-of-life preferences influence communication behavior.

Bias Mitigation:

Evidence-based strategies have been developed to reduce effects of implicit bias,[103] but few have been systematically tailored to gaps in care and measured for effectiveness in the clinical setting. There is limited evidence to support specific strategies to reduce the effects of clinician bias on clinical care.[104] Strategies that focus only on making clinicians aware of their biases are unlikely to reduce their effects in the long term without providing them with specific strategies to overcome them.[67,105,106] A strategy based on transformational learning theory and incorporating critical reflection, guided dialogue, perspective taking exercises, role plays and strategy development has been successfully used with medical students.[107]

Aims/Objectives:

The aim of this study is to assess the effects of clinician racial bias on end-of-life communication and to develop interventions to reduce the effects of implicit bias on quality of clinician communication. There are two study objectives: (1) Establish which communication behaviors in the end-of-life setting are most affected by clinician implicit racial bias and explicit stereotyping. (2) Pilot a theory-driven intervention to improve clinician communication and reduce disparities in quality end-of-life care. These objectives will be met in two study phases.

Methods/Design:

Phase 1:

Methods:

(1) I will develop a case depicting a hospitalized 72-year-old with lung cancer and sepsis due to pneumonia on high-flow nasal cannula with my mentorship team of experts in palliative medicine and critical care. I will design a clinical encounter with the caregiver to discuss goals of

care. 2) The caregiver encounter will be piloted with critical care and hospitalist physicians at Montefiore to ensure realism and achieve standardization.[108] Black standardized caregivers will be recruited from the pool of actors used by the Einstein Clinical Skills Center. (3) Standardized caregivers will be trained in the use of a communication assessment tool.[109] (4) 50 physicians will be recruited to participate in a videotaped high-fidelity simulation of the encounter. The session will be followed by a 1-hour communication skills training to allow participants to earn continuing medical education (CME) credit. (5) Immediately after the simulation subjects will complete the IAT and a questionnaire probing for attitudes about race and end-of-life care along with demographic questions. We will assess training needs by adapting a previously developed questionnaire measuring physicians' self-identified serious illness communication training needs by incorporating questions about bias mitigation skills.[110] The IAT is publicly available here: https://implicit.harvard.edu/implicit/selectatest.html.

COVID-19 Concerns:

The Clinical Skills Center will be holding in-person simulations with standardized patients for the purposes of medical education starting in May 2021. The simulations in this study will not begin until after that time and will involve less risk than typical simulations because they will not entail a physical examination of the standardized caregiver. Actors and participants will be equipped with personal protective equipment including surgical masks. Trainers and participants in the training session will be required to wear provided surgical masks and remain six feet apart during the training sessions. If COVID-19 state or institutional guidelines prohibit these types of encounters at the time the simulations will be launched, the simulations and training will be adapted to a virtual format and nonverbal behavior coding will be adjusted. These changes will be submitted to the IRB as an amendment.

Study population:

We will recruit intensivists, oncologists, emergency medicine physicians and hospitalists, including resident and fellow trainees in those specialties. Physician subjects will be recruited face-to-face by the PI, through departmental email blasts and emails to contacts of the study team. Physicians will complete a screening questionnaire to exclude those that do not routinely encounter hospitalized patients with a life expectancy of less than one year. Potential subjects will be asked about the frequency and timing of previous communication and bias training. Physicians practicing Hospice and Palliative Medicine will be excluded because of their extensive prior training in communication.

Data collection:

Encounters will be videotaped. The amount of time the physician and standardized caregiver speak will be recorded. A five-point verbal communication rating scale will be used to rate physician (1) informativeness, (2) supportiveness, and (3) partnership-building and a modified version of the Nonverbal Accommodation Analysis System (NAAS).[89,111] The NAAS will be modified to include physical distance and open/closed body language which were shown to be important in serious illness encounters.[73] Verbal communication will also be analyzed from transcripts of the videotaped encounters. Coded verbal communication will be categorized as data gathering, emotion talk, partnership building, biomedical topics and decision-making content. Videos and transcripts will be coded in the secure Dedoose™ qualitative data coding software. An extra passcode will be added for a second layer of data security.

Another questionnaire will be administered at the end of the training. We will ask physicians to rate their experiences with different educational modalities presented in the training session, such as feedback from observed encounters, communication drills and role-plays. Open-ended questions will be used to gather formative information that the researchers may not have considered. This questionnaire will be distributed at the end of the communication skills training.

Outcome measures:

The primary endpoint will be verbal dominance (ratio of clinician to patient speaking time with a ratio of >1, meaning that the clinician dominated the discussion). Empirical evidence links this communication measure to implicit bias and to patient-centered communication outcomes.[99] Secondary endpoints will include duration of the communication encounter, verbal communication ratings, nonverbal communication behaviors coded with the NAAS and standardized caregiver ratings. Inter-rater reliability will be reported using Kappa values.

Analysis plan:

Bivariate associations of communication scores with IAT scores will be estimated with Pearson or Spearman rank correlation coefficients depending on the distribution of the data. Generalized linear models (GLM) will be fit to the data to assess the associations of the IAT and racial attitudes with primary and secondary communication outcomes, while controlling for potential confounding variables including clinician age, gender and specialty. The identity link will be used in the GLM for continuous communication outcomes. Subgroup analysis will be performed in Asian, Black and Hispanic physicians if there are sufficient numbers in these groups to assess heterogeneity of the associations by race.

Power analysis:

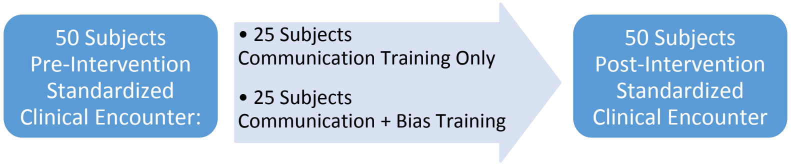
The target sample size of 50 participants would have >80% power to detect a minimum correlation between IAT score and verbal dominance of $\rho \geq 0.38$ using a two-sided hypothesis test of a single correlation with a significance level of 0.05. This correlation is similar in magnitude to associations observed in prior studies; $B=11.0$ in one study and $r = 0.32$ in another.[112]

<u>Phase 2:</u>

Methods:

This is a communication training session based on a culturally-based program developed with rural, southern Black patients and families by Dr. Ronit Elk[113] and modified for an urban, northern population. A strategy of bias mitigation successfully used with medical students will be adapted for practicing clinicians using results of phase 1. This strategy is based on transformative learning theory and incorporates critical reflection, guided dialogue, perspective taking exercises, role plays and strategy development.[107] In this study, a virtual reality (VR) experience (https://michigan.it.umich.edu/news/2023/07/31/education-and-awareness-in-vr-new-experience-illustrates-the-effects-of-racial-discrimination/) will be used as the disorienting dilemma to spark the process of transformative learning. This brief experience embodies the participant in the experiences of an African American man over his life course. It is aimed to engender empathy and perspective taking. Following the VR experience, participants will debrief with the facilitator in small groups, discuss how implicit bias impacts the clinical encounter, brainstorm bias mitigation techniques and role-play strategies to mitigate bias in the clinical encounter. If specific communication behaviors are found related to bias and stereotyping in phase 1, these will be discussed and targeted using these techniques. Otherwise, these techniques will be used to address racial bias generally. The intervention will be incorporated within the communication training session.

Design:



Clinicians will be randomized 1:1 to the active intervention or a control communication training without bias mitigation techniques. Allocation concealment will be in place to ensure the individual enrolling the subject into the study has no a priori knowledge of group assignment. Block randomization will occur with randomly mixed block sizes of 2, 4, and 6. The allocator (research assistant) will hide block size from the executer (PI) in order to prevent the executor from predicting the next assignment. Randomization will be carried out by having a piece of paper that has the phrase "Intervention (Communication + Bias)" or "Control (Communication only)" placed inside an opaque envelope. The outside of the envelopes will be labeled with the sequence number. After a subject has been enrolled into the study and consented, the next sequence numbered envelope on the stack will be opened to determine the study group that the subject will enter.

Participants will be videotaped during high-fidelity simulations of encounters with caregivers described in phase 1, before and after receiving the intervention or control. The intervention and simulations will take place in one half-day workshop.

COVID-19 Concerns:

The Clinical Skills Center will be holding in-person simulations with standardized patients for the purposes of medical education starting in May 2021. The simulations in this study will not begin until after that time and will involve less risk than typical simulations because they will not entail a physical examination of the standardized caregiver. Actors and participants will be equipped with personal protective equipment including surgical masks. Trainers and participants in the training session will be required to wear provided surgical masks and remain six feet apart during the training sessions. If COVID-19 state or institutional guidelines prohibit these types of encounters at the time the simulations will be launched, the simulations and training will be adapted to a virtual format and nonverbal behavior coding will be adjusted. These changes will be submitted to the IRB as an amendment.

Study population and Recruitment:

A new group of intensivists, oncologists, emergency medicine physicians and hospitalists will be recruited including resident and fellow trainees in those specialties. Physician subjects will be recruited face-to-face by the PI, through departmental email blasts and emails to contacts of the study team. As in phase 1, physicians will complete a screening questionnaire to exclude those that do not routinely encounter hospitalized patients with a life expectancy of less than one year. Potential subjects will be asked about the frequency and timing of previous communication and bias training. Physicians practicing Hospice and Palliative Medicine will be excluded because of their extensive prior training in communication.

Data collection:

Encounters will be videotaped. We will use the five-point verbal communication rating scale and nonverbal communication behaviors coded with the NAAS during the standardized encounter as described in phase 1 above.[111,114] A research assistant who did not participate in the training sessions and is blinded to participant group will code communication behaviors. Subjects will complete the IAT and the questionnaire described in phase 1 immediately after the first encounter.

Outcome measures:

Subjects will complete an on-line questionnaire at the close of the session with Likert-type questions on the usefulness and acceptability of the training program and self-efficacy with cross-cultural communication. In addition, the questionnaire will include the cognitive and affective empathy portions of the Interpersonal Reactivity Index. For participants in the active group only, several questions will assess the illusion of ownership of the virtual body in the VR experience. An open-ended text box will invite feedback. The primary efficacy endpoint will be verbal dominance (ratio of clinician to patient speaking time during the encounter with a ratio of >1 meaning that the clinician dominated the discussion).[99] Secondary endpoints will include verbal and nonverbal communication and encounter duration. Inter-rater reliability for the communication scores will be reported using Kappa values.

Analysis plan:

Initially, the mean change in verbal and nonverbal communication scores pre- and post-intervention will be evaluated within each intervention arm using paired *t*-tests or Wilcoxon tests if the data are not normally distributed. To assess whether communication scores improved more in the bias mitigation treatment compared with communication training only control, a generalized linear model will be fit to the data with post-intervention score as the outcome, and pre-intervention score and intervention arm as the main effects. In addition, we will investigate whether pre-intervention level of bias modifies the effect of bias mitigation training, e.g., those with more bias will have a greater difference in improvement between the intervention and control group, by including in the model an interaction term between IAT score and treatment group on communication scores. A positive interaction will indicate that implicit bias as measured by the IAT modifies the effect of treatment group on communication score. With 25 subjects per intervention arm, the study will have 80% power to detect an effect size of 0.8 between groups in pre-post change in communication scores with a two-sided Type 1 error rate of 5%. While this is considered a large effect size according to Cohen's criteria, we would like emphasize that this is a pilot study in which the primary goal is to assess feasibility and to generate preliminary data on the effect of the proposed communication training intervention for clinicians to mitigate the effects of implicit bias.

$\Delta y = \alpha + \beta_0 (Tx) + \beta_1(IAT) + \beta_2(Tx \times IAT) + \varepsilon_1$, where Δy = change in communication score, Tx = treatment group

Data Management/Analysis:

Communication behavior codes and data from the questionnaires and IAT stored on Montefiore's secure Box drive and will only be accessible by members of the research team. Video recordings will be stored on a password-protected hard drive accessible only to the research team.

Risks/Benefits:

Potential risks: This research poses two main risks to subjects: 1) emotional distress and 2) risk to privacy. There may be some emotional distress caused by learning about one's unconscious racial biases. Emotional distress may also result from passive deception; subjects will not be told that racial bias is the focus of the study until after the intervention. Privacy risk arises because racial biases may be considered sensitive information about the subject.

Adequacy of Protection Against Risks

Recruitment and Informed Consent: All subjects will be recruited by the PI through departmental email blasts, emails to contacts of the study team and departmental faculty meeting presentations. The consent process will take place in the Clinical Skills Center on the prior to the standardized patient encounter. Subjects will be informed of their right to participate or discontinue participation at any time without jeopardizing their employment, professional position or relationships with colleagues. Copies of the signed consent form will be given to the subject and placed in the subject's research folder in a locked file drawer in an office in the PI's office expressly designed for this purpose.

Incomplete disclosure of information during the consenting process: Subjects will be informed that they are participating in a study exploring physician cognition, cognitive biases and communication behavior. They will be informed that study participation includes completion of an on-line instrument after the standardized patient encounter. They will not be told during the consent process that implicit racial bias and stereotyping are the focus of the study.

Incentives: Incentives have been chosen to provide a counterbalance to the opportunity costs of participating by offering continuing medical education (CME) credits for attending physician participants. Given that CME credits can be obtained in many ways, this incentive is not to be enough to be coercive. Since resident and fellow participants are unable to use CME credits during training, they will be offered a $50 gift card to compensate them for their time.

Protections against risks: Personal identifiers not be collected in the on-line instrument; instead a unique study ID will be assigned to each participant. Video recordings will be maintained in a password protected digital folder on a hard drive in a locked office. This database of coded communication scores will be stripped of participant identifiers as soon as all data is collected, and a file linking the study ID and patient identifiers will be kept in a separate, password protected digital folder.

Debriefing: After completion of the on-line bias measurement instrument, the subjects will be shown a debriefing statement including full disclosure of the aims of the study and the intent to examine the relationship between implicit racial bias and stereotyping and communication behavior. This statement will include a reminder that they may discontinue participation at any time and request that their data be removed from the dataset without penalty. The PIs contact information will be provided.

Potential Benefits of the Proposed Research: Subjects are not expected to directly benefit from this research.

Importance of the knowledge to be gained: The information from this study will provide knowledge about the role of implicit bias and stereotyping in communication behaviors that have profound effects on the quality of end of life care for black patients. It will also inform efforts to mitigate the effects of this bias in future studies.

Necessity of withholding information in the consent process: Withholding of complete information from the consent process is only acceptable if there is no reasonably effective alternative to achieve the goals of the research. In this case, knowledge of the intent to study implicit racial bias is likely to affect the way physicians communicate in the standardized patient encounter, thus invalidating the results of the study.

Figures:

Figure 1. Proportion of Patients with a Palliative Care Need Receiving Specialist-Level Palliative Care by Race and Ethnicity (n=8,301).

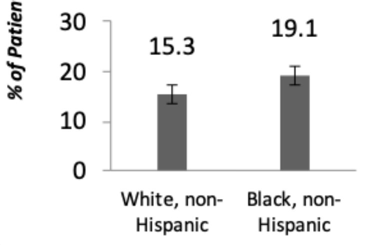
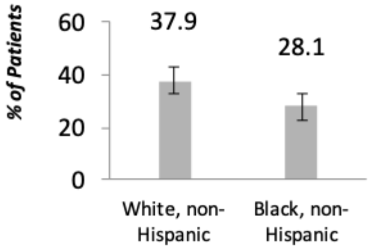


Figure 2. Proportion of Patients with a Palliative Care Need Receiving Goals of Care Discussion by Primary Team by Race and Ethnicity (n=401)



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