Evidence-based Practice Center Systematic Review Protocol

Project Title: Improving Cultural Competence to Reduce Health Disparities for Priority Populations

I. Background and Objectives for the Systematic Review

Reducing health disparities and achieving equitable health care remains an important goal for the U.S. healthcare system. Cultural competence is widely seen as a foundational pillar for reducing disparities through culturally sensitive and unbiased quality care. Culturally competent care is defined as care that respects diversity in the patient population and cultural factors that can affect health and health care, such as language, communication styles, beliefs, attitudes, and behaviors.[1] The Office of Minority Health, Department of Health and Human Services, established national standards for culturally and linguistically appropriate services in health and health care (National CLAS Standards) to provide a blueprint to implement such appropriate services to improve health care in the U.S.[2] The standards cover areas such as governance, leadership, workforce; communication and language assistance; organizational engagement, continuous improvement, and accountability.

A lack of conceptual clarity around cultural competence persists in the field and the research community. There is confusion about what cultural competence means, and different ways in which it is conceptualized and operationalized. This confusion leads to disagreement regarding the topic areas and practices in which a provider should train to attain cultural competence.[3] The populations to which the term cultural competence applies are also ill-defined. Cultural competence is often seen as encompassing only racial and ethnic differences, omitting other marginalized population groups who are ethnically and racially similar to a provider but who are at risk for stigmatization or discrimination, are different in other identities, or have differences in healthcare needs that result in health disparities. This broader concept may be termed diversity competence. In keeping with this broader view and AHRQ's commitment to a comprehensive approach to priority populations, this systematic literature review considers, alongside race and ethnicity, two of these less considered populations: persons with disabilities and persons identifying as lesbian, gay, bisexual, transgender, queer/questioning, and/or intersex (LGBTQI).

The most popular and most well studied type of cultural competence intervention is cultural competency training for healthcare providers. Two general approaches have been used in creating educational interventions to address cultural competence: programs aimed at improving knowledge that is group-specific, and programs that apply generic or universal models. Concerns have been raised about cultural competency programs that use a group-specific approach to teach providers about the attitudes, values, and beliefs of a specific cultural group leading to stereotyping and oversimplifying the diversity within a particular priority group.[4] The universal approach to training proposes that cultural competence can be taught through reflective awareness, empathy, active listening techniques, and the cognitive mechanisms contributing to cultural insensitivity or

blindness, such as implicit biases or stereotype threats. Therefore, of interest is identifying the effect of varying types of cultural competence training on patient-level outcomes.

In addition to education and training, changing clinical environments can also be key to purposeful change in behavior. The National CLAS includes several standards that address the organizational level rather than the patient/provider relationship.[1] Changes in provider knowledge, attitudes, and skills is a necessary step, but for those gains to translate into culturally competent behaviors there also needs to be changes in the structures and culture of health care systems and organizations. This review is intended to focus on the effectiveness of interventions and the provider and system level, but not at the level of policy which, while important, is beyond the scope of this review.

What outcomes are considered high priority and final patient-centered outcomes differ by priority population. For example, while access is important to all priority populations, people from the disability culture may face multiple levels or forms of access barriers, such as transportation to facilities and whether the exam room and its contents is physically accessible. Similarly, linguistic competence means something different to a provider treating a person for whom English is a second language than to a provider treating a transgendered person.

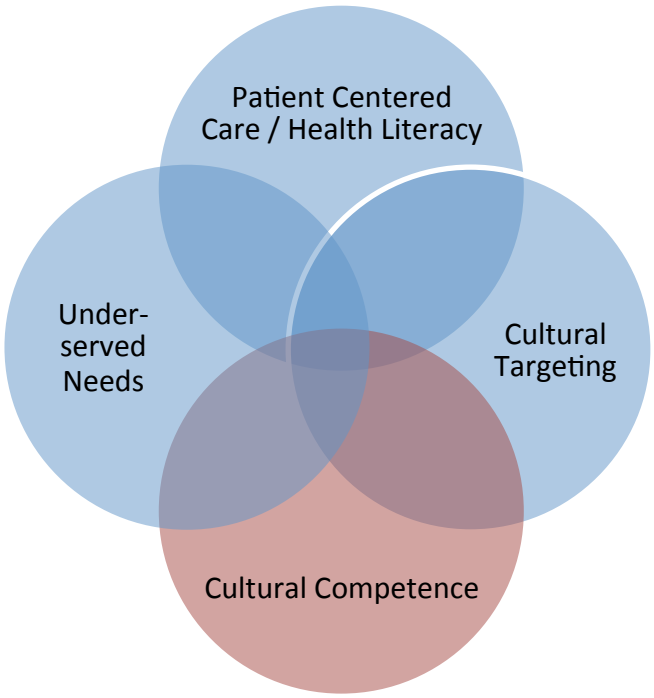
Comparative effectiveness reviews evaluate the evidence for both benefits and harms, or adverse effects, of interventions in order to provide decisionmakers with the balance of net benefits. In the case of cultural competence interventions, harms may include unintended consequences of an intervention. For example, while cultural competence interventions often aim to improve cultural sensitivity by reducing stereotyping and stigma, there remains the possibility that some interventions may inadvertently induce different stereotyping behaviors by inducing a provider to create new scripts, or ways of categorizing people, that result in negative consequences.

The review was requested by Senior Advisors in AHRQ's Division of Priority Populations. The request originally derived from general concerns regarding pervasive disparities in care for adults and children that may be associated with gender, disability and race/ethnicity. In addition, the consideration of cultural competence is usually focused on racial or ethnic minority adults, thus creating a gap in evidence-based information in racial or ethnic minority children, persons with disabilities, and LGBTQI people. This systematic literature review will consider the effect of cultural and diversity competence interventions on three populations with varying degrees of cultural identification and visibility: LGBTQI adolescents and adults, children and adults aging with disabilities, and racial/ethnic minority children and adults.

As noted previously, cultural competence is challenging to isolate as a concept. The concept of cultural competence overlaps with several other concepts related to providing high-quality, appropriate care. Figure 1 provides an illustration of a few of these overlapping concepts. When conducting systematic review, clarity in discriminating between interventions within the scope of cultural competence versus those outside is important. The review's main focus is on whether cultural competency interventions change the clinicians' behaviors (such as communication and clinical decisionmaking), the patient-provider relationship, and/or clinical systems to result in better outcomes for patients from the priority populations. Some public health outreach activities, (such as community-based HIV education in underserved, African American neighborhoods or

school-based empowerment programs for young people with disabilities), may address an unmet need. However, such studies will not be included in this review, as our focus is on the patient-provider interaction and the system of care surrounding that interaction. Within the clinical context, interventions aimed at improving care for all patients (such as patient-centered care, patient-centered medical home, health literacy), are excluded unless the intervention is specifically tailored to one of the populations of interest in this review. Because patients are also participants in the system, interventions at the provider or system level that help patients competently navigate the patient-provider relationship and/or the health system are also of interest. This review is focused on interventions that promote equity, the primary outcomes of interest are reductions in disparities between populations for a given health outcome measure.

Figure 1. Health services research concepts that overlap with cultural competence



Includable interventions that lie within the Cultural Competence circle in Figure 1 are defined as:

- "People first" care interventions that promote "individuation." These interventions prompt providers to make a conscious effort to view people in terms of their individual characteristics rather than group membership, and being aware of one's own biases and stereotypes. The interventions can also take place at the system level, engineering a system that promotes providing needed care universally, such as equitable receipt of preventive or chronic disease management.
- Cultural competence interventions that improve the ability of providers to provide health care services to patients who are unlike the providers (or the providers' culture) in important ways. Targeted providers in such cases can include physicians, nursing staff, allied health professionals,

paraprofessionals, and clinic staff who have regular contact with patients, or health system factors intended to engineer the system to support and sustain cultural competence.
- Interventions that assist patients from priority populations to competently navigate the patient-provider relationship and the larger health system
- Interventions that address physical barriers to access.
- Interventions that educate providers about, and to look for, the common secondary conditions specific to the target populations. For example, people with disabilities commonly experience an identifiable set of health conditions secondary to the disability such as urinary tract infections, asthma, obesity, hypertension, and pressure ulcers.[5]

As the overlapping circles in Figure1 suggest, there are also interventions encompassed in meeting underserved needs that are not within the scope of this review, such as interventions to address access problems due to finance/insurance coverage issue (such as Medicare/Medicaid), and general health literacy interventions.

II. The Key Questions

Key questions, PICOT, and analytic framework were posted for public comment from February 6, 2014 to February 26, 2014. In response to comments provided, we made several changes. Outcomes of interest were expanded and specified for each priority population. Young adults/transitional aged youth were added to the LGBTQI population as a subgroup of interest. Key Question 5 was rewritten to better fit systematic review methods focused on interventions targeted at the organization and structure level, which can include the built environment.

Question 1: What models have been used to conceptualize cultural competence and culturally appropriate care in health contexts, and how do those models compare?

Question 2: What is the effectiveness of interventions to improve culturally appropriate care for LGBTQI adolescents (ages 13-17), young adult (18-25), and adults?

A. Provider intermediate outcomes
    - Provider training and motivation outcomes, such as post-test competencies, knowledge, changes in attitudes
    - Provider beliefs/cognitions about the priority population, such as reducing stereotyping and stigmatization
    - Improved specific knowledge of health needs unique to LGBTQI community
    - Provider behavior, such as clinical decision-making, communication
B. Patient intermediate outcomes
    - Patient learning/knowledge, including linguistic competence regarding gender-diversity
    - Improved access to health services
    - Utilization of health services
    - Patient experience and satisfaction, such as improved perceptions of care
    - Patient health behaviors, such as tobacco use or health seeking behaviors

- Use of preventive services

C. Final health or patient-centered health outcomes, including but not limited to:
    - Improved mental health outcomes, such as depression, anxiety, suicidality, peer/familial/intimate relationships, substance use
    - Improved medical health outcomes, such as reduction in obesity, improved sexual health

D. Adverse events; unintended negative consequences of intervention

Question 3: What is the effectiveness of interventions to improve culturally appropriate health care for children and adults with disabilities?

A. Provider intermediate outcomes
    - Provider training and motivation outcomes, such as post-test competencies, knowledge, changes in attitudes, willingness to serve and perceived competence in service people with disabilities
    - Provider behavior, such as clinical decision-making, communication
    - Provider beliefs/cognitions the priority population, such as reducing stereotyping and stigmatization

B. Patient intermediate outcomes
    - Improved access to health services
    - Utilization of health services
    - Patient experience and satisfaction, such as improved perceptions of care

C. Final health or patient-centered health outcomes, including but not limited to:
    - Improved mental health outcomes, such as depression, substance use
    - Improved medical health outcomes, such as reduction in obesity, metabolic disorders, heart disease, breast cancer
    - Patient health behaviors, such as tobacco use or health seeking behaviors
    - Use of preventive services, and other access to care measures

D. Adverse effects; unintended negative consequences of interventions

Question 4: What is the effectiveness of interventions to improve culturally appropriate health care for racial/ethnic minority children and adults?

A. Provider intermediate outcomes
    - Provider training and motivation outcomes, such as post-test competencies, knowledge, changes in attitudes, willingness to serve and perceived competence in service people with disabilities
    - Provider behavior, such as clinical decision-making, communication
    - Provider beliefs/cognitions about the priority population, such as reducing stereotyping and stigmatization

B. Patient intermediate outcomes
    - Patient beliefs/attitudes such as improved trust, perceived racism
    - Utilization of health services
    - Patient experience and satisfaction, such as improved perceptions of care
    - Patient health behaviors, such as tobacco use or health seeking behaviors
    - Use of preventive services, and other access to care measures

C. Final health or patient-centered health outcomes, including but not limited to:
    - Improved mental health outcomes, such as depression, substance use

- Improved medical health outcomes, such as reduction in obesity, kidney disease, heart disease, breast cancer, sickle cell disease

D. Adverse effects; unintended negative consequences of interventions

Question 5: What is the effectiveness of organizational or structural interventions for promoting culturally appropriate care for each of the priority populations across providers?

PICOTS

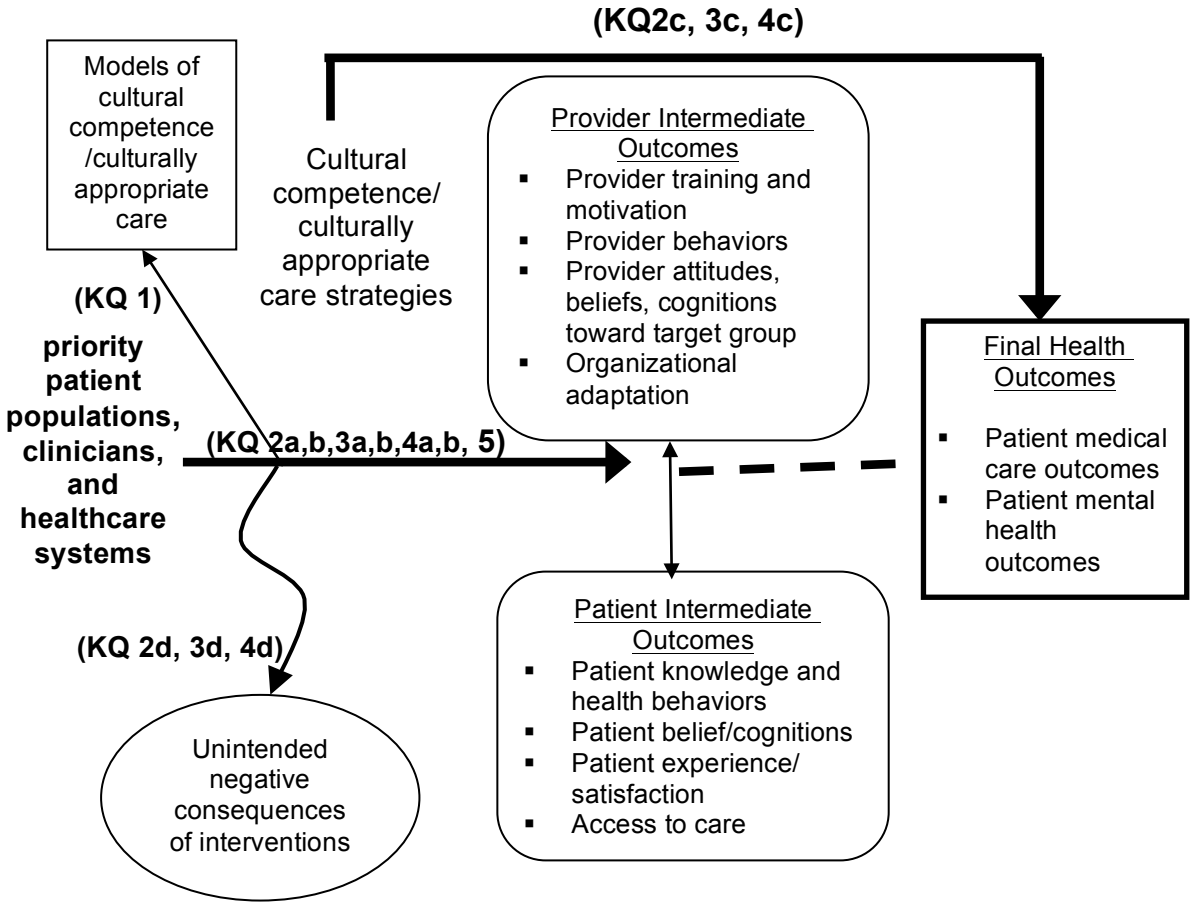
Table 1. PICOT

PICOT	KQ2	KQ3	KQ4	KQ5
Population	LGBT adolescents (ages 13-17), young adults (ages 18-25) and adults	Children and adults with disabilities, with older adults, focus on aging with a disability, rather than aging into a disability.	Racial/ethnic children and adults	Based on populations for KQs 2-4
Intervention	• Cultural competence/culturally appropriate care provider education and training • Cultural competence/culturally appropriate care clinic-based interventions targeted to patients • Cultural competence/culturally appropriate care clinic-based interventions targeted to providers	Same as KQ2	Same as KQ2	• Cultural competence/culturally appropriate care interventions targeted at the organizational level, including physical/ environmental factors.
Comparator groups	• Usual care • Head-to-head trials of different strategies	Same as KQ2	Same as KQ2	Same as KQ2
Outcomes	Intermediate outcomes • Provider training and motivation outcomes (competencies, knowledge, changes in attitudes) • Provider behavior, such as clinical decision-making, communication • Provider beliefs/cognitions about the priority population, reducing stereotyping, stigmatization • Provider improved specific knowledge of health needs unique to LGBT community • Patient learning/knowledge • Utilization of health services	Intermediate outcomes • Provider training and motivation outcomes (competencies, knowledge, changes in attitudes) • Provider behavior, such as clinical decision-making, communication • Provider beliefs/cognitions about the priority population, reducing stereotyping, stigmatization • Improved access to health services • Utilization of health services • Patient experience/satisfaction	Intermediate outcomes • Provider knowledge, attitudes, and competencies (skills) in providing culturally competent health care • Provider behavior, such as clinical decision-making, communication • Provider beliefs/cognitions about the priority population, reducing stereotyping, stigmatization • Patient beliefs/cognitions such as improved trust, perceived racism • Improved access to health services	Intermediate organizational adaptation outcomes • Process measures • Availability of culturally competent health care across population groups • Structural changes

	• Patient experience/satisfaction • Patient health behaviors • Use of preventive services and other access to care measures Final health or patient-centered outcomes – reduced disparities in terms of • Patient medical care outcomes • Patient mental health care outcomes (depression, anxiety, suicidality, substance use, peer/familial/intimate relationships) Adverse effects of intervention(s) • Unintended negative consequences of intervention	Final health or patient-centered outcomes – reduced disparities in terms of • Patient medical care outcomes • Patient mental health care outcomes (depression, substance use) • Patient health behaviors • Use of preventive services and other access to care measures Adverse effects of intervention(s) • Unintended negative consequences of intervention	• Utilization of health services • Patient experience/satisfaction • Patient health behaviors • Use of preventive services and other access to care measures Final health or patient-centered outcomes – reduced disparities in terms of • Patient medical care outcomes • Patient mental health care outcomes (depression, substance use) Adverse effects of intervention(s) • Unintended negative consequences of intervention	
Timing	Variable – depends on the purpose of the intervention	Same as KQ2	Same as KQ2	Same as KQ2
Setting	US Inpatient, outpatient, and community settings in which patients from priority populations are interacting with healthcare providers	Same as KQ2	Same as KQ2	Same as KQ2

III. Analytic Framework

Figure 2. Analytic framework for improving cultural competence to reduce disparities in priority populations



NOTE: Details of specific outcomes for a specific priority population can be found in Table1.

IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

Studies will be included in the review based on the PICOTS framework outlined in Table 1 and the study-specific inclusion criteria described in Table 2.

Table 2. Study inclusion criteria

Category	Criteria for Inclusion
Study Enrollment	Studies of any of the priority populations; LGBTQI, disability, race/ethnic groups Studies examining interventions to improve gender sensitivity that is, women as a population, rather than the listed priority populations, will be excluded.

Study Design and Quality	Systematic reviews, RCTs, nonrandomized controlled trials, and prospective and retrospective cohort studies with comparators, before/after case reports with comparators, and interrupted time series will be included for each population and treatment option. Studies specifically addressing treatment harms may also include retrospective and case series designs. Systematic reviews must include risk of bias assessment with validated tools.
Includable models	Structured depiction of factors or components that describe cultural competence defined as "as care that respects diversity in the patient population and cultural factors that can affect health and health care, such as language, communication styles, beliefs, attitudes, and behaviors." We will exclude models at organizational or system level that do not suggest possible points of intervention.
Time of Publication	Search all literature 1990 forward. Cultural competence as a concept and concerned gained traction in the published literature during the early 1990s.
Publication type	Published in peer reviewed journals, grey literature sourced from governmental or research organizations
Language of Publication	English

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

We will search Ovid Medline, Ovid PsycInfo, and the Cochrane EPOC to identify previous studies published and indexed in bibliographic databases from 1990 forward. Our search strategy, which appears in Appendix A, was created by staff and a biomedical librarian, and reviewed by a second independent librarian. Our search strategy included relevant medical subject headings and natural language terms for each of the priority populations and the concept of cultural competence. The concept terms were combined with filters to select relevant RCTs, observational studies, and systematic reviews.

Given the lack of specific and agreed-upon terms that capture cultural competence and the priority populations, and the diffused state of the literature, we will approach the search process strategically, using both inductive and deductive approaches. We will examine the LGBT literature first as a relatively easier priority group but one that does not necessarily refer to itself as a "culture" to define through keyword searches for lessons learned regarding natural language use that may help with capturing disability populations not otherwise easily identifiable as a "culture." Likewise, identified relevant LGBT cultural competence literature may also serve to help identify extensions of natural language terms for keyword search terms to use for cultural competence in the disability literature. Much of the cultural competence literature grew out of concern for the racial/ethnic implications and the terms used for racial/ethnic groups do not translate well to other priority groups that do not necessarily self-identify as a culture. We will also iteratively return to bibliographic databases to search the literature as new terms are uncovered or new relevant interventional approaches are discovered.

As bibliographic database searches are completed for each priority group, we will review the search results for studies relevant to our PICOTS framework and study-

specific criteria. The literature set identified at this phase will be examined from a content analysis perspective for emerging themes. Focused searches will then be developed to specifically search for further examples of that intervention theme in the literature.

Search results will be downloaded to EndNote.[6] Titles and abstracts will be reviewed by two independent investigators to identify studies meeting PICOTS framework and inclusion/exclusion criteria. All studies identified as relevant by either investigator will undergo full-text screening. Two investigators will independently screen full text to determine if inclusion criteria are met. Differences in screening decisions will be resolved by consultation between investigators, and, if necessary, consultation with a third investigator. We will document the inclusion and exclusion status of citations undergoing full-text screening. Throughout the screening process, team members will meet regularly to discuss training material and issues as they arise to ensure consistency of inclusion criteria application.

Bibliographic database searches will be supplemented with backward citation searches of highly relevant systematic reviews. We will also share search results with the TEP for ask for themes which may have been missed in the initial searches. We will update searches while the draft report is under public/peer review.

We will conduct additional grey literature searching to identify other search efforts into the priority populations or cultural competence for further MeSH or natural language keyword search terms. Relevant grey literature resources include trial registries and governmental or research organizations. We will search ClinicalTrials.gov and HSRProj for ongoing or completed studies.

C. Data Abstraction and Data Management

Studies meeting inclusion criteria will be distributed among investigators for data extraction. One investigator will extract relevant study, population demographics, and outcomes data. Data fields to be extracted will be determined based upon proposed summary analysis. These fields will include author, year of publication; setting, author definition of cultural competence, subject inclusion and exclusion criteria, intervention and control characteristics (intervention definition and components, timing, frequency, duration, fidelity), followup duration, participant baseline demographics, enrollment, descriptions and results of primary outcomes and adverse effects, and study funding source. Relevant data will be extracted into extraction forms created in Excel. Evidence tables will be reviewed and verified for accuracy by a second investigator.

We will use data from relevant comparisons in previous systematic reviews to replace the de novo extraction process when the comparison is sufficiently relevant. Data elements abstracted from included systematic reviews, whether the elements are at the individual study or systematic review levels, will depend on how the systematic review will be used. Use may range using individual elements to updating a review, to using the review without modification. Only systematic reviews that assess included study risk of bias will be assessed for review quality. Systematic reviews with fair or good methodology will be used. Systematic reviews that are deemed to have potential author conflict of interest, such as due to reviewing a body of literature to which the authors had substantially contributed, will be subjected to random quality checks of 10 percent of included study data abstraction. RCTs in included systematic reviews will be tracked for

contribution to unique population/treatment/outcome comparisons to avoid double-counting study results.

D. Assessment of Methodological Risk of Bias of Individual Studies

Risk of bias of eligible studies will be assessed using instruments specific to study design. For RCTs, questionnaires developed from the Cochrane Risk of Bias tool will be used. The seven domains included in this tool include sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data (i.e., was incomplete outcome data adequately addressed), selective reporting, and other sources of bias (i.e., problems not covered by other domains). Additional items will be developed to assess potential risk-of-bias not addressed by the Cochrane tool. Outcomes measurement issues inherent in the psychometric properties of the questionnaires used to measure outcomes and assessment methods used to detect change in those questionnaire results will be specifically evaluated for detection bias. Additional items may be necessary to evaluate potential risk-of-bias associated with treatment definition and implementation (treatment fidelity). Specific study methodology or conduct will be used to judge potential risk of bias with respect to each domain following guidance in the Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0.[7]

We developed an instrument for assessing risk of bias for observational studies based on the RTI Observational Studies Risk of Bias and Precision Item Bank.[8] We selected items most relevant in assessing risk of bias for this topic, including participant selection; attrition, ascertainment, and appropriateness of analytic methods. The preliminary risk of bias assessment form is provided in Appendix B. The form will be tested by investigators, with particular attention to project term definitions, using an initial sample of included studies and will be finalized by full team input.

Two investigators will independently assess risk of bias for all included studies. Investigators will consult to reconcile any discrepancies in overall risk of bias assessments. Overall summary risk of bias assessments for each study will be classified as low, moderate, or high based upon the collective risk of bias inherent in each domain and confidence that the results are believable given the study's limitations. When the two investigators disagree, a third party will be consulted to reconcile the summary judgment. Outcomes in studies assessed as having a high risk of bias will be compared to synthesized evidence as a means of sensitivity analysis. Contradictions will be investigated in further depth.

Systematic review quality and risk of bias will be assessed using modified AMSTAR criteria.[9] Study-level risk of bias must be assessed using validated risk of bias tools appropriate to study design. Since AMSTAR was not originally created as a quality review tool, an additional question regarding whether the review findings logically follow from the contributing studies will be added.

E. Data Synthesis

We will summarize the results into evidence tables and synthesize evidence for each unique population, comparison, and outcome combination. When a comparison is

adequately addressed by a previous systematic review of acceptable quality and no new studies are available, we will reiterate the conclusions drawn from that review. When new trials are available, previous systematic review data will be synthesized with data from additional trials.

We will summarize included study characteristics and outcomes in evidence tables. We do not expect pooling to be appropriate due to lack of comparable studies or heterogeneity; qualitative synthesis will be conducted in these instances. Observational literature examining treatment benefits will be used for subgroups not covered by published RCTs. We will treat cultural tailoring/targeting studies as a separate literature group that provides context for or informs current or possible future cultural competence intervention research.

The following matrixes provide a basic framework by which intervention population targets and general categories of measures may be assessed. Each of the cells may be exploded into another matrix of relevant details. Likewise, each of the outcome categories listed here may be exploded for finer detail. For example, we will distinguish between medical and mental health services, for patient intermediate outcomes. Provider types, if information is available in the literature, may be another useful way to contrast information, particularly for ethnicity- or gender-based care providers. Individual provider versus team approaches will be examined separately. We will also differentiate between models for undergraduate and graduate medical and health care education as compared to "re-training" existing providers.

Table 3. Overall outcome framework

Individual and Structural Level Outcomes*	LGBT			Disability		Race/Ethnic	
	13-17 yr old	18-25 yr old	Adult	Children	Adult	Children	Adult
Intermediate Provider Outcomes							
Intermediate Patient Outcomes							
Intermediate organizational outcomes- structural changes and availability of culturally competent healthcare across system							
Final Patient-Centered Outcomes- improved medical and mental health							

*Refer to Table 1. for complete list of provider, patient and organizational outcomes.

We will explore second order interactions if literature is identified allowing such examination. For example, we will look for intersections of disability and race, or LGBT and race, or LGBT and disability priority populations. We will also separate analyses by subgroups within the priority populations, such as different LGBT identities, if the literature provides such information.

Should there be sufficient literature available for possible pooling, decisions for pooling will be based on the homogeneity of study populations based on inclusion criteria, specific interventions, and the ability to treat outcome measures as similar. Data will be analyzed in RevMan 5.21[10] software. Observational literature examining treatment benefits will be used for subgroups not covered by published RCTs. Using a random effects model, we will calculate risk ratios (RR) and absolute risk differences (RD) with the corresponding 95 percent confidence intervals (CI) for binary primary

outcomes. Weighted mean differences (WMD) and/or standardized mean differences (SMD) with the corresponding 95 percent CIs will be calculated for continuous outcomes. We will assess the clinical and methodological heterogeneity and variation in effect size to determine appropriateness of pooling data.[11] If data are appropriate for pooling, meta-analysis will be performed. We will assess statistical heterogeneity with Cochran's Q test and measure magnitude with I^2 statistic.[11]

For KQ 1, we will compare model characteristics. The results of this comparison may be used to organize results for KQ2-5.

F. Grading the Strength of Evidence (SOE) for Major Comparisons and Outcomes

The overall strength of evidence for primary outcomes of KQ2-5 within each comparison will be evaluated based on four required domains: (1) study limitations (risk of bias); (2) directness (single, direct link between intervention and outcome); (3) consistency (similarity of effect direction and size); and (4) precision (degree of certainty around an estimate).[12] A fifth domain, reporting bias, will be assessed when SOE based upon the first four domains is moderate or high.[12] Based on study design and conduct, risk of bias will be rated as low, medium, or high. Consistency will be rated as consistent, inconsistent, or unknown/not applicable (e.g., single study) based on the direction, magnitude, and statistical significance of all studies. Directness will be rated as either direct or indirect based on the need for indirect comparisons when inference requires observations across studies. Precision will be rated as precise or imprecise based on the degree of certainty surrounding each effect estimate or qualitative finding. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions. Other factors that may be considered in assessing strength of evidence include dose-response relationship, the presence of confounders, and strength of association. Based on these factors, the overall strength of evidence for each outcome will be rated as:[12]

- **High:** Very confident that estimate of effect lies close to true effect. Few or no deficiencies in body of evidence, findings believed to be stable.
- **Moderate:** Moderately confidence that estimate of effect lies close to true effect. Some deficiencies in body of evidence; findings likely to be stable, but some doubt.
- **Low:** Limited confidence that estimate of effect lies close to true effect; major or numerous deficiencies in body of evidence. Additional evidence necessary before concluding that findings are stable or that estimate of effect is close to true effect.
- **Insufficient:** No evidence, unable to estimate an effect, or no confidence in estimate of effect. No evidence is available or the body of evidence precludes judgment.

We will assess strength of evidence for published systematic reviews replacing de novo review processes that did not provide a strength of evidence assessment based on a GRADE or GRADE-equivalent method.

We will assess strength of evidence for outcomes drawn from more than one study for a given patient population/intervention/outcome comparison. For outcomes drawn from a

single study, given the low probability that such a study is of large sample size, we will only assess strength of evidence for studies of low risk of bias. Results and risk of bias will be presented for other reported included studies to provide information across the full spectrum of included studies. However, results of studies not undergoing strength of evidence assessment will be identified as hypothesis generating, rather than hypothesis testing, in nature.

G. Assessing Applicability

Cultural competence intervention research by definition generally draws on defined priority populations, and very possibly specific subgroups of those priority populations. To the extent that similar interventions are tested in multiple studies across priority population groups, we will be able to suggest generalizability across those groups. Otherwise generalizability will be narrowly subscribed by the study populations. Applicability of studies will be determined according to the PICOTS framework. Study characteristics that may affect applicability include, but are not limited to, the population from which the study participants are enrolled, and patient or intervention characteristics different than those described by population studies of the priority populations or types of organizational settings. We will pay special attention to defined subgroups that are at the intersections of two or more priority populations. These applicability issues are present in the synthesis frameworks and sensitivity analyses described in more detail in the data synthesis section.

V. References

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VI. Definition of Terms

Not applicable.

VII. Summary of Protocol Amendments

If we need to amend this protocol, we will give the date of each amendment, describe the change and give the rationale in this section. Changes will not be incorporated into the protocol. Example table below:

Date	Section	Original Protocol	Revised Protocol	Rationale
This should be the effective date of the change in protocol	Specify where the change would be found in the protocol	Describe the language of the original protocol.	Describe the change in protocol.	Justify why the change will improve the report. If necessary, describe why the change does not introduce bias. Do not use justification as "because the AE/TOO/TEP/Peer reviewer told us to" but explain what the change hopes to accomplish.

VIII. Review of Key Questions

AHRQ posted the key questions on the Effective Health Care Website for public comment. The EPC refined and finalized the key questions after review of the public comments, and input from Key Informants and the Technical Expert Panel (TEP). This input is intended to ensure that the key questions are specific and relevant.

IX. Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform healthcare decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts constitute a multi-disciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, or outcomes and identify particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicting opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design, and methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor do they contribute to the writing of the report. They have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodological expertise. The EPC considers all peer review comments on the draft report in preparation of the final report. Peer reviewers do not participate in writing or editing of the final report or other products. The final report does not necessarily represent the views of individual reviewers. The EPC will complete a disposition of all peer review comments. The disposition of comments for systematic reviews and technical briefs will be published three months after the publication of the evidence report.

Potential Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

XII. EPC Team Disclosures

EPC core team members must disclose any financial conflicts of interest greater than $1,000 and any other relevant business or professional conflicts of interest. Related financial conflicts of interest that cumulatively total greater than $1,000 will usually disqualify EPC core team investigators.

XIII. Role of the Funder

This project was funded under Contract No. xxx-xxx from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Appendix A. Search algorithms for Cultural Competence

KQ1 Cultural Competence and Theoretical Models

1 culture/
2 cultural competency/
3 anthropology cultural/
4 cultural characteristics/
5 cultural diversity/
6 cross-cultural comparison/
7 (cultur* adj3 (competenc* or understand* or knowledge* or expertise or skill* or sensitiv* or aware* or appropriate* or acceptab* or safe* or humility or communicat* or barrier* or divers* or comparison* or identity or specific or background* or value* or belief*)).tw.

8 transcultural nursing/
9 (intercultural* or inter-cultural or transcultural* or trans-cultural or cross-cultural or crosscultural or multicultural* or multi-cultural* or multiethnic or bicultural).tw.
10 Multilingualism/
11 language/
12 ((linguistic* or language*) adj3 (competenc* or understand* or knowledge* or expertise or skill* or sensitiv* or aware* or appropriate* or acceptab* or safe* or humility or communicat* or barrier* or divers* or comparison* or identity or specific or background* or value* or belief*)).tw.

13 (multilingual* or multi-lingual* or bilingual or bi-lingual).tw.
14 or/1-13
15 exp Models, Nursing/
16 exp Models, Theoretical/
17 model*.mp. or framework*.tw.
18 exp Models, Organizational/
19 delivery of health care/
20 health knowledge attitudes practice/
21 exp Clinical Competence/ or exp Professional Competence/
22 or/15-21

KQ2 Study Filters and LGBT Population Terms

Lines 1-32 Filter for systematic reviews
Lines 33-61 Filter for controlled trials
Lines 62-75 Filter for observational studies, including training/education programs
Lines 76-88 Population terms
Lines 98-100 Intervention terms (used to limit observational studies)

#	Searches
1	meta analysis as topic/
2	meta-analy$.tw.
3	metaanaly$.tw.
4	meta-analysis/
5	(systematic adj (review$1 or overview$1)).tw.
6	exp Review Literature as Topic/
7	or/1-6
8	cochrane.ab.
9	embase.ab.
10	(psychlit or psyclit).ab.
11	(psychinfo or psycinfo).ab.
12	or/8-11
13	reference list$.ab.
14	bibliograph$.ab.
15	hand search.ab.
16	relevant journals.ab.
17	manual search$.ab.
18	or/13-17
19	selection criteria.ab.
20	(data adj2 (extract* or abstract*)).ab.
21	19 or 20
22	review/
23	21 and 22
24	Comment/
25	Letter/
26	editorial/
27	animal/
28	human/
29	27 not (28 and 27)
30	or/24-26,29
31	7 or 12 or 18 or 23
32	31 not 30
33	randomized controlled trials as topic/
34	randomized controlled trial/
35	random allocation/
36	double blind method/
37	single blind method/
38	clinical trial/
39	clinical trial, phase i.pt.

40	clinical trial, phase ii.pt.
41	clinical trial, phase iii.pt.
42	clinical trial, phase iv.pt.
43	controlled clinical trial.pt.
44	randomized controlled trial.pt.
45	multicenter study.pt.
46	clinical trial.pt.
47	exp clinical trials as topic/
48	or/33-47
49	(clinical adj trial$).tw.
50	((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw.
51	placebos/
52	placebo$.tw.
53	randomly allocated.tw.
54	(allocated adj2 random$).tw.
55	or/49-54
56	48 or 55
57	case report.tw.
58	letter/
59	historical article/
60	or/57-59
61	56 not 60
62	exp cohort studies/ or comparative study/ or follow-up studies/ or prospective studies/ or cohort.mp. or compared.mp. or groups.mp. or multivariate.mp.
63	cohort$.tw.
64	controlled clinical trial.pt.
65	exp teaching/
66	exp health personnel/ed
67	exp teaching materials/
68	exp education/
69	((education* or teaching or learning or elearning or instruction* or training or skills or didactic or pedagogic* or online or online or web* or internet or cd-rom* or dvd or multimedia or multi-media or computer*) adj2 (intervention* or session* or course* or program* or activit* or presentation* or round* or material* or package* or module* or demonstration* or method* or process*)).tw.
70	(inservice or in service or workshop* or (discussion adj1 group*) or lectur* or seminar* or (short adj2 course*) or role play* or immersion or mentor* or lifelong learning or life long learning).tw.

71	((staff or professional or workforce or work force) adj (development or training)).tw.
72	((medical or continuing or residency or distance) adj2 education).tw.
73	((cultural* or transcultural* or multicultural* or intercultural* or bicultural*) adj2 (education or train* or teach* or learn* or instruct* or coach* or skills or content*)).tw.
74	(curriculum or curricul* intervent*).tw.
75	or/62-74
76	exp Bisexuality/ or bisexual*.mp.
77	exp Transsexualism/ or transsexual*.mp.
78	exp Homosexuality/ or homosexual*.mp.
79	exp Transgendered Persons/ or transgender*.mp.
80	(lgbt* or glbt*).mp.
81	(gay or lesbian).mp.
82	("men who have sex with men" or msm or "women who have sex with women" or wsw).mp.
83	(WSMW or WSWM or MSWM or MSMW).mp.
84	sexual minority.mp.
85	gender minority.mp.
86	gender expression.mp.
87	(gender identit* or sexual orientation or sexual identit*).mp.
88	or/76-87
89	32 and 88
90	61 and 88
91	75 and 88
92	limit 89 to yr="1990-Current"
93	limit 90 to yr="1990-Current"
94	limit 91 to yr="1990-Current"
95	92 not (93 or 94)
96	93 not (92 or 94)
97	94 not (92 or 93)
98	intervention*.ti,ab.
99	program*.ti,ab.
100	curriculum.ti,ab.
101	or/98-100
102	97 and 101

KQ3 Study Filters, Disability Population Terms, and Cultural Competence Terms

Lines 1-32 Filter for systematic reviews
Lines 33-61 Filter for controlled trials
Lines 62-67 Filter for observational studies
Lines 68-81 Population terms
Lines 91-93 Intervention terms
Lines 97-121 Cultural competence in its many forms and targets

#	Searches
1	meta analysis as topic/
2	meta-analy$.tw.
3	metaanaly$.tw.
4	meta-analysis/
5	(systematic adj (review$1 or overview$1)).tw.
6	exp Review Literature as Topic/
7	or/1-6
8	cochrane.ab.
9	embase.ab.
10	(psychlit or psyclit).ab.
11	(psychinfo or psycinfo).ab.
12	or/8-11
13	reference list$.ab.
14	bibliograph$.ab.
15	hand search.ab.
16	relevant journals.ab.
17	manual search$.ab.
18	or/13-17
19	selection criteria.ab.
20	(data adj2 (extract* or abstract*)).ab.
21	19 or 20
22	review/
23	21 and 22
24	Comment/
25	Letter/
26	editorial/
27	animal/
28	human/
29	27 not (28 and 27)
30	or/24-26,29
31	7 or 12 or 18 or 23
32	31 not 30
33	randomized controlled trials as topic/
34	randomized controlled trial/
35	random allocation/
36	double blind method/
37	single blind method/
38	clinical trial/
39	clinical trial, phase i.pt.
40	clinical trial, phase ii.pt.
41	clinical trial, phase iii.pt.
42	clinical trial, phase iv.pt.
43	controlled clinical trial.pt.
44	randomized controlled trial.pt.

45	multicenter study.pt.
46	clinical trial.pt.
47	exp clinical trials as topic/
48	or/33-47
49	(clinical adj trial$).tw.
50	((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw.
51	placebos/
52	placebo$.tw.
53	randomly allocated.tw.
54	(allocated adj2 random$).tw.
55	or/49-54
56	48 or 55
57	case report.tw.
58	letter/
59	historical article/
60	or/57-59
61	56 not 60
62	exp cohort studies/ or comparative study/ or follow-up studies/ or prospective studies/ or cohort.mp. or compared.mp. or groups.mp. or multivariate.mp.
63	cohort$.tw.
64	controlled clinical trial.pt.
65	epidemiological methods/
66	limit 65 to yr=1971-1983
67	or/62-64,66
68	exp disabled person/ or (amputee$ or disabled person$ or disabled child$ or disab$ or disabled people or mentally disabled person$ or mentally disabled people or mentally ill person$ or mentally ill people or visually impaired person$ or visually impaired people or hearing impaired person$ or hearing impaired people).mp.
69	exp mental disorders diagnosed in childhood/ or (Asperger Syndrome or Aperger$ or Autism or Autistic or Autistic Disorde$ or learning disabil$ or learning disorder$ or developmental disability$ or Attention Deficit Disorder$ or Attention Deficit Disorder with Hyperactivity or behavior$ disorder$ or conduct disorder$ or dyslexia or affective Disorder$ or mood disorder$ or depress$ or depress$ disorder$ or personality disorder$).mp.
70	exp cognition disorders/ or (cognit$ disord$ or cognit$ disabil$ or Mild Cognitive Impairment$ or Huntington$ or cognitive$ impair$).mp.
71	exp intellectual disability/ or (intellectual disab$ or Down Syndrome or mental$ retard$ or Fragile X or Rett Syndrome or Prader-Willi Syndrome or Williams Syndrome).mp.
72	exp "Activities of Daily Living"/ or (activit$ of daily living or functional limitation$ or activity limitation$ or participation limitation$).mp.
73	Mobility limitation/ or (mobility limitation$ or mobility impairment$).mp.
74	Dependent ambulation/ or dependent ambulation.mp.

75	Paraplegia/ or paraplegia.mp.
76	Quadriplegia/ or quadriplegia.mp.
77	Hearing loss/ or (hearing loss or hearing impair$ or deaf$).mp.
78	Vision disorders/ or (blind$ or vis$ impair$).mp.
79	exp self-help devices/ or (assist$ techn$ or Commun$ Aid$ or commun$ device$ or Wheelchair$).mp.
80	Mental disorders/ or (mental disorder$ or psychiatric disabilit$ or mental health disabilit$ or mental health impairment$).mp.
81	or/68-80
82	32 and 81
83	61 and 81
84	67 and 81
85	limit 82 to yr="1990-Current"
86	limit 83 to yr="1990-Current"
87	limit 84 to yr="1990-Current"
88	85 not (86 or 87)
89	86 not (85 or 87)
90	87 not (85 or 86)
91	intervention*.ti,ab.
92	program*.ti,ab.
93	91 or 92
94	88 and 93
95	89 and 93
96	90 and 93
97	culture/ or cross-cultural comparison/ or cultural characteristics/ or cultural competency/ or cultural diversity/
98	multilingualism/ or language/
99	((cultur* or linguistic* or language*) adj3 (competenc* or understanding or knowledg* or expertise or skill* or sensitiv* or aware* or appropriate* or acceptab* or safe* or humility or service* or communicat* or barrier* or divers* or comparison* or identity or specific or background* or value* or belief*)).tw.
100	(intercultural* or inter-cultural or transcultural* or trans-cultural or cross-cultural or crosscultural or multicultural* or multicultural* or bicultural or bi-cultural or multilingual* or multi-lingual* or bilingual or bi-lingual).tw.
101	transcultural nursing/
102	minority groups/ or minority Health/
103	exp teaching/
104	exp health personnel/ed
105	exp teaching materials/
106	exp education/

107	((education* or teaching or learning or elearning or instruction* or training or skills or didactic or pedagogic* or online or online or web* or internet or cd-rom* or dvd or multimedia or multi-media or computer*) adj2 (intervention* or session* or course* or program* or activit* or presentation* or round* or material* or package* or module* or demonstration* or method* or process*)).tw.
108	(inservice or in service or workshop* or (discussion adj1 group*) or lectur* or seminar* or (short adj2 course*) or role play* or immersion or mentor* or lifelong learning or life long learning).tw.
109	((staff or professional or workforce or work force) adj (development or training)).tw.
110	((medical or continuing or residency or distance) adj2 education).tw.
111	(curriculum or curricul* intervent*).tw.
112	((cultural* or transcultural* or multicultural* or intercultural* or bicultural*) adj2 (education or train* or teach* or learn* or instruct* or coach* or skills or content*)).tw.
113	health education/ or health promotion/ or primary prevention/
114	health services accessibility/ or healthcare disparities/
115	"Attitude of Health Personnel"/
116	Community-Based Participatory Research/
117	Medicine, Traditional/
118	Health Communication/
119	community health workers/
120	consumer participation/ or patient participation/
121	or/97-120
122	94 and 121
123	95 and 121
124	96 and 121

KQ4 Study Filters, Racial Ethnic Population Terms, and Cultural Competence

Lines 1-32 Filter for systematic reviews
Lines 33-61 Filter for controlled trials
Lines 62-67 Filter for observational studies
Lines 68-73 Population terms
Lines 83-85 Intervention terms
Lines 89-113 Cultural competence in its many forms and targets
Line 118 To further restrict observational studies

#	Searches
1	meta analysis as topic/
2	meta-analy$.tw.
3	metaanaly$.tw.
4	meta-analysis/
5	(systematic adj (review$1 or overview$1)).tw.
6	exp Review Literature as Topic/
7	or/1-6
8	cochrane.ab.
9	embase.ab.
10	(psychlit or psyclit).ab.
11	(psychinfo or psycinfo).ab.
12	or/8-11
13	reference list$.ab.
14	bibliograph$.ab.
15	hand search.ab.
16	relevant journals.ab.
17	manual search$.ab.
18	or/13-17
19	selection criteria.ab.
20	(data adj2 (extract* or abstract*)).ab.
21	19 or 20
22	review/
23	21 and 22
24	Comment/
25	Letter/
26	editorial/
27	animal/
28	human/
29	27 not (28 and 27)
30	or/24-26,29
31	7 or 12 or 18 or 23
32	31 not 30
33	randomized controlled trials as topic/
34	randomized controlled trial/
35	random allocation/
36	double blind method/
37	single blind method/

38	clinical trial/
39	clinical trial, phase i.pt.
40	clinical trial, phase ii.pt.
41	clinical trial, phase iii.pt.
42	clinical trial, phase iv.pt.
43	controlled clinical trial.pt.
44	randomized controlled trial.pt.
45	multicenter study.pt.
46	clinical trial.pt.
47	exp clinical trials as topic/
48	or/33-47
49	(clinical adj trial$).tw.
50	((singl$ or doubl$ or treb$ or tripl$) adj (blind$3 or mask$3)).tw.
51	placebos/
52	placebo$.tw.
53	randomly allocated.tw.
54	(allocated adj2 random$).tw.
55	or/49-54
56	48 or 55
57	case report.tw.
58	letter/
59	historical article/
60	or/57-59
61	56 not 60
62	exp cohort studies/ or comparative study/ or follow-up studies/ or prospective studies/ or cohort.mp. or compared.mp. or groups.mp. or multivariate.mp.
63	cohort$.tw.
64	controlled clinical trial.pt.
65	epidemiological methods/
66	limit 65 to yr=1971-1983
67	or/62-64,66
68	population groups/ or african continental ancestry group/ or african americans/ or indians, north american/ or inuits/ or asian americans/ or oceanic ancestry group/ or ethnic groups/ or arabs/ or hispanic americans/ or mexican americans/
69	"Emigration and Immigration"/ or "Emigrants and Immigrants"/ or "Transients and Migrants"/ or refugees/
70	race relations/ or racism/
71	(immigrant* or migrant* or refugee* or (displaced and (people or person*)) or ("foreign born" or "non us born" or "non-us born") or undocumented or second language* or ((language or english) and proficien*) or interpreter* or "minority group*" or "ethnic group*" or "urban health" or "urban population" or "inner city" or ethnic* or race or racial or minorit* or urban or inner-city or multiethnic).tw.
72	(non-english or hispanic* or latin* or ((african or black or asian or native or mexican) adj american*) or inuit* or islander*).tw.
73	or/68-72
74	32 and 73

75	61 and 73
76	67 and 73
77	limit 74 to yr="1990-Current"
78	limit 75 to yr="1990-Current"
79	limit 76 to yr="1990-Current"
80	77 not (78 or 79)
81	78 not (77 or 79)
82	79 not (77 or 78)
83	intervention*.ti,ab.
84	program*.ti,ab.
85	83 or 84
86	80 and 85
87	81 and 85
88	82 and 85
89	culture/ or cross-cultural comparison/ or cultural characteristics/ or cultural competency/ or cultural diversity/
90	multilingualism/ or language/
91	((cultur* or linguistic* or language*) adj3 (competenc* or understanding or knowledg* or expertise or skill* or sensitiv* or aware* or appropriate* or acceptab* or safe* or humility or service* or communicat* or barrier* or divers* or comparison* or identity or specific or background* or value* or belief*)).tw.
92	(intercultural* or inter-cultural or transcultural* or trans-cultural or cross-cultural or crosscultural or multicultural* or multicultural* or bicultural or bi-cultural or multilingual* or multi-lingual* or bilingual or bi-lingual).tw.
93	transcultural nursing/
94	minority groups/ or minority Health/
95	exp teaching/
96	exp health personnel/ed
97	exp teaching materials/
98	exp education/
99	((education* or teaching or learning or elearning or instruction* or training or skills or didactic or pedagogic* or online or online or web* or internet or cd-rom* or dvd or multimedia or multi-media or computer*) adj2 (intervention* or session* or course* or program* or activit* or presentation* or round* or material* or package* or module* or demonstration* or method* or process*)).tw.
100	(inservice or in service or workshop* or (discussion adj1 group*) or lectur* or seminar* or (short adj2 course*) or role play* or immersion or mentor* or lifelong learning or life long learning).tw.
101	((staff or professional or workforce or work force) adj (development or training)).tw.
102	((medical or continuing or residency or distance) adj2 education).tw.
103	(curriculum or curricul* intervent*).tw.
104	((cultural* or transcultural* or multicultural* or intercultural* or bicultural*) adj2 (education or train* or teach* or learn* or instruct* or coach* or skills or content*)).tw.
105	health education/ or health promotion/ or primary prevention/
106	health services accessibility/ or healthcare disparities/
107	"Attitude of Health Personnel"/

108	Community-Based Participatory Research/
109	Medicine, Traditional/
110	Health Communication/
111	community health workers/
112	consumer participation/ or patient participation/
113	or/89-112
114	86 and 113
115	87 and 113
116	88 and 113
117	or/89-94
118	Healthcare Disparities/
119	117 or 118
120	116 and 119

Appendix B. Risk of Bias Assessment Form for Observational Studies

_____ ***Author*** _____ ***Year*** _____ [PMID] _____ **Reviewer** _____

Question	Response	Criteria	Justification
	Internal Validity		
1. Is the study design prospective, retrospective, or mixed?	Prospective ☐	Outcome has not occurred at the time the study is initiated and information is collected over time to assess relationships with the outcome.	
	Mixed ☐	Studies in which one group is studied prospectively and the other retrospectively.	
	Retrospective ☐	Analyzes data from past records.	
2. Are inclusion/exclusion criteria clearly stated?	Yes ☐		
	Partially ☐	Some, but not all, criteria stated or some not clearly stated.	
	No ☐		
3. Are baseline characteristics measured using valid and reliable measures and equivalent in both groups?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained.	
4. Is the level of detail describing the intervention adequate?	Yes ☐	Intervention described included adequate service details	
	Partially ☐	Some of the above features.	
	No ☐	None of the above features.	
5. Is the selection of the comparison group appropriate?	Yes ☐	Considering patient characteristics	
6. Did researchers isolate the impact from a concurrent intervention or an unintended exposure that might bias results?	Yes ☐	Accounted for concurrent informal care.	
	Partially ☐		
	No ☐		
7. Any attempt to balance the allocation between the groups (e.g. stratification, matching, propensity scores)?	Yes ☐	(if yes, what was used?)	
	No ☐		
	Uncertain ☐	Could not be ascertained.	
8. Were outcomes assessors blinded?	☐	Who were outcome assessors?	
9. Are outcomes assessed using valid and reliable measures, implemented consistently across all study participants?	Yes ☐	Measure valid and reliable (i.e. objective measures, well validated scale, provider report); and equivalent across groups.	
	Partially ☐	Some of the above features (partially validated scale)	
	No ☐	None of the above features. (self-report, scales with lower validity, reliability); not equivalent across groups	
	Uncertain ☐	Could not be ascertained.	
10. Is the length of follow-up the same for all groups?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained.	
11. Did attrition result in a difference in group	Yes ☐	(measurement period of interest if repeated measures)	

characteristics between baseline and follow-up?	No ☐		
	Uncertain ☐	Could not be ascertained (i.e. retrospective designs where eligible at baseline could not be determined)	
12. If baseline characteristics are not similar, does the analysis control for baseline differences between groups?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained (i.e. retrospective designs where eligible at baseline could not be determined)	
13. Are confounding and/or effect modifying variables assessed using valid and reliable measures across all study participants?	Yes ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained (i.e. retrospective designs where eligible at baseline could not be determined)	
	NA ☐	No confounders or effect modifiers included in the study.	
14. Were the important confounding and effect modifying variables taken into account in the design and/or analysis (e.g. through matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment)?	Yes ☐		
	Partially ☐	Some variables taken into account or adjustment achieved to some extent.	
	No ☐	Not accounted for or not identified.	
	Uncertain ☐	Could not be ascertained	
15. Are the statistical methods used to assess the primary outcomes appropriate to the data?	Yes ☐	Statistical techniques used must be appropriate to the data.	
	Partially ☐		
	No ☐		
	Uncertain ☐	Could not be ascertained	
16. Are reports of the study free of suggestion of selective outcome reporting?	Yes ☐		
	No ☐	Not all prespecified outcomes reported, subscales not prespecified reported, outcomes reported incompletely.	
	Uncertain ☐	Could not be ascertained.	
17. Funding source identified	No ☐		Industry, government, university, Foundation (funded by what money source?)
	Yes ☐	Who provided funding?	
	Uncertain ☐		
	Overall Assessment		
18. Overall Risk of Bias assessment	Low ☐	Results are believable taking study limitations into consideration	
	Moderate ☐	Results are probably believable taking study limitations into consideration	
	High ☐	Results are uncertain taking study limitations into consideration	