BMJ Open

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for rapid systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034247
Article Type:	Protocol
Date Submitted by the Author:	11-Sep-2019
Complete List of Authors:	Roberts, Brian; Cooper University Health Care; Rowan University Cooper Medical School Trzeciak, Christian; Cooper University Health Care Puri, Nitin; Cooper University Health Care; Rowan University Cooper Medical School Mazzarelli, Anthony; Cooper University Health Care; Rowan University Cooper Medical School Trzeciak, Stephen; Cooper University Health Care; Rowan University Cooper Medical School
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, SOCIAL MEDICINE

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for rapid systematic review and meta-analysis

Brian W. Roberts, MD, MSc; Christian J. Trzeciak; Nitin K. Puri, MD;
Anthony J. Mazzarelli, MD, JD, MBE; and Stephen Trzeciak, MD, MPH

From Cooper University Health Care and the Center for Humanism at Cooper Medical School
of Rowan University, Camden, New Jersey, USA

For submission to *BMJ Open*

Address for correspondence:
Brian W. Roberts, MD, MSc
Cooper University Hospital
One Cooper Plaza, K152
Camden, New Jersey, USA 08103

Email addresses of the authors:
roberts-brian-w@cooperhealth.edu
christian.j.trzeciak@gmail.com
puri-nitin@cooperhealth.edu
mazzarelli-anthony@cooperhealth.edu
trzeciak-stephen@cooperhealth.edu

Word count: 2938

Abstract

Introduction: Clinician empathy is a vital component of high quality health care. Health care disparities may reflect a societal lack of empathy for disadvantaged persons in general, and recent research suggests that socioeconomic disparities exist in patient satisfaction with clinicians. However, it is currently unclear if there are disparities in patient experience of empathy from clinicians. Our objective is to systematically analyze the biomedical literature to test the hypothesis that racial and socioeconomic status (SES) disparities exist in patient-reported experience of clinician empathy.

Methods and analysis: In accordance with published methodological guidelines for conducting a rapid systematic review, we will analyze studies reporting patient assessment of clinician empathy using the Consultation and Relational Empathy (CARE) measure, which to date is the most commonly used and well-validated methodology in clinical research for measuring clinician empathy from the patient perspective. We will use a standardized data collection template and assess study quality (risk of bias) using the Newcastle-Ottawa Scale. We will abstract data for the CARE measure stratified by race and SES, and we will contact the corresponding authors to obtain race/SES stratified data if not reported in the original manuscript. Where appropriate, we will pool the data and perform quantitative meta-analysis to test if non-white (compared to white) patients and low SES (compared to high SES) patients report lower scores for clinician empathy.

Ethics and dissemination: No individual patient level data will be collected and thus the proposed systematic review does not require ethical approval. This systematic review will test if racial and SES differences exist in patient experience of clinician empathy, and will inform future research to help promote health care equity.

Registration: PROSPERO international prospective register of systematic reviews: [submitted July 16, 2019 – registration number pending]

Abstract word count: 281

Keywords: empathy, compassion, patient experience, patient satisfaction, health care, health care quality, health care disparities, health care equity, discrimination, bias.

Strengths:

- Rather than testing for racial and socioeconomic status (SES) differences in patient satisfaction in general, this protocol design will focus specifically on racial/SES differences in patient-reported experience of clinician empathy.
- This protocol design is consistent with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement, the Cochrane Handbook for systematic reviews, and published methodological guidelines for conducting a rapid systematic review.

Limitations:

- This protocol design is restricted to studies of the Consultation and Relational Empathy (CARE) measure, to date the most commonly used and well-validated methodology to assess clinician empathy from the patient perspective. Other less frequently employed measures will be excluded in order to reduce heterogeneity and permit pooling of data.
- Data on race of the clinicians, and racial concordance/discordance between patients and clinicians, is unlikely to be available. Thus secondary analyses of the potential effect of in-group/out-group bias will not be possible.

Introduction

Empathy is the ability to sense and understand the emotions of another person, resonate with their thoughts and feelings, and share their perspective. In health care, empathy is conceptualized as a communication competency for clinicians – an emotional bridge that facilitates helping behaviors (i.e. compassionate care for patients).[1] There is broad agreement among patients and clinicians, as well as health care leaders and educators, that empathy is a vital component of health care quality. Abundant evidence in the scientific literature shows that clinician empathy for patients is associated with better outcomes for patients across a multitude of clinical conditions.[2-14]

Health care disparities refer to differences in the quality of health care between population groups, e.g. race or ethnicity, socioeconomic status (SES), age, gender, disability status, or sexual orientation. These inequalities are often linked with socioeconomic disadvantage, and cannot be explained by variation in health needs, patient preferences, or treatment recommendations. In the broad sense, all health care disparities may reflect a societal lack of empathy for disadvantaged persons. These include system-level factors (e.g. barriers to accessing health care), but also include disparities at the point of care due to clinician bias (usually implicit or unconscious bias) possibly manifesting as a lack of empathy for individual patients.[1,15,16] Evidence-based examples at the point of care include: inadequate administration of analgesia for non-white patients with painful conditions,[17,18] inappropriately low use of cardiac catheterization for non-white patients with possible acute myocardial infarction,[19] and clinician assumption that non-white patients will have poor adherence to treatment recommendations,[20] among many others. In addition, recent data indicate that SES differences exist in patient satisfaction with clinicians.[21] However, it is currently unclear if racial and SES disparities exist in patient experience of clinician empathy, specifically.

In clinical research, the most commonly used and well-validated methodology (i.e. proven reliability, internal validity and consistency[22]) for measuring patient assessment of clinician empathy is the Consultation and Relational Empathy (CARE) measure.[23,24] The specific questions comprising the CARE measure are available online from the creators,[23] and are shown in **Online Supplementary Material 1**. Briefly, the CARE measure is a patient assessment of the empathy of a clinician, including: listening and understanding, showing care and compassion, and being interested in the patient as a whole person.

Our objective is to perform a systematic review and meta-analysis of all studies published in the biomedical literature that contain data for patient-reported experience of clinician empathy using the CARE measure. Our hypothesis is that racial and SES disparities exist in patient-reported experience of clinician empathy. Specifically, our hypothesis is that non-white (compared to white) patients and low SES (compared to high SES) patients report lower empathy from clinicians.

Methods and analysis

Protocol design and registration

This systematic review protocol was designed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement (**Online Supplemental Material 2**),[25] as well as the Cochrane Handbook for systematic reviews.[26] The results will be reported according to PRISMA and the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines.[27,28] This protocol has been registered in the PROSPERO international prospective register of systematic reviews (submitted July 16, 2019 – registration number pending).

This protocol describes a rapid systematic review,[29,30] which is a simplified and accelerated, yet rigorous, approach to synthesizing evidence.[31] Rapid systematic reviews omit or simplify some of the components of a full systematic review, speeding up the evidence synthesis process by restricting the review in a way that has sufficiently low incremental risk of bias.[29]

This protocol follows published methodological guidelines for conducting a rapid systematic review, and was designed in accordance with the rapid review framework developed by the Oxford University Centre for Evidence-Based Medicine.[30] Specifically, our review satisfies the following recommended criteria: [1] is conducted by researchers who are experienced in the design, conduct, and publication of full systematic reviews (B.W.R., S.T.);[32-39] [2] has a clearly formulated research question, with clear rationale for why the research is needed; [3] has published the protocol on a prospective register (e.g. PROSPERO); [4] includes at least one major scientific database (e.g. PubMed) and one other source (e.g. EMBASE) in the search strategy; [5] includes a risk of bias assessment; and [6] includes both narrative synthesis and summary tables in the data syntheses.[30] In addition, we are undertaking the following recommended additional steps to further minimize the risk of bias: [1] peer review and publication of the full protocol; [2] full text manuscripts reviewed by two independent reviewers and data extraction verified by a second reviewer; and [3] all risk of bias assessment verified by a second reviewer.[30]

This systematic review qualifies as a rapid review in two key ways. First, we will restrict the analysis to include studies of the CARE measure only, rather than also including studies of other less frequently employed measures of clinician empathy. We did this because a single measure approach is needed in order to reduce heterogeneity and permit pooling of the data for a quantitative meta-analysis, and the CARE measure is the most commonly used and well-validated methodology (i.e. the only patient-reported measure with demonstrated reliability, internal validity, and consistency).[22] Second, with a rigorously conducted systematic review of the CARE measure already having been completed and recently published by Howick and colleagues,[22] we will use the results of their review as a starting point for our review and update the literature search rather than starting over *de novo*. This is an accepted methodology for rapid systematic reviews according to expert recommendations.[30] Thus our systematic review will build upon this previous work for the search strategy and identification of studies, but the analyses will be entirely different (as described below). Rather than analyzing clinician factors in patient experience of clinician empathy as Howick and colleagues did, we will examine patient factors (i.e. race, SES) in patient experience of clinician empathy.

Search for and identification of studies

The methodology of the comprehensive systematic review by Howick and colleagues is described in detail elsewhere.[22] Briefly, the authors searched: MEDLINE, EMBASE, PsycINFO, CINAHL, Science & Social Science Citation Indexes, the Cochrane Library and PubMed from database inception to 2016 without restriction to language, provided that translation of the

CARE measure was validated in that language. They also searched the Web of Science Core Collection, Scopus, and Google Scholar for studies that cited the CARE measure. Their methodology yielded a total of 69 studies with patient-reported data for clinician empathy using the CARE measure for potential analysis.

Consistent with the recommended methods for rapid systematic review we will use these 69 studies as a starting point,[30] and we will update the search by searching the three bibliographic databases considered to be the most important sources according to the Cochrane Handbook (CENTRAL, PubMed (MEDLINE), and EMBASE)[26] from 2017 through 2019. Our search terms will be adopted from Howick and colleagues[22] and appear in **Box 1**.

Eligibility criteria

We will consider any study where patients rated their clinicians' empathy using the CARE measure eligible for potential inclusion. Because our analyses will be dependent on availability of CARE measure data stratified by race and SES, inclusion and exclusion of studies will be determined according to the methodology shown in **Figure 1**. We will exclude studies that (a) do not contain data for patient-reported assessment of clinician empathy using the CARE measure, and (b) do not provide CARE measure data stratified by race/SES (including attempts to contact corresponding authors to obtain stratified data, when necessary). We will consider studies eligible for review regardless of language, provided that translation of the CARE measure was validated in that language. We will exclude studies that are secondary reports of previously published studies. We also will exclude papers that are reviews, correspondence, or editorials; however, we will screen the reference lists of review articles to identify further studies for inclusion.

Study selection and data abstraction

Two members of the research team will independently screen the titles and abstracts of identified studies for potential eligibility. After the relevance screen, exclusion logs will be compared between the two reviewers in order to determine whether there is disagreement and the Kappa statistic will be used to quantify the inter-observer agreement. In cases of disagreement, the full manuscript will be reviewed for inclusion. All studies deemed potentially relevant will be obtained and the full manuscripts will be reviewed for inclusion. Two reviewers will independently abstract data using a standardized data collection form. Any disagreements in these processes will be resolved by consensus with a third reviewer.

We will abstract data for the CARE measure stratified by race and SES in the following format: mean, standard deviation (SD), and sample size (n). For studies that report stratified data in another format, we will contact the corresponding author and request the data in the format above. For SES stratification, we will adopt the definition of low SES utilized in each of the studies.

Assessment of risk of bias

We will assess the quality of all included studies using the Newcastle-Ottawa Scale[40] for assessing methodological quality and risk of bias in observational studies as recommended in the Cochrane Handbook.[41] We customized the Newcastle-Ottawa Scale to specifically evaluate studies of the CARE measure. Details of the scale appear in the online supplementary material (**Online Supplemental Material 3**). Briefly, the scale assesses quality and risk of bias across five methodological domains: (1) representativeness of the cohort (i.e. representative of the general population); (2) ascertainment of the exposure (i.e. prospective enrollment versus retrospective recall); (3) assessment of the outcome (i.e. administration of the CARE measure by an investigator versus other methods with risk of outcome misassignment); (4) completeness of follow-up (i.e. capturing CARE measure data for all enrolled subjects); and (5) risk of selective outcome reporting. We defined a high quality study as a study with 4 or 5 stars (out of 5 possible) across these domains.

Analysis

We will begin with a qualitative analysis of the data in accordance with the recommended methodology for qualitative reviews published in the Cochrane Handbook.[26] We will collate and summarize studies in table format, stratified by individual publication. We will table: (1) country of origin; (2) clinical context (e.g. primary care); (3) number of study sites; (4) number of clinicians in the study; (5) total number of patients; (6) number of patients stratified by race; (7) definition of low SES used (if applicable); (7) number of patients stratified by SES; (8) overall CARE measure data (all patients); (9) CARE measure data stratified by race; (10) CARE measure data stratified by SES.

We will also perform a quantitative analysis of pooled data, where possible. We will only perform quantitative analysis for studies that have sufficient diversity in race/SES in the patient population (defined as no single race/SES group comprising >90% of the study population), on the grounds that heterogeneous populations are needed to detect differences between race/SES groups. Where the CARE measure data can be pooled, we will use a meta-analytic approach to analysis. We will use separate random effects models to calculate pooled effect sizes and corresponding 95% confidence intervals (CIs) for non-white versus white patients, as well as low SES versus high SES patients. We will generate overall effect estimates using a z-test, and present the data as mean differences. We will also analyze the data restricted to high quality studies only, i.e. 4 or 5 stars on the Newcastle-Ottawa Scale as described above. Given that there are 40 potential outcomes for the CARE measure (potential score range 10-50), we believe that calculating a proportional odds ratio would be inappropriate, and instead we will treat the CARE measure as a continuous variable.

We will use the I^2 statistic to assess heterogeneity between studies. The following thresholds will be used for the I^2 statistic: low (25-49%), moderate (50-74%), and high (≥75%).[42] For pooled data, we will assess publication bias using funnel plots (graphical display of the size of the effect of race/SES on the CARE measure against the precision of the study).

Protocol amendments

Any future amendments to this protocol will be described in the subsequent manuscript, along with the rationale for the amendment and the date that the change was implemented.

Patient and Public Involvement

Our study design was informed by the fact that previous research has demonstrated that empathy is considered by patients to be one of the most important aspects of high quality health care.[1,43] Patients were not involved in the actual design of this study. Given this is a systematic review of previously published research, patients will not be enrolled in this study.

Ethics and dissemination

This is a systematic review of completed studies published in the public domain, and thus ethical (e.g. Institutional Review Board) approval will not be required. The results from this systematic review will be submitted for publication to a peer-reviewed journal, and to national scientific meetings in presentation form. We anticipate that this study will help determine if racial and socioeconomic disparities exist in clinician empathy, as assessed by patients. The results from this study will be used to inform future research to help promote health care equity.

Discussion

The aim of this research is to test the hypothesis that measurable racial and SES disparities exist in patient-reported experience of clinician empathy (i.e. an empathy “gap”). To test this hypothesis, the proposed systematic review will collate and quantitatively analyze all of the published data for the CARE measure, which is the most commonly used and well-validated methodology in clinical research to assess clinician empathy from the patient perspective.[22] Although a societal lack of empathy for disadvantaged persons may underlie any institutionalized discrimination leading to health care disparities, we have equipoise about the hypothesis proposed above, which pertains to empathy for individual patients, on the following grounds.

First, the foundation of the relationship between clinicians and their patients is supposed to be a special, inviolable trust that racial/SES bias should never infringe upon. For example, the World Medical Association Declaration of Geneva, which is a physician’s pledge upon entering the medical profession commonly recited at medical school graduation ceremonies, explicitly prohibits *“considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient.”*[44] Although bias is pervasive in society, clinicians have a duty to treat all patients the same. This duty includes empathy for patients. Second, clinicians may consciously put forth extra effort to treat disadvantaged persons with empathy (i.e. most inclined to show empathy to those who need it the most). Thus, disadvantaged persons may experience equal (or more) empathy from clinicians, not less.

However, there is also sound rationale for why an empathy gap could exist, despite clinicians' duty to be unbiased in the care of patients. Racial/SES bias in health care is commonly implicit bias (also termed implicit association or unconscious bias), not intentional. Although clinicians may be reluctant to accept that they may treat patients of different backgrounds differently, there are abundant data that implicit bias is common and could affect clinician empathy for patients.[45,46] This underscores the need for research such as the systematic review proposed here, in order to examine what patients experience from clinicians (i.e. the patient perspective).

The strengths of this protocol design include its uniqueness. Rather than testing for racial/SES differences in patient satisfaction in general, this systematic review will focus specifically on racial/SES differences in patient-reported experience of clinician empathy. We are not aware of any prior systematic reviews that have specifically tested this hypothesis, and finding disparities in clinician empathy would have important public health implications, as clinician empathy is vital for high quality health care. Another strength is that this protocol design is methodologically consistent with the PRISMA-P statement, the Cochrane Handbook, and published guidelines for conducting a rapid systematic review.

This protocol design also has important limitations to consider. The first is that we must restrict the review to only include studies using the CARE measure, rather than also including less frequently employed empathy measures, on the grounds that a quantitative analysis requires a single measure approach. However, this potential concern is attenuated by the facts that the CARE measure is the most commonly used assessment of clinician empathy from the patient perspective in clinical research, and the CARE measure is the only patient-reported empathy assessment with demonstrated reliability, internal validity, and consistency.[22] We also acknowledge that data on race of the clinicians, and racial concordance/discordance between patients and clinicians, is unlikely to be available. Thus, secondary analyses of the potential effect of in-group/out-group bias will not be possible. This protocol also will not test if there are racial or SES differences in patient expectations for clinician empathy. Because individual patient level data will not be collected, we will not be able to establish our own uniform definition of low SES, and instead we will rely on the definition that the authors used in each individual study. Importantly, the results of the proposed meta-analysis will be limited to the communities in which the included studies were performed. Therefore, if no disparity in clinician empathy is identified, it is possible that disparities could still exist in other populations. Lastly, we also acknowledge that some of the studies may not be conducted in racially and SES diverse communities and thus testing for an empathy gap may not be possible; however, this in itself would be an important finding as it would justify further research in this area.

In conclusion, this protocol design for a rapid systematic review is an initial step in determining if racial and socioeconomic disparities exist in clinician empathy from the patient perspective. We will use the results from this systematic review to inform future research aimed to promote health care equity.

References

1. Riess H. The Science of Empathy. *Journal of patient experience.* Jun 2017;4(2):74-77.

2. Attar HS, Chandramani S. Impact of physician empathy on migraine disability and migraineur compliance. *Annals of Indian Academy of Neurology.* Aug 2012;15(Suppl 1):S89-94.

3. Burns DD, Nolen-Hoeksema S. Therapeutic empathy and recovery from depression in cognitive-behavioral therapy: a structural equation model. *Journal of consulting and clinical psychology.* Jun 1992;60(3):441-449.

4. Del Canale S, Louis DZ, Maio V, et al. The relationship between physician empathy and disease complications: an empirical study of primary care physicians and their diabetic patients in Parma, Italy. *Academic medicine : journal of the Association of American Medical Colleges.* Sep 2012;87(9):1243-1249.

5. Flickinger TE, Saha S, Roter D, et al. Clinician empathy is associated with differences in patient-clinician communication behaviors and higher medication self-efficacy in HIV care. *Patient education and counseling.* Feb 2016;99(2):220-226.

6. Hojat M, Louis DZ, Markham FW, Wender R, Rabinowitz C, Gonnella JS. Physicians' empathy and clinical outcomes for diabetic patients. *Academic medicine : journal of the Association of American Medical Colleges.* Mar 2011;86(3):359-364.

7. Hollinger-Samson N, Pearson JL. The relationship between staff empathy and depressive symptoms in nursing home residents. *Aging & Mental Health.* 2000;4(1):56-65.

8. Kim SS, Kaplowitz S, Johnston MV. The effects of physician empathy on patient satisfaction and compliance. *Evaluation & the health professions.* Sep 2004;27(3):237-251.

9. Lelorain S, Bredart A, Dolbeault S, Sultan S. A systematic review of the associations between empathy measures and patient outcomes in cancer care. *Psycho-oncology.* Dec 2012;21(12):1255-1264.

10. Mercer SW, Jani BD, Maxwell M, Wong SY, Watt GC. Patient enablement requires physician empathy: a cross-sectional study of general practice consultations in areas of high and low socioeconomic deprivation in Scotland. *BMC family practice.* Feb 8 2012;13:6.

11. Pereira L, Figueiredo-Braga M, Carvalho IP. Preoperative anxiety in ambulatory surgery: The impact of an empathic patient-centered approach on psychological and clinical outcomes. *Patient education and counseling.* May 2016;99(5):733-738.

12. Rakel DP, Hoeft TJ, Barrett BP, Chewning BA, Craig BM, Niu M. Practitioner empathy and the duration of the common cold. *Family medicine.* Jul-Aug 2009;41(7):494-501.

13. Steinhausen S, Ommen O, Antoine SL, Koehler T, Pfaff H, Neugebauer E. Short- and long-term subjective medical treatment outcome of trauma surgery patients: the importance of physician empathy. *Patient preference and adherence.* 2014;8:1239-1253.

14. West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *Jama.* Sep 6 2006;296(9):1071-1078.

15. Kaiser Family Foundation. Disparities in health and health care. https://www.kff.org/disparities-policy/issue-brief/disparities-in-health-and-health-care-five-key-questions-and-answers/.

16. Centers for Disease Control and Prevention. Social determinants of health: Definitions. https://www.cdc.gov/nchhstp/socialdeterminants/definitions.html.

17. Tamayo-Sarver JH, Hinze SW, Cydulka RK, Baker DW. Racial and ethnic disparities in emergency department analgesic prescription. *American journal of public health.* Dec 2003;93(12):2067-2073.

18. Todd KH, Samaroo N, Hoffman JR. Ethnicity as a risk factor for inadequate emergency department analgesia. *Jama.* Mar 24-31 1993;269(12):1537-1539.

19. Schulman KA, Berlin JA, Harless W, et al. The effect of race and sex on physicians' recommendations for cardiac catheterization. *The New England journal of medicine.* Feb 25 1999;340(8):618-626.

20. van Ryn M, Burke J. The effect of patient race and socio-economic status on physicians' perceptions of patients. *Social science & medicine.* Mar 2000;50(6):813-828.

21. Okunrintemi V, Khera R, Spatz ES, et al. Association of Income Disparities with Patient-Reported Healthcare Experience. *Journal of general internal medicine.* Jun 2019;34(6):884-892.

22. Howick J, Steinkopf L, Ulyte A, Roberts N, Meissner K. How empathic is your healthcare practitioner? A systematic review and meta-analysis of patient surveys. *BMC medical education.* Aug 21 2017;17(1):136.

23. Mercer SW. The CARE Measure. http://www.caremeasure.org/CAREEng.pdf.

24. Mercer SW, Maxwell M, Heaney D, Watt GC. The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure. *Family practice.* Dec 2004;21(6):699-705.

25. Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *Bmj.* Jan 2 2015;350:g7647.

26. Higgins JPT, Green S (eds). *Cochrane handbook for systematic reviews of interventions, version 5.1.0 [updated March 2011].* The Cochrane Collaboration; 2011. http://handbook-5-1.cochrane.org.

27. Moher D, Liberati A, Tetzlaff J, Altman DG, Group P. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Annals of internal medicine.* Aug 18 2009;151(4):264-269, W264.

28. Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. *Jama.* Apr 19 2000;283(15):2008-2012.

29. Aronson JK, Heneghan C, Mahtani KR, Pluddemann A. A word about evidence: 'rapid reviews' or 'restricted reviews'? *BMJ evidence-based medicine.* Dec 2018;23(6):204-205.

30. Pluddemann A, Aronson JK, Onakpoya I, Heneghan C, Mahtani KR. Redefining rapid reviews: a flexible framework for restricted systematic reviews. *BMJ evidence-based medicine.* Dec 2018;23(6):201-203.

31. Kelly SE, Moher D, Clifford TJ. Defining Rapid Reviews: A Modified Delphi Consensus Approach. *International journal of technology assessment in health care.* Jan 2016;32(4):265-275.

32. Damuth E, Mitchell JA, Bartock JL, Roberts BW, Trzeciak S. Long-term survival of critically ill patients treated with prolonged mechanical ventilation: a systematic review and meta-analysis. *The Lancet. Respiratory medicine.* Jul 2015;3(7):544-553.

33. Dettmer MR, Damuth E, Zarbiv S, Mitchell JA, Bartock JL, Trzeciak S. Prognostic Factors for Long-Term Mortality in Critically Ill Patients Treated With Prolonged Mechanical Ventilation: A Systematic Review. *Critical care medicine.* Jan 2017;45(1):69-74.

34. Jones AE, Brown MD, Trzeciak S, et al. The effect of a quantitative resuscitation strategy on mortality in patients with sepsis: a meta-analysis. *Critical care medicine.* Oct 2008;36(10):2734-2739.

35. Jones AE, Shapiro NI, Kilgannon JH, Trzeciak S, Emergency Medicine Shock Research Network i. Goal-directed hemodynamic optimization in the post-cardiac arrest syndrome: a systematic review. *Resuscitation.* Apr 2008;77(1):26-29.

36. Patel S, Pelletier-Bui A, Smith S, et al. Curricula and methods for physician compassion training: protocol for a systematic review. *BMJ open.* Sep 17 2018;8(9):e024320.

37. Roberts BW, Karagiannis P, Coletta M, Kilgannon JH, Chansky ME, Trzeciak S. Effects of PaCO2 derangements on clinical outcomes after cerebral injury: A systematic review. *Resuscitation.* Jun 2015;91:32-41.

38. Roberts BW, Mitchell J, Kilgannon JH, Chansky ME, Trzeciak S. Nitric oxide donor agents for the treatment of ischemia/reperfusion injury in human subjects: a systematic review. *Shock.* Mar 2013;39(3):229-239.

39. Roberts MB, Glaspey LJ, Mazzarelli A, et al. Early Interventions for the Prevention of Posttraumatic Stress Symptoms in Survivors of Critical Illness: A Qualitative Systematic Review. *Critical care medicine.* Aug 2018;46(8):1328-1333.

40. Wells GA, Shea B, O'Connell D, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp.

41. Higgins JPT, Green S. Tools for assessing methodological quality or risk of bias in non-randomized studies (section 13.5.2.3). In: Higgins JPT, Green S, eds. *Cochrane handbook for systematic reviews of interventions. version 5.1.0, updated March 2011*: The Cochrane Collaboration; 2011. http://handbook-5-1.cochrane.org.

42. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Statistics in medicine.* Jun 15 2002;21(11):1539-1558.

43. Sinclair S, Norris JM, McConnell SJ, et al. Compassion: a scoping review of the healthcare literature. *BMC Palliat Care.* Jan 19 2016;15:6.

44. World Medical Association. Declaration of Geneva. 1948; https://www.wma.net/policies-post/wma-declaration-of-geneva/.

45. FitzGerald C, Hurst S. Implicit bias in healthcare professionals: a systematic review. *BMC medical ethics.* Mar 1 2017;18(1):19.

46. Hall WJ, Chapman MV, Lee KM, et al. Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systematic Review. *American journal of public health.* Dec 2015;105(12):e60-76.

Authors' contributions

All authors have made substantial contributions to this paper and have satisfied International Committee of Medical Journal Editors (ICMJE) criteria for authorship. BWR and ST supervised all aspects of the protocol design and take responsibility for the paper as a whole. CJT, NKP, and AJM contributed to protocol development, including overall approach, selection criteria, risk of bias assessment strategy, and data extraction strategy. ST developed the search strategy. BWR provided statistical expertise. ST drafted the manuscript. BWR, CJT, NKP, and AJM read and contributed substantially to revision of the final manuscript. All authors approved the manuscript in its final form.

Funding

This research receives no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interest statement

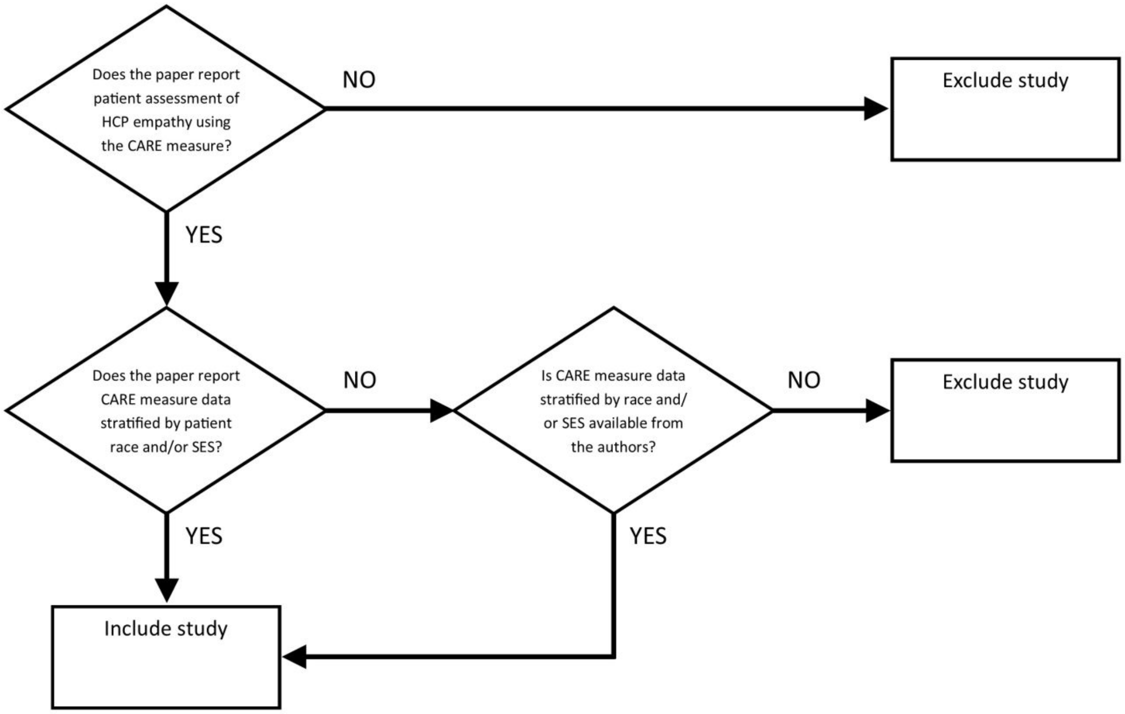
Anthony Mazzarelli and Stephen Trzeciak are authors of a book on compassion science, entitled "Compassionomics". None of the other authors potential competing interests to disclose.

BOX 1: Search strategy

PubMed, and adapted for other databases:

1. "consultation and relational empathy”
2. “CARE measure”
3. “CARE question”
4. “CARE index”
5. 1 or 2 or 3 or 4

Figure 1: Inclusion and exclusion of studies



HCP = health care provider; CARE = Consultation and Relational Empathy; SES = socioeconomic status

ONLINE SUPPLEMENTARY MATERIAL

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for rapid systematic review and meta-analysis

Brian W. Roberts, MD, MSc; Christian J. Trzeciak; Nitin K. Puri, MD;
Anthony J. Mazzarelli, MD, JD, MBE; and Stephen Trzeciak, MD, MPH

From Cooper University Health Care and the Center for Humanism at Cooper Medical School of Rowan University, Camden, New Jersey, USA

For submission to *BMJ Open*

Address for correspondence:
Brian W. Roberts, MD, MSc
Cooper University Hospital
One Cooper Plaza, K152
Camden, New Jersey, USA 08103
roberts-brian-w@cooperhealth.edu

Online Supplementary Material 1: The Consultation and Relational Empathy (CARE) measure. Source: http://www.caremeasure.org/CAREEng.pdf

CARE Patient Feedback Measure for

*** Type name of Practitioner here ***

Please write today's date here:

☐☐ / ☐☐ / ☐☐
D D M M Y Y

Please rate the following statements about today's consultation.

Please mark the box like this ✓ with a ball point pen. If you change your mind just cross out your old response and make your new choice. Please answer every statement.

How good was the practitioner at...	Poor	Fair	Good	Very Good	Excellent	Does not apply
1) Making you feel at ease (introducing him/herself, explaining his/her position, being friendly and warm towards you, treating you with respect; not cold or abrupt)	☐	☐	☐	☐	☐	☐
2) Letting you tell your "story" (giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you)	☐	☐	☐	☐	☐	☐
3) Really listening (paying close attention to what you were saying; not looking at the notes or computer as you were talking)	☐	☐	☐	☐	☐	☐
4) Being interested in you as a whole person (asking/knowing relevant details about your life, your situation; not treating you as "just a number")	☐	☐	☐	☐	☐	☐
5) Fully understanding your concerns (communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything)	☐	☐	☐	☐	☐	☐
6) Showing care and compassion (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")	☐	☐	☐	☐	☐	☐
7) Being positive (having a positive approach and a positive attitude; being honest but not negative about your problems)	☐	☐	☐	☐	☐	☐
8) Explaining things clearly (fully answering your questions; explaining clearly, giving you adequate information; not being vague)	☐	☐	☐	☐	☐	☐
9) Helping you to take control (exploring with you what you can do to improve you health yourself; encouraging rather than "lecturing" you)	☐	☐	☐	☐	☐	☐
10) Making a plan of action with you (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)	☐	☐	☐	☐	☐	☐

Comments: If you would like to add further comments on this consultation, please do so here.

4571132878

Online Supplementary Material 2: The PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	(Page No.#)
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	7
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	22
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	11
Support:			
Sources	5a	Indicate sources of financial or other support for the review	22
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7-8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	23
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	9-10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5, 10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9-10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A – not testing intervention

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Online Supplementary Material 3: Newcastle-Ottawa Scale for assessment of study quality in observational research (customized). A study can be awarded a maximum of one star in each of the five methodological domains below. We define a high quality study as a study with four or five stars across the domains. We define the exposure as the patient's visit with an individual clinician, and the outcome as the patient's assessment of clinician empathy during the visit using the CARE measure.

Patient selection:

1. Representativeness of the cohort
    a. Representative of the general population *
    b. Select population, not necessarily representative of general population
    c. No description of derivation of the cohort, or unclear

Exposure:

2. Ascertainment of the exposure (patient visit to clinician)
    a. Prospective ascertainment (i.e. enrollment prior to the patient visit or at the point of care) with no risk of recall bias *
    b. Retrospective ascertainment (i.e. enrollment after the patient visit, but within 30 days) with minimal risk of recall bias *
    c. Remote retrospective ascertainment (i.e. enrollment more than 30 days after the patient visit) subject to recall bias
    d. No description or unclear

Outcome:

3. Assessment of outcome (CARE measure)
    a. Independent assessment (i.e. CARE measure administered by an investigator) *
    b. Record linkage *
    c. Method allows possibility for outcome misassignment
    d. No description or unclear
4. Adequacy of follow-up
    a. Complete follow-up (i.e. have CARE measure data for all enrolled subjects) *
    b. Subjects lost to follow-up (i.e. no CARE measure data) are unlikely to introduce bias due to small number (≤5% of cohort) lost, or description provided of those lost *
    c. Subjects lost to follow-up >5% of cohort and no description of those lost
    d. No statement or unclear
5. Selective outcome reporting
    a. Free of suggestion of selective outcome reporting *
    b. Suggestion of selective outcome reporting
    c. Unknown

SES = socioeconomic status

BMJ Open

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034247.R1
Article Type:	Protocol
Date Submitted by the Author:	24-Mar-2020
Complete List of Authors:	Roberts, Brian; Cooper University Health Care; Rowan University Cooper Medical School Trzeciak, Christian; Cooper University Health Care Puri, Nitin; Cooper University Health Care; Rowan University Cooper Medical School Mazzarelli, Anthony; Cooper University Health Care; Rowan University Cooper Medical School Trzeciak, Stephen; Cooper University Health Care; Rowan University Cooper Medical School
Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Public health
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, SOCIAL MEDICINE

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for systematic review and meta-analysis

Brian W. Roberts, MD, MSc; Christian J. Trzeciak; Nitin K. Puri, MD;
Anthony J. Mazzarelli, MD, JD, MBE; and Stephen Trzeciak, MD, MPH

From Cooper University Health Care and the Center for Humanism at Cooper Medical School of Rowan University, Camden, New Jersey, USA

For submission to *BMJ Open*

Address for correspondence:
Brian W. Roberts, MD, MSc
Cooper University Hospital
One Cooper Plaza, K152
Camden, New Jersey, USA 08103

Email addresses of the authors:
roberts-brian-w@cooperhealth.edu
christian.j.trzeciak@gmail.com
puri-nitin@cooperhealth.edu
mazzarelli-anthony@cooperhealth.edu
trzeciak-stephen@cooperhealth.edu

Word count: 2400

Abstract

Introduction: Clinician empathy is a vital component of high quality health care. Health care disparities may reflect a societal lack of empathy for disadvantaged persons in general, and recent research suggests that socioeconomic disparities exist in patient satisfaction with clinicians. However, it is currently unclear if there are disparities in patient experience of empathy from clinicians. Our objective is to systematically analyze the scientific literature to test the hypothesis that racial and socioeconomic status (SES) disparities exist in patient-reported experience of clinician empathy.

Methods and analysis: In accordance with published methodological guidelines for conducting a systematic review, we will analyze studies reporting patient assessment of clinician empathy using the Consultation and Relational Empathy (CARE) measure, which to date is the most commonly used and well-validated methodology in clinical research for measuring clinician empathy from the patient perspective. We will use a standardized data collection template and assess study quality (risk of bias) using the Newcastle-Ottawa Scale. We will abstract data for the CARE measure stratified by race and SES, and we will contact the corresponding authors to obtain race/SES stratified data if not reported in the original manuscript. Where appropriate, we will pool the data and perform quantitative meta-analysis to test if non-white (compared to white) patients and low SES (compared to high SES) patients report lower scores for clinician empathy.

Ethics and dissemination: No individual patient level data will be collected and thus the proposed systematic review does not require ethical approval. This systematic review will test if racial and SES differences exist in patient experience of clinician empathy, and will inform future research to help promote health care equity.

Registration: PROSPERO international prospective register of systematic reviews (CRD42019142809)

Abstract word count: 280

Keywords: empathy, compassion, patient experience, patient satisfaction, health care, health care quality, health care disparities, health care equity, discrimination, bias.

Strengths:

- Rather than testing for racial and socioeconomic status (SES) differences in patient satisfaction in general, this protocol focuses specifically on racial/SES differences in patient-reported experience of clinician empathy.
- This protocol was developed in accordance with published methodological guidelines in the Cochrane Handbook for systematic reviews, and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement.

Limitations:

- This protocol is restricted to studies of the Consultation and Relational Empathy (CARE) measure, to date the most commonly used and well-validated methodology to assess clinician empathy from the patient perspective. Other less frequently employed measures will be excluded in order to reduce heterogeneity and permit pooling of data.
- Data on race of the clinicians, and racial concordance/discordance between patients and clinicians, is unlikely to be available. Thus secondary analyses of the potential effect of in-group/out-group bias will not be possible.

Introduction

Empathy is the ability to sense and understand the emotions of another person, resonate with their thoughts and feelings, and share their perspective. In health care, empathy is conceptualized as a communication competency for clinicians – an emotional bridge that facilitates helping behaviors (i.e. compassionate care for patients).[1] There is broad agreement among patients and clinicians, as well as health care leaders and educators, that empathy is a vital component of health care quality. Abundant evidence in the scientific literature shows that clinician empathy for patients is associated with better outcomes for patients across a multitude of clinical conditions.[2-14]

Health care disparities refer to differences in the quality of health care between population groups, e.g. race or ethnicity, socioeconomic status (SES), age, gender, disability status, or sexual orientation. These inequalities are often linked with socioeconomic disadvantage, and cannot be explained by variation in health needs, patient preferences, or treatment recommendations. In the broad sense, all health care disparities may reflect a societal lack of empathy for disadvantaged persons. These include system-level factors (e.g. barriers to accessing health care), but also include disparities at the point of care due to clinician bias (usually implicit or unconscious bias) possibly manifesting as a lack of empathy for individual patients.[1 15 16] Evidence-based examples at the point of care include: inadequate administration of analgesia for non-white patients with painful conditions,[17 18] inappropriately low use of cardiac catheterization for non-white patients with possible acute myocardial infarction,[19] and clinician assumption that non-white patients will have poor adherence to treatment recommendations,[20] among many others. In addition, recent data indicate that SES differences exist in patient satisfaction with clinicians.[21] However, it is currently unclear if racial and SES disparities exist in patient experience of clinician empathy, specifically.

In clinical research, the most commonly used and well-validated methodology (i.e. proven reliability, internal validity and consistency[22]) for measuring patient assessment of clinician empathy is the Consultation and Relational Empathy (CARE) measure.[23 24] The specific questions comprising the CARE measure are available online from the creators,[23] and are shown in **Online Supplementary Material 1**. Briefly, the CARE measure is a patient assessment of the empathy of a clinician, including: listening and understanding, showing care and compassion, and being interested in the patient as a whole person.

Our objective is to perform a systematic review and meta-analysis of all studies published in the scientific literature that contain data for patient-reported experience of clinician empathy using the CARE measure. Our hypothesis is that racial and SES disparities exist in patient-reported experience of clinician empathy. Specifically, our hypothesis is that non-white (compared to white) patients and low SES (compared to high SES) patients report lower empathy from clinicians.

Methods and analysis

Protocol and registration

This systematic review protocol was registered and published in PROSPERO, the international prospective register of systematic reviews (CRD42016037456). This protocol was designed in accordance with published methodological guidelines in the Cochrane Handbook for systematic reviews,[25] and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement (**Online Supplemental Material 2**).[26]

Eligibility criteria

We will consider any clinical study where patients rated their clinicians' empathy using the CARE measure eligible for potential inclusion. Although we expect the vast majority of studies will be observational designs (e.g. cohort studies), we will also include interventional studies (e.g. clinical trials) if patient ratings of the CARE measure are reported. We will exclude studies that (a) do not contain data for patient-reported assessment of clinician empathy using the CARE measure, and (b) do not provide CARE measure data stratified by race/SES (including attempts to contact corresponding authors to obtain stratified data, when necessary). The **Figure** displays this approach to inclusion and exclusion of studies.

We will consider studies eligible for review regardless of language, provided that translation of the CARE measure was validated in that language. We will exclude studies that are secondary reports of previously published studies. We also will exclude papers that are reviews, correspondence, or editorials.

Search strategy and identification of studies

We will search the following databases from December 1, 2004 (date of first publication of the CARE measure[24]) until present: MEDLINE, CINAHL, EMBASE, CENTRAL, PsycINFO, PubMed, and Google Scholar. We will not search the grey literature, on the grounds that we only want to include published research. We will use the following search terms adopted from another systematic review of the CARE measure previously published (2016) by Howick[22] and colleagues:

MEDLINE (and adapted for other databases)

1. "consultation and relational empathy".mp.
2. (CARE adj3 (measure* or question* or index*)).ti,ab. and empath*.mp.
3. (CARE adj3 (measure* or question* or index*)).ti,ab. and mercer.af.
4. 1 or 2 or 3

We consulted with a health librarian / information specialist who confirmed that this search strategy is methodologically sound.

Study selection and data abstraction

Two members of the research team will independently screen the titles and abstracts of identified studies for potential eligibility. After the relevance screen, exclusion logs will be compared between the two reviewers in order to determine whether there is disagreement and the Kappa statistic will be used to quantify the interobserver agreement. In cases of disagreement, the full manuscript will be reviewed for inclusion. All studies deemed potentially relevant will be obtained and the full manuscripts will be reviewed for inclusion. Two reviewers will independently abstract data using a standardized data collection form. Any disagreements in these processes will be resolved by consensus with a third reviewer.

We will abstract from each manuscript: (1) country of origin; (2) clinical context (e.g. primary care); (3) total number of patients; (4) number of patients stratified by race; (5) definition of low SES used (if applicable); (6) number of patients stratified by SES; (7) CARE measure data stratified by race; (8) CARE measure data stratified by SES. We will abstract data for the CARE measure stratified by race and SES in the following format: mean, standard deviation (SD), and sample size (n). For studies that report stratified data in another format, we will contact the corresponding author and request the data in the format above. For SES stratification, we will adopt the definition of low SES utilized in each of the studies.

We will use EndNote X9 (Clarivate Analytics, Philadelphia, PA) for reference management and Google Sheets (Google, Mountain View, CA) for data extraction and management.

Assessment of risk of bias

We will assess the quality of all included studies using the Newcastle-Ottawa Scale[27] for assessing methodological quality and risk of bias in observational studies as recommended in the Cochrane Handbook.[28] Details of the scale appear in the online supplementary material (**Online Supplemental Material 3**). Briefly, the scale assesses quality and risk of bias in multiple domains, such as representativeness of the cohort, ascertainment of the exposure and outcome, and completeness of follow-up.

Analysis

We will begin with a qualitative analysis of the data in accordance with the recommended methodology for qualitative reviews published in the Cochrane Handbook.[25] We will collate and summarize studies in table format, stratified by individual publication. We will also perform a quantitative analysis of pooled data, where possible. We will only perform quantitative analysis for studies that have sufficient diversity in race/SES in the patient population (defined as no single race/SES group comprising >90% of the study population), on the grounds that heterogeneous populations are needed to detect differences between race/SES groups. Where the CARE measure data can be pooled, we will use a meta-analytic approach to analysis. We will use separate random effects models to calculate pooled effect sizes and corresponding 95% confidence intervals (CIs) for non-white versus white patients, as well as low SES versus high SES patients. We will generate overall effect estimates using a z-test, and present the data as mean differences. We will also analyze for possible interaction between race and SES, where possible, by comparing CARE measure scores between SES categories stratified by race.

We also plan to analyze the data restricted to high quality studies only, e.g. four or more stars on the Newcastle-Ottawa Scale as described above. Given that there are 40 potential outcomes for the CARE measure (potential score range 10-50), we believe that calculating a proportional odds ratio would be inappropriate, and instead we will treat the CARE measure as a continuous variable.

We will use the I^2 statistic to assess heterogeneity between studies. The following thresholds will be used for the I^2 statistic: low (25-49%), moderate (50-74%), and high (≥75%).[29] For pooled data, we will assess publication bias using funnel plots (graphical display of the size of the effect of race/SES on the CARE measure against the precision of the study).

We will use Stata 16 (StataCorp, College Station, TX) for all analyses.

Protocol amendments

Any amendments to this protocol will be described in the subsequent manuscript, along with the rationale for the amendment and the date that the change was implemented.

Patient and Public Involvement

Our study design was informed by the fact that previous research has demonstrated that empathy is considered by patients to be one of the most important aspects of high quality health care.[1 30] Patients were not involved in the actual design of this study. Given this is a systematic review of previously published research, patients will not be enrolled in this study.

Ethics and dissemination

This is a systematic review of completed studies published in the public domain, and thus ethical (e.g. Institutional Review Board) approval will not be required. The results from this systematic review will be submitted for publication to a peer-reviewed journal, and to national scientific meetings in presentation form. We anticipate that this study will help determine if racial and socioeconomic disparities exist in clinician empathy, as assessed by patients. The results from this study will be used to inform future research to help promote health care equity.

Discussion

The aim of this research is to test the hypothesis that measurable racial and SES disparities exist in patient-reported experience of clinician empathy (i.e. an empathy "gap"). To test this hypothesis, the proposed systematic review will collate and quantitatively analyze all of the published data for the CARE measure, which is the most commonly used and well-validated methodology in clinical research to assess clinician empathy from the patient perspective.[22] Although a societal lack of empathy for disadvantaged persons may underlie any institutionalized discrimination leading to health care disparities, we have equipoise about the hypothesis proposed above, which pertains to empathy for individual patients, on the following grounds.

First, the foundation of the relationship between clinicians and their patients is supposed to be a special, inviolable trust that racial/SES bias should never infringe upon. For example, the World Medical Association Declaration of Geneva, which is a physician's pledge upon entering the medical profession commonly recited at medical school graduation ceremonies, explicitly prohibits *"considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient."*[31] Although bias is pervasive in society, clinicians have a duty to treat all patients the same. This duty includes empathy for patients. Second, clinicians may consciously put forth extra effort to treat disadvantaged persons with empathy (i.e. most inclined to show empathy to those who need it the most). Thus, disadvantaged persons may experience equal (or more) empathy from clinicians, not less.

However, there is also sound rationale for why an empathy gap could exist, despite clinicians' duty to be unbiased in the care of patients. Racial/SES bias in health care is commonly implicit bias (also termed implicit association or unconscious bias), not intentional. Although clinicians may be reluctant to accept that they may treat patients of different backgrounds differently, there are abundant data that implicit bias is common and could affect clinician empathy for patients.[32 33] This underscores the need for research such as the systematic review proposed here, in order to examine what patients experience from clinicians (i.e. the patient perspective).

The strengths of this protocol design include its uniqueness. Rather than testing for racial/SES differences in patient satisfaction in general, this systematic review will focus specifically on racial/SES differences in patient-reported experience of clinician empathy. We are not aware of any prior systematic reviews that have specifically tested this hypothesis, and finding disparities in clinician empathy would have important public health implications, as clinician empathy is vital for high quality health care.

This protocol design also has important limitations to consider. The first is that we must restrict the review to only include studies using the CARE measure, rather than also including less frequently employed empathy measures, on the grounds that a quantitative analysis requires a single measure approach. However, this potential concern is attenuated by the facts that the CARE measure is the most commonly used assessment of clinician empathy from the patient perspective in clinical research, and the CARE measure is the only patient-reported empathy assessment with demonstrated reliability, internal validity, and consistency.[22] We also acknowledge that data on race of the clinicians, and racial concordance/discordance between patients and clinicians, is unlikely to be available. Thus, secondary analyses of the potential effect of in-group/out-group bias will not be possible. This protocol also will not test if there are racial or SES differences in patient expectations for clinician empathy. We also acknowledge that factors that covary with race, e.g. SES, may explain any racial differences found in the CARE measure. For this reason, we will analyze the interaction between race and SES, where possible.

Because individual patient level data will not be collected, we will not be able to establish our own uniform definition of low SES, and instead we will rely on the definition that the authors used in each individual study. We also acknowledge that we will not be able to make a distinction between clinician empathy for patients and their effectiveness with empathic communication to patients, which may differ.

Lastly, we acknowledge that some of the studies may not be conducted in racially and SES diverse communities and thus testing for an empathy gap may not be possible; however, this in itself would be an important finding as it would justify further research in this area.

In conclusion, this protocol design for a rapid systematic review is an initial step in determining if racial and socioeconomic disparities exist in clinician empathy from the patient perspective. We will use the results from this systematic review to inform future research aimed to promote health care equity.

References

1. Riess H. The Science of Empathy. *Journal of Patient Experience* 2017;4(2):74-77. doi: 10.1177/2374373517699267
2. Attar HS, Chandramani S. Impact of physician empathy on migraine disability and migraineur compliance. *Annals of Indian Academy of Neurology* 2012;15(Suppl 1):S89-94. doi: 10.4103/0972-2327.100025
3. Burns DD, Nolen-Hoeksema S. Therapeutic empathy and recovery from depression in cognitive-behavioral therapy: a structural equation model. *Journal of Consulting and Clinical Psychology* 1992;60(3):441-9.
4. Del Canale S, Louis DZ, Maio V, et al. The relationship between physician empathy and disease complications: an empirical study of primary care physicians and their diabetic patients in Parma, Italy. *Academic Medicine : Journal of the Association of American Medical Colleges* 2012;87(9):1243-9. doi: 10.1097/ACM.0b013e3182628fbf
5. Flickinger TE, Saha S, Roter D, et al. Clinician empathy is associated with differences in patient-clinician communication behaviors and higher medication self-efficacy in HIV care. *Patient Education and Counseling* 2016;99(2):220-6. doi: 10.1016/j.pec.2015.09.001
6. Hojat M, Louis DZ, Markham FW, et al. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine : Journal of the Association of American Medical Colleges* 2011;86(3):359-64. doi: 10.1097/ACM.0b013e3182086fe1
7. Hollinger-Samson N, Pearson JL. The relationship between staff empathy and depressive symptoms in nursing home residents. *Aging & Mental Health* 2000;4(1):56-65. doi: 10.1080/13607860055982

8. Kim SS, Kaplowitz S, Johnston MV. The effects of physician empathy on patient satisfaction and compliance. *Evaluation & the Health Professions* 2004;27(3):237-51. doi: 10.1177/0163278704267037

9. Lelorain S, Bredart A, Dolbeault S, et al. A systematic review of the associations between empathy measures and patient outcomes in cancer care. *Psycho-oncology* 2012;21(12):1255-64. doi: 10.1002/pon.2115

10. Mercer SW, Jani BD, Maxwell M, et al. Patient enablement requires physician empathy: a cross-sectional study of general practice consultations in areas of high and low socioeconomic deprivation in Scotland. *BMC Family Practice* 2012;13:6. doi: 10.1186/1471-2296-13-6

11. Pereira L, Figueiredo-Braga M, Carvalho IP. Preoperative anxiety in ambulatory surgery: The impact of an empathic patient-centered approach on psychological and clinical outcomes. *Patient Education and Counseling* 2016;99(5):733-8. doi: 10.1016/j.pec.2015.11.016

12. Rakel DP, Hoeft TJ, Barrett BP, et al. Practitioner empathy and the duration of the common cold. *Family Medicine* 2009;41(7):494-501.

13. Steinhausen S, Ommen O, Antoine SL, et al. Short- and long-term subjective medical treatment outcome of trauma surgery patients: the importance of physician empathy. *Patient Preference and Adherence* 2014;8:1239-53. doi: 10.2147/PPA.S62925

14. West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *JAMA* 2006;296(9):1071-8. doi: 10.1001/jama.296.9.1071

15. Kaiser Family Foundation. Disparities in health and health care. Available from: https://www.kff.org/disparities-policy/issue-brief/disparities-in-health-and-health-care-five-key-questions-and-answers/.

16. The Centers for Disease Control and Prevention. Social determinants of health: Definitions. Available from: https://www.cdc.gov/nchhstp/socialdeterminants/definitions.html.

17. Tamayo-Sarver JH, Hinze SW, Cydulka RK, et al. Racial and ethnic disparities in emergency department analgesic prescription. *American Journal of Public Health* 2003;93(12):2067-73. doi: 10.2105/ajph.93.12.2067

18. Todd KH, Samaroo N, Hoffman JR. Ethnicity as a risk factor for inadequate emergency department analgesia. *JAMA* 1993;269(12):1537-9.

19. Schulman KA, Berlin JA, Harless W, et al. The effect of race and sex on physicians' recommendations for cardiac catheterization. *The New England Journal of Medicine* 1999;340(8):618-26. doi: 10.1056/NEJM199902253400806

20. van Ryn M, Burke J. The effect of patient race and socio-economic status on physicians' perceptions of patients. *Social Science & Medicine* 2000;50(6):813-28.

21. Okunrintemi V, Khera R, Spatz ES, et al. Association of Income Disparities with Patient-Reported Healthcare Experience. *Journal of General Internal Medicine* 2019;34(6):884-92. doi: 10.1007/s11606-019-04848-4

22. Howick J, Steinkopf L, Ulyte A, et al. How empathic is your healthcare practitioner? A systematic review and meta-analysis of patient surveys. *BMC Medical Education* 2017;17(1):136. doi: 10.1186/s12909-017-0967-3

23. Mercer SW. The CARE Measure: Scottish Government Chief Scientist Office. Available from: http://www.caremeasure.org/CAREEng.pdf.

24. Mercer SW, Maxwell M, Heaney D, et al. The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure. *Family Practice* 2004;21(6):699-705. doi: 10.1093/fampra/cmh621

25. Higgins JPT, Green S. Cochrane Handbook for systematic reviews of interventions, version 5.1.0 [updated March 2011]: The Cochrane Collaboration 2011.

26. Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ* 2015;350:g7647. doi: 10.1136/bmj.g7647

27. Wells GA, Shea B, O'Connell D, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses. Available from: http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp.

28. Higgins JPT, Green S. Tools for assessing methodological quality or risk of bias in non-randomized studies (section 13.5.2.3). In: Higgins JPT, Green S, eds. Cochrane Handbook for systematic reviews of interventions version 5.1.0, updated March 2011: The Cochrane Collaboration 2011.

29. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Statistics in Medicine* 2002;21(11):1539-58. doi: 10.1002/sim.1186

30. Sinclair S, Norris JM, McConnell SJ, et al. Compassion: a scoping review of the healthcare literature. *BMC Palliat Care* 2016;15:6. doi: 10.1186/s12904-016-0080-0

31. World Medical Association. Declaration of Geneva 1948. Available from: https://www.wma.net/policies-post/wma-declaration-of-geneva/.

32. FitzGerald C, Hurst S. Implicit bias in healthcare professionals: a systematic review. *BMC Medical Ethics* 2017;18(1):19. doi: 10.1186/s12910-017-0179-8

33. Hall WJ, Chapman MV, Lee KM, et al. Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systematic Review. *American Journal of Public Health* 2015;105(12):e60-76. doi: 10.2105/AJPH.2015.302903

Authors' contributions

All authors have made substantial contributions to this paper and have satisfied International Committee of Medical Journal Editors (ICMJE) criteria for authorship. BWR and ST supervised all aspects of the protocol design and take responsibility for the paper as a whole. CJT, NKP, and AJM contributed to protocol development, including overall approach, selection criteria, risk of bias assessment strategy, and data extraction strategy. ST developed the search strategy. BWR provided statistical expertise. ST drafted the manuscript. BWR, CJT, NKP, and AJM read and contributed substantially to revision of the final manuscript. All authors approved the manuscript in its final form.

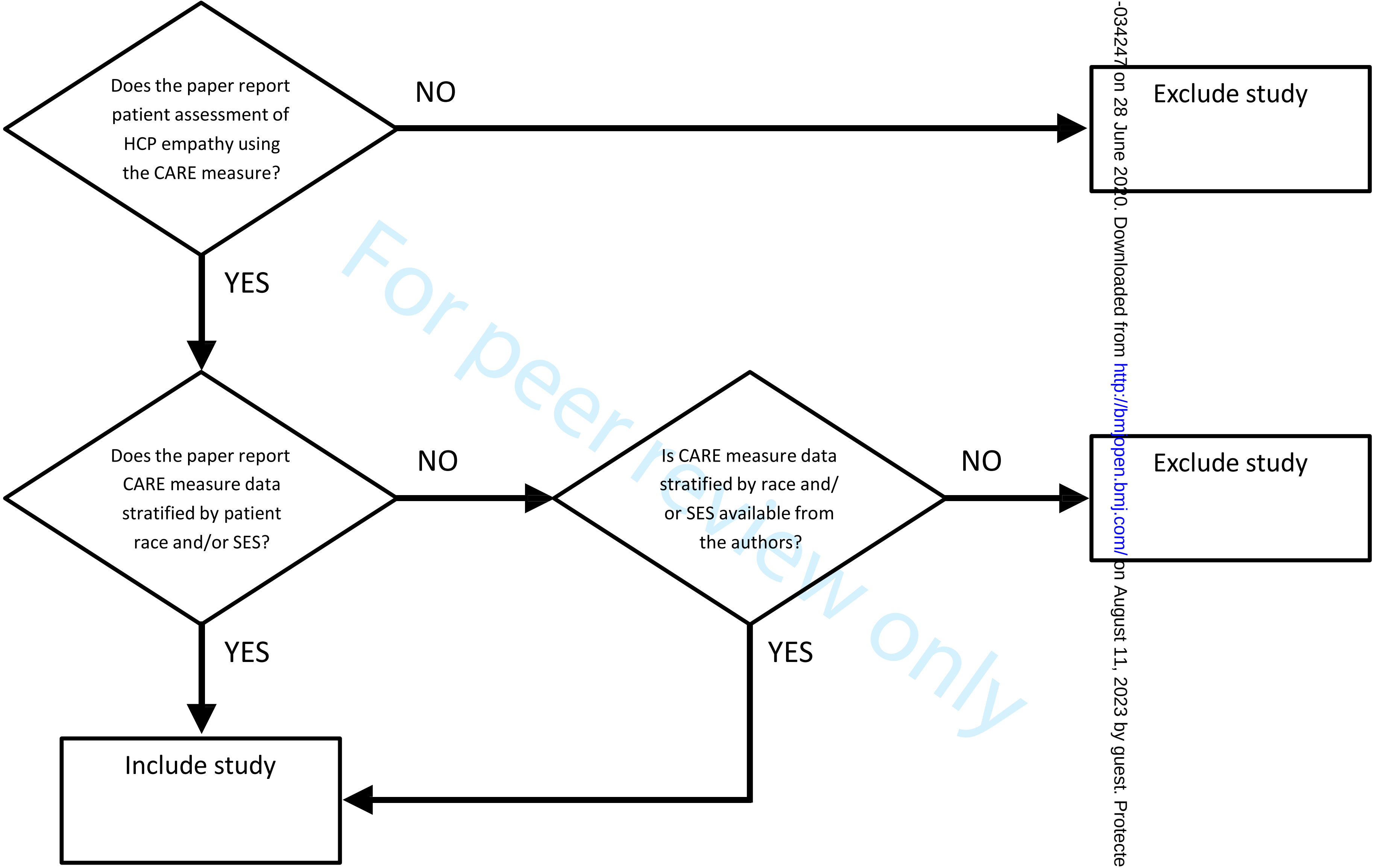
Funding

This research receives no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interest statement

Anthony Mazzarelli and Stephen Trzeciak are authors of a book on compassion science, entitled "Compassionomics". None of the other authors potential competing interests to disclose.

Figure: Inclusion and exclusion of studies



HCP = health care provider; CARE = Consultation and Relational Empathy; SES = socioeconomic status

ONLINE SUPPLEMENTARY MATERIAL

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for systematic review and meta-analysis

Brian W. Roberts, MD, MSc; Christian J. Trzeciak; Nitin K. Puri, MD;
Anthony J. Mazzarelli, MD, JD, MBE; and Stephen Trzeciak, MD, MPH

From Cooper University Health Care and the Center for Humanism at Cooper Medical School
of Rowan University, Camden, New Jersey, USA

For submission to *BMJ Open*

Address for correspondence:
Brian W. Roberts, MD, MSc
Cooper University Hospital
One Cooper Plaza, K152
Camden, New Jersey, USA 08103
roberts-brian-w@cooperhealth.edu

Online Supplementary Material 1: The Consultation and Relational Empathy (CARE) measure. Source: http://www.caremeasure.org/CAREEng.pdf

CARE Patient Feedback Measure for

*** Type name of Practitioner here ***

Please write today's date here:

☐☐ / ☐☐ / ☐☐
D D M M Y Y

Please rate the following statements about today's consultation.

Please mark the box like this ☑ with a ball point pen. If you change your mind just cross out your old response and make your new choice. Please answer every statement.

How good was the practitioner at...	Poor	Fair	Good	Very Good	Excellent	Does not apply
1) **Making you feel at ease** (introducing him/herself, explaining his/her position, being friendly and warm towards you, treating you with respect; not cold or abrupt)	☐	☐	☐	☐	☐	☐
2) **Letting you tell your "story"** (giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you)	☐	☐	☐	☐	☐	☐
3) **Really listening** (paying close attention to what you were saying; not looking at the notes or computer as you were talking)	☐	☐	☐	☐	☐	☐
4) **Being interested in you as a whole person** (asking/knowing relevant details about your life, your situation; not treating you as "just a number")	☐	☐	☐	☐	☐	☐
5) **Fully understanding your concerns** (communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything)	☐	☐	☐	☐	☐	☐
6) **Showing care and compassion** (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")	☐	☐	☐	☐	☐	☐
7) **Being positive** (having a positive approach and a positive attitude; being honest but not negative about your problems)	☐	☐	☐	☐	☐	☐
8) **Explaining things clearly** (fully answering your questions; explaining clearly, giving you adequate information; not being vague)	☐	☐	☐	☐	☐	☐
9) **Helping you to take control** (exploring with you what you can do to improve you health yourself; encouraging rather than "lecturing" you)	☐	☐	☐	☐	☐	☐
10) **Making a plan of action with you** (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)	☐	☐	☐	☐	☐	☐

Comments: If you would like to add further comments on this consultation, please do so here.

4571132878

Online Supplementary Material 2: The PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	(Page No.#)
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	7
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	22
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	11
Support:			
Sources	5a	Indicate sources of financial or other support for the review	22
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7-8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	23
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	9-10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5, 10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9-10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A – not testing intervention

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.

Online Supplementary Material 3: Newcastle-Ottawa Scale for assessment of study quality in observational research

FOR CASE CONTROL STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

1) Is the case definition adequate?
  - a) yes, with independent validation ❋
  - b) yes, eg record linkage or based on self reports
  - c) no description

2) Representativeness of the cases
  - a) consecutive or obviously representative series of cases ❋
  - b) potential for selection biases or not stated

3) Selection of Controls
  - a) community controls ❋
  - b) hospital controls
  - c) no description

4) Definition of Controls
  - a) no history of disease (endpoint) ❋
  - b) no description of source

Comparability

1) Comparability of cases and controls on the basis of the design or analysis
  - a) study controls for socioeconomic status (Select the most important factor.) ❋
  - b) study controls for race ❋ (This criteria could be modified to indicate specific control for a second important factor.)

Exposure

1) Ascertainment of exposure
  - a) secure record (eg surgical records) ❋
  - b) structured interview where blind to case/control status ❋
  - c) interview not blinded to case/control status
  - d) written self report or medical record only
  - e) no description

2) Same method of ascertainment for cases and controls
  - a) yes ❋
  - b) no

3) Non-Response rate
  - a) same rate for both groups ❋
  - b) non respondents described
  - c) rate different and no designation

FOR COHORT STUDIES

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

1) Representativeness of the exposed cohort
    a) truly representative of the average _patient population_ (describe) in the community ❋
    b) somewhat representative of the average _patient population_ in the community ❋
    c) selected group of users eg nurses, volunteers
    d) no description of the derivation of the cohort

2) Selection of the non exposed cohort
    a) drawn from the same community as the exposed cohort ❋
    b) drawn from a different source
    c) no description of the derivation of the non exposed cohort

3) Ascertainment of exposure
    a) secure record (eg surgical records) ❋
    b) structured interview ❋
    c) written self report
    d) no description

4) Demonstration that outcome of interest was not present at start of study
    a) yes ❋
    b) no

Comparability

1) Comparability of cohorts on the basis of the design or analysis
    a) study controls for _socioeconomic status_ (select the most important factor) ❋
    b) study controls for _race_ ❋ (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

1) Assessment of outcome
    a) independent blind assessment ❋
    b) record linkage ❋
    c) self report
    d) no description

2) Was follow-up long enough for outcomes to occur
    a) yes (select an adequate follow up period for outcome of interest) ❋
    b) no

3) Adequacy of follow up of cohorts
    a) complete follow up - all subjects accounted for ❋
    b) subjects lost to follow up unlikely to introduce bias - small number lost - > _10_ % (select an adequate %) follow up, or description provided of those lost) ❋
    c) follow up rate < _10_ % (select an adequate %) and no description of those lost
    d) no statement

BMJ Open

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for systematic review and meta-analysis

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-034247.R2
Article Type:	Protocol
Date Submitted by the Author:	23-Apr-2020
Complete List of Authors:	Roberts, Brian; Cooper University Health Care; Rowan University Cooper Medical School Trzeciak, Christian; Cooper University Health Care Puri, Nitin; Cooper University Health Care; Rowan University Cooper Medical School Mazzarelli, Anthony; Cooper University Health Care; Rowan University Cooper Medical School Trzeciak, Stephen; Cooper University Health Care; Rowan University Cooper Medical School
Primary Subject Heading:	Patient-centred medicine
Secondary Subject Heading:	Public health
Keywords:	Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, SOCIAL MEDICINE

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for systematic review and meta-analysis

Brian W. Roberts, MD, MSc; Christian J. Trzeciak; Nitin K. Puri, MD;
Anthony J. Mazzarelli, MD, JD, MBE; and Stephen Trzeciak, MD, MPH

From Cooper University Health Care and the Center for Humanism at Cooper Medical School of Rowan University, Camden, New Jersey, USA

For submission to *BMJ Open*

Address for correspondence:
Brian W. Roberts, MD, MSc
Cooper University Hospital
One Cooper Plaza, K152
Camden, New Jersey, USA 08103

Email addresses of the authors:
roberts-brian-w@cooperhealth.edu
christian.j.trzeciak@gmail.com
puri-nitin@cooperhealth.edu
mazzarelli-anthony@cooperhealth.edu
trzeciak-stephen@cooperhealth.edu

Word count: 2477

Abstract

Introduction: Clinician empathy is a vital component of high quality health care. Health care disparities may reflect a societal lack of empathy for disadvantaged persons in general, and recent research suggests that socioeconomic disparities exist in patient satisfaction with clinicians. However, it is currently unclear if there are disparities in patient experience of empathy from clinicians. Our objective is to systematically analyze the scientific literature to test the hypothesis that racial and socioeconomic status (SES) disparities exist in patient-reported experience of clinician empathy.

Methods and analysis: In accordance with published methodological guidelines for conducting a systematic review, we will analyze studies reporting patient assessment of clinician empathy using the Consultation and Relational Empathy (CARE) measure, which to date is the most commonly used and well-validated methodology in clinical research for measuring clinician empathy from the patient perspective. We will use a standardized data collection template and assess study quality (risk of bias) using the Newcastle-Ottawa Scale. We will abstract data for the CARE measure stratified by race and SES, and we will contact the corresponding authors to obtain race/SES stratified data if not reported in the original manuscript. Where appropriate, we will pool the data and perform quantitative meta-analysis to test if non-white (compared to white) patients and low SES (compared to high SES) patients report lower scores for clinician empathy.

Ethics and dissemination: No individual patient level data will be collected and thus the proposed systematic review does not require ethical approval. This systematic review will test if racial and SES differences exist in patient experience of clinician empathy, and will inform future research to help promote health care equity.

Registration: PROSPERO international prospective register of systematic reviews (CRD42019142809)

Abstract word count: 280

Keywords: empathy, compassion, patient experience, patient satisfaction, health care, health care quality, health care disparities, health care equity, discrimination, bias.

Strengths:

- Rather than testing for racial and socioeconomic status (SES) differences in patient satisfaction in general, this protocol focuses specifically on racial/SES differences in patient-reported experience of clinician empathy.
- This protocol was developed in accordance with published methodological guidelines in the Cochrane Handbook for systematic reviews, and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement.

Limitations:

- This protocol is restricted to studies of the Consultation and Relational Empathy (CARE) measure, to date the most commonly used and well-validated methodology to assess clinician empathy from the patient perspective. Other less frequently employed measures will be excluded in order to reduce heterogeneity and permit pooling of data.
- Data on race of the clinicians, and racial concordance/discordance between patients and clinicians, is unlikely to be available. Thus secondary analyses of the potential effect of in-group/out-group bias will not be possible.

Introduction

Empathy is the ability to sense and understand the emotions of another person, resonate with their thoughts and feelings, and share their perspective. In health care, empathy is conceptualized as a communication competency for clinicians – an emotional bridge that facilitates helping behaviors (i.e. compassionate care for patients).[1] There is broad agreement among patients and clinicians, as well as health care leaders and educators, that empathy is a vital component of health care quality. Abundant evidence in the scientific literature shows that clinician empathy for patients is associated with better outcomes for patients across a multitude of clinical conditions.[2-14]

Health care disparities refer to differences in the quality of health care between population groups, e.g. race or ethnicity, socioeconomic status (SES), age, gender, disability status, or sexual orientation. These inequalities are often linked with socioeconomic disadvantage, and cannot be explained by variation in health needs, patient preferences, or treatment recommendations. In the broad sense, all health care disparities may reflect a societal lack of empathy for disadvantaged persons. These include system-level factors (e.g. barriers to accessing health care), but also include disparities at the point of care due to clinician bias (usually implicit or unconscious bias) possibly manifesting as a lack of empathy for individual patients.[1 15 16] Evidence-based examples at the point of care include: inadequate administration of analgesia for non-white patients with painful conditions,[17 18] inappropriately low use of cardiac catheterization for non-white patients with possible acute myocardial infarction,[19] and clinician assumption that non-white patients will have poor adherence to treatment recommendations,[20] among many others. In addition, recent data indicate that SES differences exist in patient satisfaction with clinicians.[21] However, it is currently unclear if racial and SES disparities exist in patient experience of clinician empathy, specifically.

In clinical research, the most commonly used and well-validated methodology (i.e. proven reliability, internal validity and consistency[22]) for measuring patient assessment of clinician empathy is the Consultation and Relational Empathy (CARE) measure.[23 24] The specific questions comprising the CARE measure are available online from the creators,[23] and are shown in **Online Supplementary Material 1**. Briefly, the CARE measure is a patient assessment of the empathy of a clinician, including: listening and understanding, showing care and compassion, and being interested in the patient as a whole person.

Our objective is to perform a systematic review and meta-analysis of all studies published in the scientific literature that contain data for patient-reported experience of clinician empathy using the CARE measure. Our hypothesis is that racial and SES disparities exist in patient-reported experience of clinician empathy. Specifically, our hypothesis is that non-white (compared to white) patients and low SES (compared to high SES) patients report lower empathy from clinicians.

Methods and analysis

Protocol and registration

This systematic review protocol was registered and published in PROSPERO, the international prospective register of systematic reviews (CRD42019142809). This protocol was designed in accordance with published methodological guidelines in the Cochrane Handbook for systematic reviews,[25] and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement (**Online Supplemental Material 2**).[26]

Eligibility criteria

We will consider any clinical study where patients rated their clinicians' empathy using the CARE measure eligible for potential inclusion. Although we expect the vast majority of studies will be observational designs (e.g. cohort studies), we will also include interventional studies (e.g. clinical trials) if patient ratings of the CARE measure are reported. We will exclude studies that (a) do not contain data for patient-reported assessment of clinician empathy using the CARE measure, and (b) do not provide CARE measure data stratified by race/SES (including attempts to contact corresponding authors to obtain stratified data, when necessary). The **Figure** displays this approach to inclusion and exclusion of studies.

We will consider studies eligible for review regardless of language, provided that translation of the CARE measure was validated in that language. We will exclude studies that are secondary reports of previously published studies. We also will exclude papers that are reviews, correspondence, or editorials.

Search strategy and identification of studies

We will search the following databases from December 1, 2004 (date of first publication of the CARE measure[24]) until present: MEDLINE, CINAHL, EMBASE, CENTRAL, PsycINFO, PubMed, and Google Scholar. We will not search the grey literature, on the grounds that we only want to include published research. We will use the following search terms adopted from another systematic review of the CARE measure previously published (2016) by Howick[22] and colleagues:

MEDLINE (and adapted for other databases)

1. "consultation and relational empathy".mp.
2. (CARE adj3 (measure* or question* or index*)).ti,ab. and empath*.mp.
3. (CARE adj3 (measure* or question* or index*)).ti,ab. and mercer.af.
4. 1 or 2 or 3

We consulted with a health librarian / information specialist who confirmed that this search strategy is methodologically sound.

Study selection and data abstraction

Two members of the research team will independently screen the titles and abstracts of identified studies for potential eligibility. After the relevance screen, exclusion logs will be compared between the two reviewers in order to determine whether there is disagreement and the Kappa statistic will be used to quantify the interobserver agreement. In cases of disagreement, the full manuscript will be reviewed for inclusion. All studies deemed potentially relevant will be obtained and the full manuscripts will be reviewed for inclusion. Two reviewers will independently abstract data using a standardized data collection form. Any disagreements in these processes will be resolved by consensus with a third reviewer.

We will abstract from each manuscript: (1) country of origin; (2) clinical context (e.g. primary care); (3) total number of patients; (4) number of patients stratified by race; (5) definition of low SES used (if applicable); (6) number of patients stratified by SES; (7) CARE measure data stratified by race; (8) CARE measure data stratified by SES. We will abstract data for the CARE measure stratified by race and SES in the following format: mean, standard deviation (SD), and sample size (n). For studies that report stratified data in another format, we will contact the corresponding author and request the data in the format above. For SES stratification, we will adopt the definition of low SES utilized in each of the studies.

We will collect both race and ethnicity information, as described in the manuscripts, for all patients enrolled in the identified studies. If clarification is needed, including clarification for combining data for populations according to race or ethnicity, we will send queries to the corresponding authors. This systematic review will use the race/ethnicity categories typically used for human subjects research sponsored by the United States National Institutes of Health.[27]

We will use EndNote X9 (Clarivate Analytics, Philadelphia, PA) for reference management and Google Sheets (Google, Mountain View, CA) for data extraction and management.

Assessment of risk of bias

We will assess the quality of observational studies using the Newcastle-Ottawa Scale[28] for assessing methodological quality and risk of bias in observational studies as recommended in the Cochrane Handbook.[29] Briefly, the scale assesses quality and risk of bias in multiple domains, such as representativeness of the cohort, ascertainment of the exposure and outcome, and completeness of follow-up. For any interventional studies included, we will assess risk of bias using the Cochrane Collaboration’s tool for assessing risk of bias in clinical trials.[25]

Analysis

We will begin with a qualitative analysis of the data in accordance with the recommended methodology for qualitative reviews published in the Cochrane Handbook.[25] We will collate and summarize studies in table format, stratified by individual publication. We will also perform a quantitative analysis of pooled data, where possible. We will only perform quantitative analysis for studies that have sufficient diversity in race/SES in the patient population (defined as no single race/SES group comprising >90% of the study population), on the grounds that heterogeneous populations are needed to detect differences between race/SES groups. Where the CARE measure data can be pooled, we will use a meta-analytic approach to analysis. We will use separate random effects models to calculate pooled effect sizes and corresponding 95% confidence intervals (CIs) for non-white versus white patients, as well as low SES versus high SES patients. We will generate overall effect estimates using a z-test, and present the data as mean differences. We will also analyze for possible interaction between race and SES, where possible, by comparing CARE measure scores between SES categories stratified by race.

We also plan to analyze the data restricted to high quality studies only, e.g. four or more stars on the Newcastle-Ottawa Scale as described above. Given that there are 40 potential outcomes for the CARE measure (potential score range 10-50), we believe that calculating a proportional odds ratio would be inappropriate, and instead we will treat the CARE measure as a continuous variable.

We will use the I^2 statistic to assess heterogeneity between studies. The following thresholds will be used for the I^2 statistic: low (25-49%), moderate (50-74%), and high (≥75%).[30] For pooled data, we will assess publication bias using funnel plots (graphical display of the size of the effect of race/SES on the CARE measure against the precision of the study).

We will use Stata 16 (StataCorp, College Station, TX) for all analyses.

Protocol amendments

Any amendments to this protocol will be described in the subsequent manuscript, along with the rationale for the amendment and the date that the change was implemented.

Patient and Public Involvement

Our study design was informed by the fact that previous research has demonstrated that empathy is considered by patients to be one of the most important aspects of high quality health care.[1 31] Patients were not involved in the actual design of this study. Given this is a systematic review of previously published research, patients will not be enrolled in this study.

Ethics and dissemination

This is a systematic review of completed studies published in the public domain, and thus ethical (e.g. Institutional Review Board) approval will not be required. The results from this systematic review will be submitted for publication to a peer-reviewed journal, and to national scientific meetings in presentation form. We anticipate that this study will help determine if racial and socioeconomic disparities exist in clinician empathy, as assessed by patients. The results from this study will be used to inform future research to help promote health care equity.

Discussion

The aim of this research is to test the hypothesis that measurable racial and SES disparities exist in patient-reported experience of clinician empathy (i.e. an empathy “gap”). To test this hypothesis, the proposed systematic review will collate and quantitatively analyze all of the published data for the CARE measure, which is the most commonly used and well-validated methodology in clinical research to assess clinician empathy from the patient perspective.[22] Although a societal lack of empathy for disadvantaged persons may underlie any institutionalized discrimination leading to health care disparities, we have equipoise about the hypothesis proposed above, which pertains to empathy for individual patients, on the following grounds.

First, the foundation of the relationship between clinicians and their patients is supposed to be a special, inviolable trust that racial/SES bias should never infringe upon. For example, the World Medical Association Declaration of Geneva, which is a physician’s pledge upon entering the medical profession commonly recited at medical school graduation ceremonies, explicitly prohibits *“considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient.”*[32] Although bias is pervasive in society, clinicians have a duty to treat all patients the same. This duty includes empathy for patients. Second, clinicians may consciously put forth extra effort to treat disadvantaged persons with empathy (i.e. most inclined to show empathy to those who need it the most). Thus, disadvantaged persons may experience equal (or more) empathy from clinicians, not less.

However, there is also sound rationale for why an empathy gap could exist, despite clinicians' duty to be unbiased in the care of patients. Racial/SES bias in health care is commonly implicit bias (also termed implicit association or unconscious bias), not intentional. Although clinicians may be reluctant to accept that they may treat patients of different backgrounds differently, there are abundant data that implicit bias is common and could affect clinician empathy for patients.[33] [34] This underscores the need for research such as the systematic review proposed here, in order to examine what patients experience from clinicians (i.e. the patient perspective).

The strengths of this protocol design include its uniqueness. Rather than testing for racial/SES differences in patient satisfaction in general, this systematic review will focus specifically on racial/SES differences in patient-reported experience of clinician empathy. We are not aware of any prior systematic reviews that have specifically tested this hypothesis, and finding disparities in clinician empathy would have important public health implications, as clinician empathy is vital for high quality health care.

This protocol design also has important limitations to consider. The first is that we must restrict the review to only include studies using the CARE measure, rather than also including less frequently employed empathy measures, on the grounds that a quantitative analysis requires a single measure approach. However, this potential concern is attenuated by the facts that the CARE measure is the most commonly used assessment of clinician empathy from the patient perspective in clinical research, and the CARE measure is the only patient-reported empathy assessment with demonstrated reliability, internal validity, and consistency.[22] We also acknowledge that data on race of the clinicians, and racial concordance/discordance between patients and clinicians, is unlikely to be available. Thus, secondary analyses of the potential effect of in-group/out-group bias will not be possible. This protocol also will not test if there are racial or SES differences in patient expectations for clinician empathy. We also acknowledge that factors that covary with race, e.g. SES, may explain any racial differences found in the CARE measure. For this reason, we will analyze the interaction between race and SES, where possible.

Because individual patient level data will not be collected, we will not be able to establish our own uniform definition of low SES, and instead we will rely on the definition that the authors used in each individual study. We also acknowledge that we will not be able to make a distinction between clinician empathy for patients and their effectiveness with empathic communication to patients, which may differ.

Lastly, we acknowledge that some of the studies may not be conducted in racially and SES diverse communities and thus testing for an empathy gap may not be possible; however, this in itself would be an important finding as it would justify further research in this area.

In conclusion, this protocol design for a rapid systematic review is an initial step in determining if racial and socioeconomic disparities exist in clinician empathy from the patient perspective. We will use the results from this systematic review to inform future research aimed to promote health care equity.

References

1. Riess H. The Science of Empathy. *Journal of Patient Experience* 2017;4(2):74-77. doi: 10.1177/2374373517699267

2. Attar HS, Chandramani S. Impact of physician empathy on migraine disability and migraineur compliance. *Annals of Indian Academy of Neurology* 2012;15(Suppl 1):S89-94. doi: 10.4103/0972-2327.100025

3. Burns DD, Nolen-Hoeksema S. Therapeutic empathy and recovery from depression in cognitive-behavioral therapy: a structural equation model. *Journal of Consulting and Clinical Psychology* 1992;60(3):441-9.

4. Del Canale S, Louis DZ, Maio V, et al. The relationship between physician empathy and disease complications: an empirical study of primary care physicians and their diabetic patients in Parma, Italy. *Academic Medicine* 2012;87(9):1243-9. doi: 10.1097/ACM.0b013e3182628fbf

5. Flickinger TE, Saha S, Roter D, et al. Clinician empathy is associated with differences in patient-clinician communication behaviors and higher medication self-efficacy in HIV care. *Patient Education and Counseling* 2016;99(2):220-6. doi: 10.1016/j.pec.2015.09.001

6. Hojat M, Louis DZ, Markham FW, et al. Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine* 2011;86(3):359-64. doi: 10.1097/ACM.0b013e3182086fe1

7. Hollinger-Samson N, Pearson JL. The relationship between staff empathy and depressive symptoms in nursing home residents. *Aging & Mental Health* 2000;4(1):56-65. doi: 10.1080/13607860055982

8. Kim SS, Kaplowitz S, Johnston MV. The effects of physician empathy on patient satisfaction and compliance. *Evaluation & the Health Professions* 2004;27(3):237-51. doi: 10.1177/0163278704267037

9. Lelorain S, Bredart A, Dolbeault S, et al. A systematic review of the associations between empathy measures and patient outcomes in cancer care. *Psycho-oncology* 2012;21(12):1255-64. doi: 10.1002/pon.2115

10. Mercer SW, Jani BD, Maxwell M, et al. Patient enablement requires physician empathy: a cross-sectional study of general practice consultations in areas of high and low socioeconomic deprivation in Scotland. *BMC Family Practice* 2012;13:6. doi: 10.1186/1471-2296-13-6

11. Pereira L, Figueiredo-Braga M, Carvalho IP. Preoperative anxiety in ambulatory surgery: The impact of an empathic patient-centered approach on psychological and clinical outcomes. *Patient Education and Counseling* 2016;99(5):733-8. doi: 10.1016/j.pec.2015.11.016

12. Rakel DP, Hoeft TJ, Barrett BP, et al. Practitioner empathy and the duration of the common cold. *Family Medicine* 2009;41(7):494-501.

13. Steinhausen S, Ommen O, Antoine SL, et al. Short- and long-term subjective medical treatment outcome of trauma surgery patients: the importance of physician empathy. *Patient Preference and Adherence* 2014;8:1239-53. doi: 10.2147/PPA.S62925

14. West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. *JAMA* 2006;296(9):1071-8. doi: 10.1001/jama.296.9.1071

15. Kaiser Family Foundation. Disparities in health and health care [Available from: https://www.kff.org/disparities-policy/issue-brief/disparities-in-health-and-health-care-five-key-questions-and-answers/]

16. Centers for Disease Control and Prevention. Social determinants of health: Definitions [Available from: https://www.cdc.gov/nchhstp/socialdeterminants/definitions.html]

17. Tamayo-Sarver JH, Hinze SW, Cydulka RK, et al. Racial and ethnic disparities in emergency department analgesic prescription. *American Journal of Public Health* 2003;93(12):2067-73. doi: 10.2105/ajph.93.12.2067

18. Todd KH, Samaroo N, Hoffman JR. Ethnicity as a risk factor for inadequate emergency department analgesia. *JAMA* 1993;269(12):1537-9.

19. Schulman KA, Berlin JA, Harless W, et al. The effect of race and sex on physicians' recommendations for cardiac catheterization. *The New England Journal of Medicine* 1999;340(8):618-26. doi: 10.1056/NEJM199902253400806

20. van Ryn M, Burke J. The effect of patient race and socio-economic status on physicians' perceptions of patients. *Social Science & Medicine* 2000;50(6):813-28.

21. Okunrintemi V, Khera R, Spatz ES, et al. Association of Income Disparities with Patient-Reported Healthcare Experience. *Journal of General Internal Medicine* 2019;34(6):884-92. doi: 10.1007/s11606-019-04848-4

22. Howick J, Steinkopf L, Ulyte A, et al. How empathic is your healthcare practitioner? A systematic review and meta-analysis of patient surveys. *BMC Medical Education* 2017;17(1):136. doi: 10.1186/s12909-017-0967-3

23. Mercer SW. The CARE Measure: Scottish Government Chief Scientist Office; [Available from: http://www.caremeasure.org/CAREEng.pdf]

24. Mercer SW, Maxwell M, Heaney D, et al. The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure. *Family Practice* 2004;21(6):699-705. doi: 10.1093/fampra/cmh621

25. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions, version 6.0 [updated July

2019]: The Cochrane Collaboration 2019. Available at: https://training.cochrane.org/handbook.

26. Shamseer L, Moher D, Clarke M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. *BMJ* 2015;350:g7647. doi: 10.1136/bmj.g7647
27. National Institutes of Health. Race/ethnicity inclusion enrollment report [Available from: https://grants.nih.gov/grants/funding/2590/enrollmentreport.pdf]
28. Wells GA, Shea B, O'Connell D, et al. The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses [Available from: http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp]
29. Higgins JPT, Green S. Tools for assessing methodological quality or risk of bias in non-randomized studies (section 13.5.2.3). In: Higgins JPT, Green S, eds. Cochrane Handbook for Systematic Reviews of Interventions version 5.10, updated March 2011: The Cochrane Collaboration 2011.
30. Higgins JP, Thompson SG. Quantifying heterogeneity in a meta-analysis. *Statistics in Medicine* 2002;21(11):1539-58. doi: 10.1002/sim.1186
31. Sinclair S, Norris JM, McConnell SJ, et al. Compassion: a scoping review of the healthcare literature. *BMC Palliative Care* 2016;15:6. doi: 10.1186/s12904-016-0080-0
32. World Medical Association. Declaration of Geneva 1948 [Available from: https://www.wma.net/policies-post/wma-declaration-of-geneva/]
33. FitzGerald C, Hurst S. Implicit bias in healthcare professionals: a systematic review. *BMC Medical Ethics* 2017;18(1):19. doi: 10.1186/s12910-017-0179-8
34. Hall WJ, Chapman MV, Lee KM, et al. Implicit Racial/Ethnic Bias Among Health Care Professionals and Its Influence on Health Care Outcomes: A Systematic Review. *American Journal of Public Health* 2015;105(12):e60-76. doi: 10.2105/AJPH.2015.302903

Authors' contributions

All authors have made substantial contributions to this paper and have satisfied International Committee of Medical Journal Editors (ICMJE) criteria for authorship. BWR and ST supervised all aspects of the protocol design and take responsibility for the paper as a whole. CJT, NKP, and AJM contributed to protocol development, including overall approach, selection criteria, risk of bias assessment strategy, and data extraction strategy. ST developed the search strategy. BWR provided statistical expertise. ST drafted the manuscript. BWR, CJT, NKP, and AJM read and contributed substantially to revision of the final manuscript. All authors approved the manuscript in its final form.

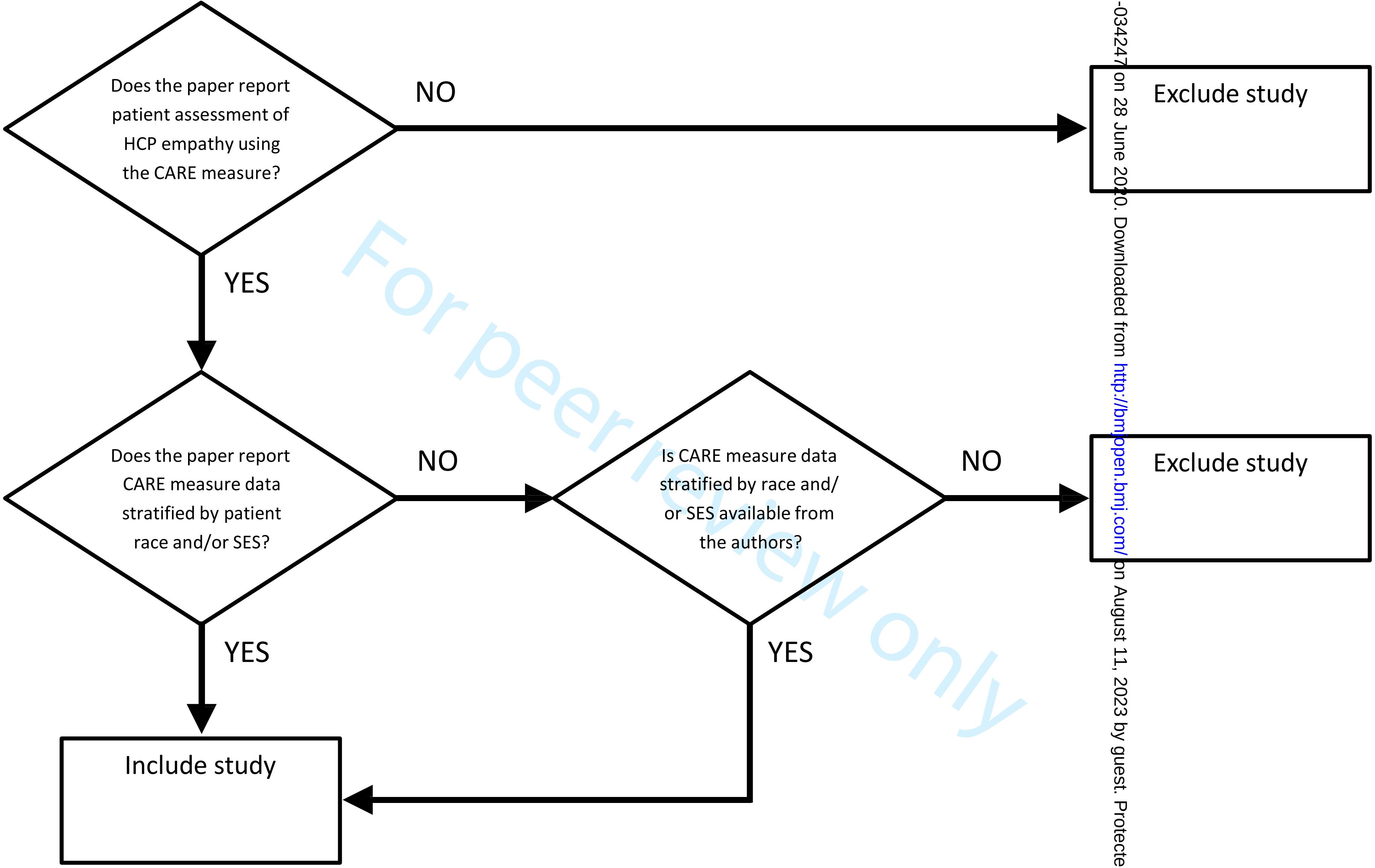
Funding

This research receives no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interest statement

Anthony Mazzarelli and Stephen Trzeciak are authors of a book on compassion science, entitled “Compassionomics”. None of the other authors potential competing interests to disclose.

Figure: Inclusion and exclusion of studies



HCP = health care provider; CARE = Consultation and Relational Empathy; SES = socioeconomic status

ONLINE SUPPLEMENTARY MATERIAL

Racial and socioeconomic disparities in patient experience of clinician empathy: a protocol for systematic review and meta-analysis

Brian W. Roberts, MD, MSc; Christian J. Trzeciak; Nitin K. Puri, MD;
Anthony J. Mazzarelli, MD, JD, MBE; and Stephen Trzeciak, MD, MPH

From Cooper University Health Care and the Center for Humanism at Cooper Medical School of Rowan University, Camden, New Jersey, USA

For submission to *BMJ Open*

Address for correspondence:
Brian W. Roberts, MD, MSc
Cooper University Hospital
One Cooper Plaza, K152
Camden, New Jersey, USA 08103
roberts-brian-w@cooperhealth.edu

Online Supplementary Material 1: The Consultation and Relational Empathy (CARE) measure. Source: http://www.caremeasure.org/CAREEng.pdf

CARE Patient Feedback Measure for

*** Type name of Practitioner here ***

Please write today's date here:

☐☐ / ☐☐ / ☐☐
D D M M Y Y

Please rate the following statements about today's consultation.

Please mark the box like this ☑ with a ball point pen. If you change your mind just cross out your old response and make your new choice. Please answer every statement.

How good was the practitioner at...	Poor	Fair	Good	Very Good	Excellent	Does not apply
1) Making you feel at ease (introducing him/herself, explaining his/her position, being friendly and warm towards you, treating you with respect; not cold or abrupt)	☐	☐	☐	☐	☐	☐
2) Letting you tell your "story" (giving you time to fully describe your condition in your own words; not interrupting, rushing or diverting you)	☐	☐	☐	☐	☐	☐
3) Really listening (paying close attention to what you were saying; not looking at the notes or computer as you were talking)	☐	☐	☐	☐	☐	☐
4) Being interested in you as a whole person (asking/knowing relevant details about your life, your situation; not treating you as "just a number")	☐	☐	☐	☐	☐	☐
5) Fully understanding your concerns (communicating that he/she had accurately understood your concerns and anxieties; not overlooking or dismissing anything)	☐	☐	☐	☐	☐	☐
6) Showing care and compassion (seeming genuinely concerned, connecting with you on a human level; not being indifferent or "detached")	☐	☐	☐	☐	☐	☐
7) Being positive (having a positive approach and a positive attitude; being honest but not negative about your problems)	☐	☐	☐	☐	☐	☐
8) Explaining things clearly (fully answering your questions; explaining clearly, giving you adequate information; not being vague)	☐	☐	☐	☐	☐	☐
9) Helping you to take control (exploring with you what you can do to improve you health yourself; encouraging rather than "lecturing" you)	☐	☐	☐	☐	☐	☐
10) Making a plan of action with you (discussing the options, involving you in decisions as much as you want to be involved; not ignoring your views)	☐	☐	☐	☐	☐	☐

Comments: If you would like to add further comments on this consultation, please do so here.

4571132878

Online Supplementary Material 2: The PRISMA-P checklist

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	(Page No.#)
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	7
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	22
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	11
Support:			
Sources	5a	Indicate sources of financial or other support for the review	22
Sponsor	5b	Provide name for the review funder and/or sponsor	
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	4-5
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	8
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	7-8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	23
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	9
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	9
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	9
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	9-10
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5, 10
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	9-10
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	10-11
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	11
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A – not testing intervention

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.