Evidence-based Practice Center Systematic Review Protocol

Project Title: Closing the Quality Gap 2010: Quality Improvement Interventions to Address Health Disparities

I.   Objective, Background, and Focus of the Systematic Review

Objective: The purpose of the planned systematic review is to evaluate the effectiveness of quality improvement strategies in reducing disparities in health, with a focus on a select set of both disparities and clinical conditions. The resulting report will create a foundation of evidence to evaluate the effectiveness of existing quality improvement interventions and to inform the development of novel quality improvement frameworks.

Background: By definition, a disparity in health care quality is not due to differences in health care needs or preferences of the patient, but to other factors.[1] Such disparities, defined by the Centers for Disease Control and Prevention as "differences in health outcomes between groups," are persistent and known to be associated with differences in race/ethnicity, economic status, education and literacy and other social conditions.[2] They are associated with differences in access to and utilization of health care, in addition to numerous environmental or contextual differences that may range from resource availability and transportation to geographic differences in air pollution. Solutions to observed disparities likely will require multidisciplinary approaches that range from public health and health education to improving the way care is provided in the health care setting, the latter of which is the basis for this report.

Quality Improvement (QI) practitioners often engage in an interdisciplinary process to raise the likelihood of the delivery of best practices for preventive, diagnostic, therapeutic, and rehabilitative care to maintain, restore, or improve health outcomes of individuals and populations. In these instances, QI is an organizational strategy that formally involves the analysis of process and outcomes data and the application of systematic efforts to improve performance. A few examples of formal models that have been developed and tested in the QI field are: Focus Analyze Develop Execute (FADE); Plan Do Study Act (PDSA); Six Sigma; Continuous Quality Improvement (CQI); and Total Quality Management (TQM).[3]

Where applicable, specific interventions will be categorized based upon the taxonomy of quality improvement strategies derived from the original "Closing the Quality Gap" Series.[4] Interventions that appear to fit the definition of a quality improvement process, but do not fit into one of the example categories will be recorded and will be organized as obvious groupings emerge. The original series used the following taxonomy[a], which we use here for starting purposes only:

---

[a] An abbreviated list was selected from the taxonomy of nine broad categories delineated in the antecedent series, "Closing the Quality Gap: A Critical Analysis of Quality Improvement". [4]

- Provider reminder systems
- Facilitated relay of clinical data to providers
- Audit and feedback
- Provider education
- Broad organizational strategies (including formal models noted above)
- Patient education
- Promotion of self-management
- Patient reminder systems

We will make efforts to exclude studies that overlap with other reports within the series. Quality improvement strategies aimed at public reporting, payment bundling, and medication adherence are being addressed by other reports within the "Closing the Quality Gap" series.[a]

Focus of this Report: The National Healthcare Disparities Report (NHDR) clearly demonstrates that some Americans receive worse care than others.[5] Consistent with extensive research and findings in previous reports, the 2009 NHDR report found that disparities related to race, ethnicity, and socioeconomic status still pervade the American health care system. Within the scope of health care delivery, these disparities may be due to differences in access to care, provider biases, poor provider-patient communication, poor health literacy, or other factors.

The Agency for Healthcare Research and Quality (AHRQ) has identified a list of priority populations associated with health care disparities and unequal care.[5] For the purposes of our report, we will focus on the following primary classifications associated with disparity in health outcomes: race/ethnicity; socioeconomic status (SES); insurance status; sex; sexual orientation; health literacy/numeracy; and language barriers. Furthermore, we will seek studies of interventions to reduce disparities in health and process outcomes associated with a targeted set of clinical conditions, namely:

- Colorectal cancer
- Breast cancer
- Diabetes
- Congestive heart failure
- Coronary artery disease (including ischemic heart disease, myocardial infarction, and acute coronary syndrome)
- Hypertension
- Pregnancy
- Major depressive disorder
- Asthma
- Cystic fibrosis

---

[a] See Appendix 1 for a complete list of series topics.

- Pneumonia, including pneumococcal vaccination
- End-stage renal disease

The selection of these conditions is based on a review of priority lists previously published by AHRQ and the Institute of Medicine [6-8] and consultation with a Technical Expert Panel. Each of the priority conditions has been determined to meet the Institute of Medicine (IOM) criteria for impact, improvability, and inclusiveness.[7]

II. The Key Questions

The key questions for this review were based on an initial survey of the existing literature and input from team members with subject expertise. The key questions are intentionally broad to capture all available data from a diverse set of papers in the literature.

Key Question 1: What evidence is available about the effectiveness of quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?

Key Question 2: What evidence is available about the harms related to quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?

The following PICOTS framework elements apply to both Key Question 1 and Key Question 2:

- **Population(s):**

Individuals in the United States with a priority condition (i.e. breast cancer, colorectal cancer, diabetes, congestive heart failure, hypertension, coronary artery disease [including ischemic heart disease, myocardial infarction, and acute coronary syndrome]; asthma, major depressive disorder asthma, cystic fibrosis, pneumonia, and end-stage renal disease). The study must include populations in which the purpose of the study is to examine a change in disparity observed in health outcomes. These populations will be defined by race/ethnicity, socioeconomic status, insurance status, sex, sexual orientation, health literacy/numeracy, or language barrier.

- **Interventions:**

Interventions will include quality improvement strategies. A quality improvement intervention is a change process in health care systems, services, or suppliers for the purpose of increasing the likelihood of optimal clinical quality of care measured by positive health outcomes for individuals and populations. Examples include: physician reminder systems, facilitated relay of clinical data to providers, audit and

feedback, benchmarking, physician education, practice guidelines, critical pathways, patient education, promotion of self-management, and patient reminder systems. Other quality improvement strategies will also be identified through the literature search.

- **Comparators:**

The comparator must be either non-use of a quality improvement strategy or use of an alternate strategy.

- **Outcomes measures for each question:**

The outcome measures of interest include: health outcome measures (e.g. morbidity and mortality, indirect health outcomes such as blood pressure and HbA1c); process measures (e.g. proportion of patients treated according to clinical guidelines); changes in disparity; and harms. Studies must include outcomes for the target population and an appropriate internal or external referent group,[a] such that changes in disparity can be assessed. Harms of the intervention to the individual patients or the health care system will be captured if they are measured.

- **Timing:**

No set timing is required for inclusion. We anticipate that most studies will report immediate or short term outcomes following a quality improvement intervention; however, there will be no limits placed on timing of the outcomes.

- **Settings:**

We will include strategies conducted in or based out of a hospital, provider office, and/or health care clinic.
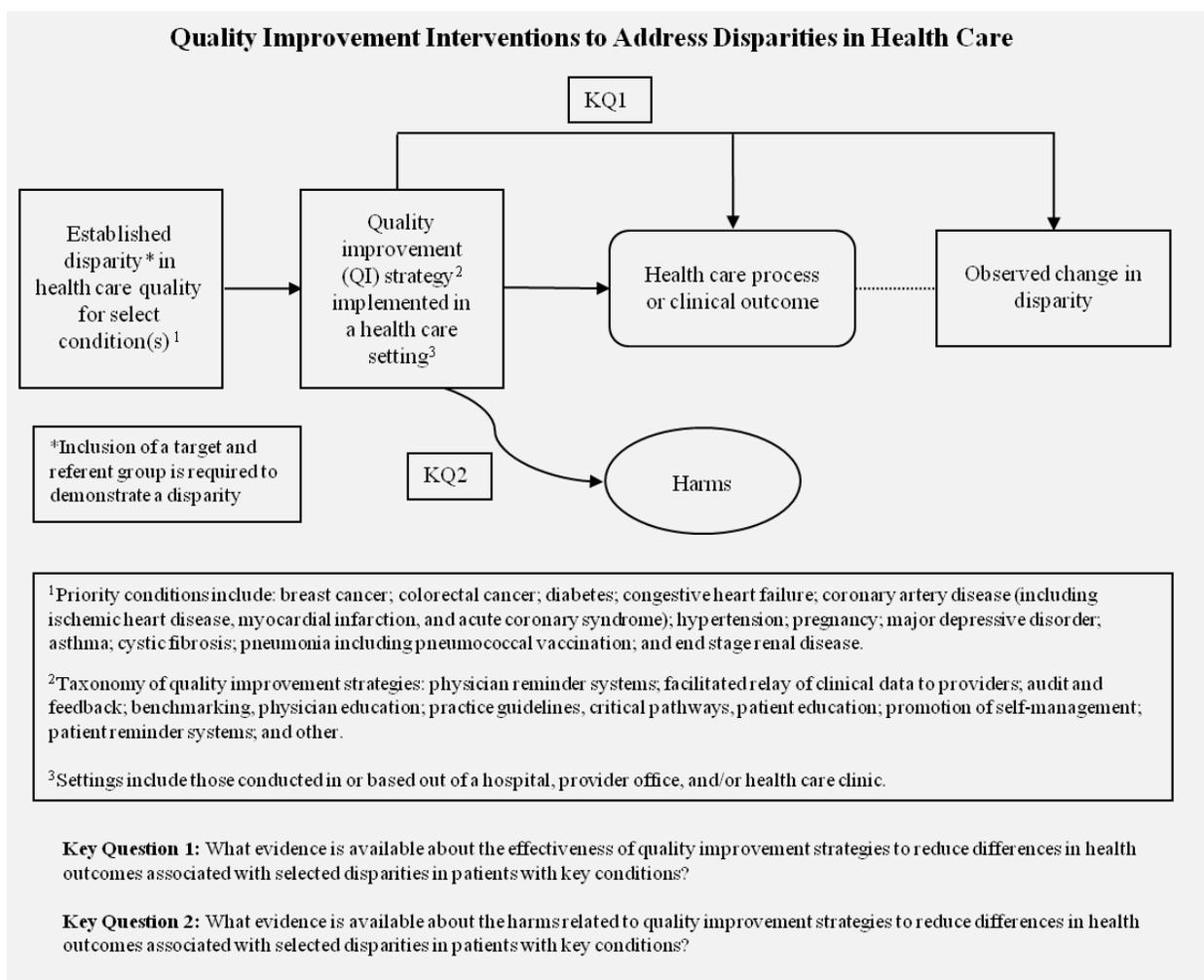
---

[a] Data regarding external referent populations must have been published within four years of a given study's date of data collection, and must include a population that is geographically loca (no higher than the state level) with respect to the target population.

III.   Analytic Framework

The analytic framework outlines the proposed review of the available evidence on the effectiveness of quality improvement (QI) strategies in the reduction of disparities in health outcomes and other measures of health care delivery for selected conditions and groups. The intervention is any tool or process aimed at reducing the quality gap for a group of patients typical of those seen in routine practice. To measure potential changes in the inequity of care between patient groups, priority condition studies must include a target and referent population. Specific QI interventions will be identified from a broad list of quality improvement strategies previously described in the antecedent "Closing the Quality Gap Series." The review will include studies which report health care processes, and/or individual health outcomes associated with the quality of care in selected groups and conditions. Adverse outcomes or harms resulting from a quality improvement intervention are also illustrated.

Figure 1: Analytic Framework[a]

Quality Improvement Interventions to Address Disparities in Health Care

KQ1

Established disparity* in health care quality for select condition(s)[1] → Quality improvement (QI) strategy[2] implemented in a health care setting[3] → Health care process or clinical outcome ······ Observed change in disparity

*Inclusion of a target and referent group is required to demonstrate a disparity

KQ2 → Harms

[1]Priority conditions include: breast cancer; colorectal cancer; diabetes; congestive heart failure; coronary artery disease (including ischemic heart disease, myocardial infarction, and acute coronary syndrome); hypertension; pregnancy; major depressive disorder; asthma; cystic fibrosis; pneumonia including pneumococcal vaccination; and end stage renal disease.

[2]Taxonomy of quality improvement strategies: physician reminder systems; facilitated relay of clinical data to providers; audit and feedback; benchmarking, physician education; practice guidelines, critical pathways, patient education; promotion of self-management; patient reminder systems; and other.

[3]Settings include those conducted in or based out of a hospital, provider office, and/or health care clinic.

Key Question 1: What evidence is available about the effectiveness of quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?

Key Question 2: What evidence is available about the harms related to quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?

[a] See Appendix 2 for "Alternate Text."

IV. Methods

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

- *Disparity Measure.* In identifying studies, we will include studies that capture and report a measure of disparity in health outcomes by race/ethnicity, socioeconomic status, insurance status, sex, sexual orientation, health literacy/numeracy, and language barriers[a]. The disparity may be established by measuring the difference between outcomes in two groups internal to the study, or by referencing measures in an appropriate external referent group.

- *Geographic Limit.* As health care systems, disparity indicators, and groups subject to disparities vary geographically, papers will be limited to studies of patients within the U. S. health care system. Consistent with this inclusion criterion, only papers published in English will be included.

- *Publication Dates.* Research on quality improvement interventions in health care, and more specifically, research on quality improvement with respect to disparities, is a relatively new area of health services research. Seminal publications in quality improvement were published in the 1980s. The team decided to limit the search to articles published in or since 1983.

- *Study Design.* Acceptable study designs will include randomized controlled trials, including cluster randomized controlled trials; controlled trials, including quasi-randomized studies; controlled before-after studies; prospective cohort studies; interrupted time series with comparison groups; and stepped wedge designs. In all cases, the study must assess whether or not a disparity was reduced.

- *Study Groups.* Studies should identify and include a target and a referent (i.e., comparison) group. Included studies should report data from these groups both before and after the introduction of a quality improvement intervention. A referent group is necessary for comparison to demonstrate a change in disparity. The target group must comprise individuals with one of more of the disparity indicators. The referent group or referent group data must comprise individuals without the given disparity. This group may be internal (i.e., a comparison group within the study without the indicator(s) of disparity in the target group) or external (i.e., data or statistics from a population with close geographic proximity[b] but without the indicator(s) of disparity in the target group within the study). An example of a study eligible for inclusion is one that describes a quality improvement intervention at a hospital that primarily treats African American

---

[a] The selected measures of disparity will also be referred to as "disparity indicators" or "indicator(s) of disparity"

[b] Data regarding external referent populations must have been published within four years of a given study's date of data collection, and must include a population that is geographically local (no higher than the state level) with respect to the target population.

patients. This study will report data from the target and comparison groups both before and after the intervention. Additionally, the study will reference county-wide hospital data published within the preceding four years to measure a change in disparity between the African American patient group and the larger referent population.

- *Outcomes*. Included studies should capture health outcome measures and/or process measures. Harms, such as negative unintended consequences, misallocation of effort, and decreased patient satisfaction[9, 10] of the quality improvement intervention to the individual participants or the health care system will be captured as reported. Any change in the disparity gap will be captured as reported.

- *Other*. The conditions included are those that appear on at least three of the four priority lists from the AHRQ and IOM reports, with the exception of smoking and HIV/AIDS. To ensure representation of the pediatric population, we will also include studies that evaluate a quality improvement intervention for patients with asthma or cystic fibrosis. The team will not include studies that overlap with the topic areas and specific interventions that are covered by other reports within the series (e.g., studies that target public reporting, payment bundling, and medication adherence in HIV/AIDS).

Table 1: Inclusion/Exclusion Criteria

Category	Criteria
Study population	Individuals receiving health care in the United States for a priority condition: • Colorectal cancer • Breast cancer • Diabetes • Congestive heart failure • Coronary artery disease (including ischemic heart disease, myocardial infarction, and acute coronary syndrome) • Hypertension • Pregnancy • Major depressive disorder • Asthma • Cystic fibrosis • Pneumonia including pneumococcal vaccination • End-stage renal disease Studies must include: (a) members of a target population as defined by one or more of the following indicators of disparity: race/ethnicity, socioeconomic status, insurance status, sex, sexual orientation, health literacy/numeracy, and language barriers; and (b) data from an external or internal referent population.
Time period	1983-present
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs • Randomized controlled trials, including cluster randomized controlled trials • Controlled trials, including quasi-randomized trials • Controlled before-after studies • Prospective cohort studies • Interrupted time series studies with comparison groups • Stepped-wedge design studies Other criteria • Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and

results.

- Inclusion of a target group and an internal or external referent group to measure changes in disparities.
- The minimum sample size for inclusion is 50 per study-intervention group.[a]
- Studies must address one or more of the following:
  - Quality improvement modality aimed at modifying a health care process or outcome.
  - Outcomes (including harms) related to quality improvement strategies that address disparities.
- Studies must include extractable data on relevant outcomes, including data presented in text or tables (versus solely in figures).

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

To ensure comprehensive retrieval of relevant studies of quality improvement interventions to address disparities, we will use the following key databases: the PubMed medical literature database, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), ISI Web of Science Social Science Index, and PsycINFO (CSA Illumina interface). The search strategies for each of these databases will focus specifically on terms related to quality improvement, disparity, and priority conditions. The search strategies will use a combination of subject headings (i.e. controlled vocabulary) and keywords.

We will update the literature search quarterly. We will also update the search when the draft report is submitted, and add relevant studies as needed while the draft report is undergoing peer review. We will also incorporate studies that meet our inclusion criteria or are relevant as background material that may be identified by both the public and peer reviewers.

We will carry out hand searches of the reference lists of recent systematic reviews or meta-analyses of related quality improvement studies; the investigative team will also scan for studies that potentially could meet our inclusion criteria from the reference lists of articles included after the full-text review.

c. Data Extraction and Data Management

Data Extraction Forms. We will develop data-collection forms for the abstract review, the full-text review, and data extraction. The forms used for the abstract review will contain questions about the primary exclusion and inclusion criteria. The team Methods Lead and Lead Scientist will test the abstract review form on multiple

---

[a] In the absence of published information (e.g., minimum effect size, standard error), to inform a power calculation, the minimum sample size was derived from expert opinion.

articles before beginning the abstract review process. The full-text review form will be more detailed and is intended to assist in a) identifying studies that meet inclusion criteria; and b) initially sorting the studies according to the intervention and outcomes. Finally, data-extraction forms will collect those data necessary to create evidence tables and perform data synthesis.

We anticipate that these data will include those related to population characteristics, including measures of disparity and condition, intervention characteristics, and outcomes including harms. Data collection forms may undergo several revisions following input from the technical expert panel and testing by the team Methods Lead and Scientific Lead. Prior to data collection, we will develop lists informed by clinical expertise of potential confounders and effect modifiers (e.g., demographics, clinical characteristics) and expected outcomes for the data extraction form.

Initial Review of Abstracts. We will review all the titles and abstracts identified through searches against the inclusion/exclusion criteria. Each abstract will be reviewed by at least two members of the investigative team. When differences between the reviewers arise, we will err on the side of inclusion. For studies without adequate information to make the determination, we will retrieve the full-text articles and review them against the inclusion/exclusion criteria.

Retrieving and Reviewing Articles. We will retrieve and review all articles that meet our predetermined inclusion/exclusion criteria, or for which we have insufficient information to make a decision about eligibility. Each article will be reviewed by at least two members of the investigative team. Disagreements between reviewers will be resolved through third party adjudication.

For studies that meet the conditions of the second-round assessment, the abstractors will extract key data into evidence tables and conduct quality reviews. The Methods Lead, the Lead Scientist, and the content experts will review those data-extraction forms against the original articles for quality control. Differences in data coding between the abstractor and the reviewer will be resolved by consensus.

We will develop a simple categorization scheme for coding the reasons that articles, at the stage of full review, are not finally included in the report. The abstractor will note the reason(s) for exclusion on the article abstraction form. We will then record those codes in an EndNote® bibliographic database so that we can later compile a listing of excluded articles and the reasons for such exclusions.

d. Assessment of Methodologic Quality of Individual Studies

Assessing Study Quality. The quality of individual studies will be assessed using specific assessment tools for each type of study. Data from studies that are considered to be fair or good quality will be included in the analysis. Poor studies will be identified but not further assessed. For RCTs, the fundamental domains will include:

adequate sequence generation, allocation concealment, blinding, incomplete outcome data addressed, and freedom from selective reporting bias.

For observational studies, we anticipate assessing three broad characteristics: (1) the selection of the study groups, (2) the comparability of the study groups, and (3) the outcome of interest (for cohort studies). For example, for a cohort study, the fundamental criteria will include: representativeness of the cohort, selection of a nonexposed cohort, ascertainment of treatment exposure, outcome of interest, comparability of cohorts, assessment of outcome, adequate duration of followup, and adequate followup of the cohort (i.e. reporting of loss to followup). Other sources of bias would include imbalances in baseline measures, source of funding, stopping treatment early for benefit, and inappropriateness of crossover design.

Decision rules regarding detailed use of the quality-assessment tools will be specified a priori by the review team. Two senior staff will independently perform quality assessment of the included studies; disagreements will be resolved through discussion or third-party adjudication as needed. We will record quality assessments in tables, summarizing each study. Studies will be given a quality grade of good, fair, or poor per the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[11]

e. Data Synthesis

Preparing Evidence Tables. We will enter data into evidence tables by using predetermined abbreviations and acronyms consistently across all entries. The dimensions (i.e., areas of special focus, or the columns) of each evidence table may vary by key question as appropriate, but the tables will contain some common elements, such as author, year of publication, study location (e.g., city, state) and time period, population description, sample size, and study type (e.g., RCT, prospective observational study). We will conduct quantitative syntheses such as meta-analyses if the data are appropriate (i.e., lack excessive heterogeneity).

f. Grading the Evidence for Each Intervention

Assessing the Strength of Evidence. We will also utilize explicit criteria for rating the overall strength of the collective evidence on each intervention into qualitative categories (e.g., high, moderate, low, insufficient).

The strength of evidence evaluation will be that stipulated in *the Methods Guide for Effectiveness and Comparative Effectiveness Reviews,*[12] which emphasizes the following four major domains: risk of bias (low, medium, high); consistency (inconsistency not present, inconsistency present, unknown or not applicable); directness (direct, indirect); and precision (precise, imprecise). Risk of bias is derived from the quality assessment of the individual studies that addressed the KQ and specific outcome under consideration. Each key outcome on each comparison of

interest will be given an overall evidence grade based on the ratings for the individual domains.

The overall strength of evidence will be graded as "high" (indicating high confidence that the evidence reflects the true effect and further research is very unlikely to change our confidence in the estimate of effect), "moderate" (indicating moderate confidence that the evidence reflects the true effect and further research may change our confidence in the estimate of effect and may change the estimate), "low" (indicating low confidence that the evidence reflects the true effect and further research is likely to change our confidence in the estimate of effect and is likely to change the estimate), or "insufficient" (indicating that evidence is either unavailable or does not permit estimation of an effect).[12] When no studies are available for an outcome or comparison of interest, the evidence will be graded as insufficient.

Two senior staff will independently grade the body of evidence; disagreements will be resolved as needed through discussion or third-party adjudication. We will record strength of evidence assessments in tables, summarizing for each outcome.

g. Assessing Applicability

Our team will assess the applicability of the results gathered from the literature according to EPC methods guidance.[13] This will be done to account for any factors limiting the ability to apply interventions to other populations or other settings, such as inadequate description of the intervention or failure to report follow-up data.

h. Methodological Challenges

The team recognizes several challenges that will limit the identification and assessment of quality studies that address the topic, including scope, classification/definitions, and admissible study designs. Identification of the definitions and classification for quality improvement interventions, disparities, and appropriate outcome measures require numerous revisions and reiterations. The topic scope is broad: quality improvement interventions are not clearly identified and may be multifaceted; disparities in health care between certain groups of patients are numerous and well described but not clearly measured; the topic is not limited to a single clinical condition. The literature on quality improvement interventions in the health care setting is also not indexed well. Furthermore, spurious effects and other trends (e.g. changes over time unrelated to the intervention) may complicate the interpretation of intervention effects. The challenge that is most anticipated by the team and the TEP is a lack of rigorous data from studies that can demonstrate both the value of a given quality improvement intervention and measure a change in outcomes relative to a referent group. The choice of referent group will be evaluated when assessing applicability. To evaluate the value of quality improvement interventions for disparity reduction, eligible studies must include a referent group or referent group data that is geographically and temporally proximal to the target group.

V.   Definitions of Terms

Quality Improvement Intervention: An change process in health care systems, services, or suppliers for the purpose of increasing the likelihood of optimal clinical quality of care, measured by positive health outcomes for individuals and populations.[14]

Improvement of quality: Broadly defined to include the safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity of care.[15]

Disparities: Racial or ethnic differences in the quality of health care that are not due to access-related factors or clinical needs, preferences, and appropriateness of intervention.[16]

Health disparities: Differences in health outcomes and their determinants between segments of the population, as defined by social, demographic, environmental, and geographic attributes.[17]

Health inequities: A subset of health inequalities that are modifiable, associated with social disadvantage, and considered ethically unfair.[18]

VI.   References

1. Smedley BD, Stith AY, Nelson AR, et al. Unequal treatment : confronting racial and ethnic disparities in health care. Washington, D.C.: National Academies Press; 2003.

2. Centers for Disease Control and Prevention (U.S.). Epidemiology and Analysis Program Office; Surveillance Epidemiology and Laboratory Services. Health disparities and inequalities report--United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services Centers for Disease Control and Prevention; 2011.

3. Kaplan HC, Brady PW, Dritz MC, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. Milbank Q. 2010 Dec;88(4):500-59.

4. Agency for Healthcare Research and Quality. Closing the Quality Gap: A Critical Analysis of Quality Improvement Stategies [Fact Sheet]. Rockville, MD: Agency for Healthcare Research and Quality; March 2004 [cited January 2011]. Available from: http://purl.access.gpo.gov/GPO/LPS110179. Accessed April 14, 2011.

5. Agency for Healthcare Research and Quality. National Healthcare Disparities Report. Rockville, MD: U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; March 2010 [cited January 2011]. Available from: http://www.ahrq.gov/qual/qrdr09.htm. Accessed April 14, 2011.

6. Agency for Healthcare Research and Quality. National Healthcare Quality Report Rockville, MD: U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; March 2010 [cited January 2011]. Available from: http://www.ahrq.gov/qual/nhqr09/nhqr09.pdf. Accessed April 14, 2011.

7. Adams K, Corrigan J and Institute of Medicine (U.S.). Priority areas for national action : transforming health care quality. Washington, D.C.: National Academies Press; 2003.

8. Agency for Healthcare Research and Quality. Evidence-based Practice Partner's Guide [Chapter 2: Report Topics]. Rockville, MD: U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; May 2009 [cited January 2011]. Available from: http://www.ahrq.gov/clinic/epcpartner/. Accessed April 14, 2011.

9. Bardach NS and Cabana MD. The unintended consequences of qua

14

AHRQ
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Effective Health Care Program

lity improvement. Curr Opin Pediatr. 2009 Dec;21(6):777-82.

10. Casalino LP. The unintended consequences of measuring quality on the quality of medical care. N Engl J Med. 1999 Oct 7;341(15):1147-50.

11. Agency for Healthcare Research and Quality. Methods Reference Guide for Effectiveness and Comparative Effectiveness Reviews [Chapter 6: Assessing the Quality and Applicability of Included Studies]. Rockville, MD: U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; Draft posted October 2007 [cited January 2011]. Available from: http://www.effectivehealthcare.ahrq.gov/repFiles/2007_10DraftMethodsGuide.pdf. Accessed April 14, 2011.

12. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions--agency for healthcare research and quality and the effective health-care program. J Clin Epidemiol. 2010 May;63(5):513-23.

13. Atkins D, Chang S, Gartiehner G, et al. Assessing the Applicability of Studies When Comparing Medical Interventions. Agency for Healthcare Research and Quality [Methods Guide for Comparative Effectiveness Reviews. AHRQ Publication No. 11-EHC019-EF]. U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality; January 2011 [cited February 2011]. Available from: http://www.effectivehealthcare.ahrq.gov/tasks/sites/ehc/assets/File/Methods_Guide_Atkins.pdf. Accessed April 14, 2011.

14. American College of Medical Quality (ACMQ). Professional Policies. Policy 2: Definition of Clinical Quality Improvement. [cited February 2011]. Available from: http://www.acmq.org/policies/policyindex.cfm. Accessed April 14, 2011.

15. Davidoff F, Batalden P, Stevens D, et al. Publication guidelines for quality improvement studies in health care: evolution of the SQUIRE project. BMJ.338.

16. Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare. Smedley BD, Sith AY and Nelson AR, editors. Washington, D.C.: Institute of Medicine, The National Academies Press; 2003.

17. Carter-Pokras O and Baquet C. What is a "health disparity"? Public Health Rep. 2002 Sep-Oct;117(5):426-34.

18. Braveman P and Gruskin S. Defining equity in health. J Epidemiol Community Health. 2003 Apr;57(4):254-8.

VII.   Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VIII.   Review of Key Questions

The key questions were reviewed and refined by the EPC with input from the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed.

IX.   Technical Experts

Technical Experts comprise a multi-disciplinary group of clinical, content, and methodologic experts who provide input in defining populations, interventions, comparisons, or outcomes as well as in identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the

topic under development. Divergent and conflicted opinions are common and are perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design, and/or 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 contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the 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. Individuals are invited to serve as Technical Experts because of their unique clinical or content expertise, and those who present with potential conflicts may be retained. The task order officer (TOO) and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X.   Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the evidence report.

Potential 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.

Appendix 1: Closing the Quality Gap Series' Topics

Series EPC Topics
Healthcare-associated infections
Medication adherence
Public reporting
Medical home
Disability outcomes
Payment bundling
Disparities
End of life

Appendix 2: Alternate text for Figure 1

Illustration of a various shapes connected by arrows, a curved line and a dashed line, representing the project topic (established disparity in health care quality for select condition(s)); the intervention of interest (quality improvement strategy implemented in a health care setting); the outcome of interest (health care process or clinical outcome); and the associated observed change in disparity. A small box for key question 1: "What evidence is available about the effectiveness of quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?" is situated between the intervention box and the outcome box. Harms of the intervention are represented within an oval with an attached box for key question 2: "What evidence is available about the harms related to quality improvement strategies to reduce differences in health outcomes associated with selected disparities in patients with key conditions?" The first box includes an asterisk to note that a target and referent group must be included to demonstrate a disparity. There are three footnotes at the bottom of the illustration. Footnote one states: Priority conditions include: colorectal cancer screening; diabetes; congestive heart failure; hypertension; maternal/neonatal health including preterm birth; major depressive disorder; asthma; cystic fibrosis; pneumonia including pneumococcal vaccination; and end stage renal disease. Footnote two states: Taxonomy of quality improvement strategies: physician reminder systems; facilitated relay of clinical data to providers; audit and feedback; benchmarking, physician education; practice guidelines, critical pathways, patient education; promotion of self-management; patient reminder systems; and other. Footnote three states: Settings include those conducted in or based out of a hospital, provider office, and/or health care clinic.