Appendixes

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Appendix A

National Priority Areas Summary with Key Associated Goals

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Appendix A: National Priority Areas Summary with Key Associated Goals

Care coordination (cross-cutting area)—About 60 million Americans live with multiple chronic conditions, such as hypertension and diabetes. Clinicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.

Children with special health care needs—Children with a chronic physical, developmental, behavioral, or emotional condition, or an increased risk of developing one, require more than the typical level of pediatric care. This vulnerable population requires caregivers to work closely with families to develop and coordinate care plans.

Diabetes—Diabetes is the fifth-leading cause of death in America, predisposing people to serious, long-term medical complications, including heart disease, hypertension, and blindness. There are several well-known and effective models for improving the delivery of care, with the goal of preventing progression through early and proper management.

End of life with advanced organ system failure—Heart, lung, and liver failures account for about one-fifth of all fatalities in America. Care should minimize symptoms and reduce the rate of exacerbations of organ malfunction. Improving care requires continuity of care over time and across settings, close monitoring, and rapid responses.

Evidence-based cancer screening—Cancer is the second-leading cause of death in the United States. Screening can significantly reduce death rates for several forms of cancer, especially colorectal and cervical cancer. Goals should be to increase the number of people who receive screenings and to provide timely followup.

Frailty associated with old age—With more Americans living longer, more people will experience the multiple mental and physical health challenges associated with advanced age. Health care efforts should focus on preventing falls and pressure ulcers, maximizing function, and developing advanced care plans.

Hypertension—Although this disease affects one in four adults in the United States, nearly a third of people with high blood pressure are undiagnosed. Untreated hypertension can lead to life-threatening complications, including stroke, heart attack, and kidney failure. Interventions should emphasize early detection and management.

Immunization—Timely vaccination could prevent the deaths of about 300 children and between 50,000 and 70,000 adults annually. Influenza and pneumonia account for most of the adult deaths. Vaccination efforts should target nursing-home residents, who are susceptible to contagious illnesses because of advanced age and close living quarters. Also, new strategies should be developed to reach out to black and Hispanic adults, as well as low-income, inner-city children – populations that tend to have lower-than-average immunization rates.

Ischemic heart disease—Ischemic, or coronary, heart disease, is the leading cause of death among adults in the United States. Efforts should focus on preventing heart disease and reducing recurrence of heart attacks through promotion of healthy lifestyle changes and use of cholesterol-lowering drugs, surgery, and timely administration of medications after a heart attack. In addition, efforts should ensure that those with heart disease are functioning at their greatest capacity.

Major depression—Treatment rates for depression are significantly lower than those for many other chronic conditions; fewer than half of individuals with depression are correctly diagnosed. National rates of screening and treatment should be improved.

Medication management—Efforts should focus on preventing medication errors, particularly through greater use of computer technology. In addition, educational interventions that warn physicians and patients about problems associated with overuse of antibiotics have been successful.

Nosocomial infections—Hospital-acquired infections kill nearly 90,000 patients in the United States each year, and cost an additional $5 billion to treat. Wider implementation of the nosocomial infection guidelines from the Centers for Disease Control and Prevention would save more than 40,000 lives annually, reduce infection rates by up to 50 percent, and save nearly $2.75 billion each year.

Obesity (emerging area)—Each year more than 300,000 deaths can be attributed to obesity. The condition eventually could become the nation's single most preventable cause of premature death and disability. Changes in social norms and national policies to promote physical activity and healthy diets are essential. Effective national strategies for obesity prevention, treatment, and control will require a combination of public health and clinical interventions.

Pain control in advanced cancer—Twenty percent of Americans die from cancer, often after months of painful, progressive illness. Effective pain control programs have been developed. Efforts should emphasize cooperation in protocols across care settings, advance planning for changes in settings as well as heightened pain, and public education regarding the merits of opioid medications in this area.

Pregnancy and childbirth—The quality of prenatal care and care related to labor and delivery should be enhanced to boost the long-term health of women and their children. Some key goals should be to increase the number of women who start prenatal care in the first trimester and to screen more pregnant women for sexually transmitted diseases.

Self-management/health literacy (cross-cutting area)—Public and private entities should systematically provide educational programs and interventions that boost patients' skills and confidence in managing and assessing their health problems. Higher levels of health literacy allow people to understand and act on health care information.

Severe and persistent mental illness—The quality of mental health care in the public sector, including state hospitals, community mental-health centers, and various federal and state programs should be improved. The federal government should play a larger role to assure higher standards of care across states.

Stroke—Stroke is the third-leading cause of death in the United States. Efforts should focus on seamlessly integrating care across health care settings and clinical disciplines. Beginning rehabilitation as soon as possible after a stroke also helps patients regain their abilities.

Tobacco-dependence treatment in adults—Tobacco use and dependence are the nation's most preventable causes of disease and death. Many successful efforts to improve health care in this area have used multilayered interventions that include systems to remind caregivers to discuss tobacco use with patients, as well as provider-education programs centered on best practices.

Adapted from National Academy of Medicine Press Release, January 7, 2003 “Officials Should Target 20 Key Areas to Transform Health Care System” http://www4.nas.edu/news.nsf/isbn/0309085438?OpenDocument; accessed April 11, 2003.

Appendix B: Search Strategy Exemplar: Quality Improvement and Hypertension

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Appendix B: Search Strategy Exemplar: Quality Improvement and Hypertension

I. MEDLINE search

Search		Search String	Citations[‡]
#1	Care coord, Disease Mx, etc.	Disease Management [mh] OR Patient Care Planning [mh] OR Patient-Centered Care [mh] OR Primary Health Care [mh] OR Progressive Patient Care [mh] OR Critical Pathways [mh] OR Delivery of Health Care, Integrated [mh] OR Health Services Accessibility [mh] OR Managed Care Programs [mh] OR Product Line Management [mh] OR Patient Care Team [mh] OR Patient-Centered Care [mh] OR Behavior Control [mh] OR Counseling [mh] OR Health Promotion [mh] OR Patient Compliance [mh] OR After-Hours Care [mh] OR ((coordination [ti] OR coordinated [ti] OR Multifactorial [ti] OR Multi-factorial [ti] OR Multicomponent [ti] OR Multi-component [ti] OR multidisciplinary [ti] OR multi-disciplinary [ti] OR interdisciplinary [ti] OR inter-disciplinary [ti] OR integrated [ti] OR community-based [ti] OR organized [ti]) AND (care [ti] OR approach [ti] OR intervention [ti] OR strategy [ti] OR strategies [ti] OR management [ti] OR managing [ti] OR center* [ti] OR clinic*[ti])) OR Organization and Administration [mh]	683,000
#2	TQM, CQI	Total Quality Management [mh] OR Quality control [mh] OR TQM [ti] OR CQI [ti] OR (quality [ti] AND (continuous [ti] OR total [ti]) AND (management [ti] OR improvement [ti]))	28,087
#3	CME, educ outreach	Education, Continuing [mh] OR (Education [ti] AND Continuing [ti] AND (medical [ti] OR professional* [ti] OR nursing [ti] OR physician* [ti] OR nurse* [ti])) OR (outreach [ti] AND (visit*[ti] OR educational [ti]) OR (academic [ti] AND detailing [ti]))	35,276
#4		Diffusion of Innovation [mh] OR (Diffusion [ti] AND (Innovation [ti] OR technology [ti]))	4,889
#5	Audit, feedback financial incentive	Medical audit [mh] OR ((Audit [ti] OR feedback [ti] OR compliance [ti] OR adherence [ti] OR training [ti]) AND (improvement* [ti] OR improving [ti] OR improves [ti] OR improve [ti] OR guideline* [ti] OR practice* [ti] OR medical [ti] OR provider* [ti] OR physician* [ti] OR nurse* [ti] OR clinician* [ti] OR practice guidelines [mh] OR academic [ti] OR visit* [ti])) OR Reminder Systems [mh] OR Reminder* [ti] OR ((financial [ti] OR economic [ti] OR physician* [ti] OR patient*) AND incentive* [ti]) OR Reimbursement Mechanisms [mh]	36,852

[‡] Numbers of citations reflect search results from July 8, 2003

#6	IT, telemed	Medical Informatics [mh] OR computer [ti] OR (decision [ti] AND support [ti]) OR Telemedicine[mh] OR Telemedicine [ti] OR telecommunication* [ti] OR Internet [mh] OR web [ti] OR modem [ti] OR telephone* [ti] OR telephone [mh]	306,703
#7		#1 OR #2 OR #3 OR #4 OR #5 OR #6	988,356
#8		#7 AND (Hypertension [mh] OR Hypertension [ti] OR (blood [ti] AND pressure [ti]))	7,574
#9		#8 AND (systematic review search string[§] OR original research string[**])	3,698
#10		#9 Limit to English	3,144
#11		#10 Limit to Pub since 1980	2,942
#12	Main result	#11 BUTNOT (editorial [pt] OR comment [pt] OR letter [pt])	2,842
#13	Additional yield of journal search	(#8 AND Journal Search String [††]) BUTNOT (#9 OR editorial [pt] OR comment [pt] OR letter [pt]) [Limited to English, 1980]	220

[§] ((meta-analysis [pt] OR meta-analysis [tw] OR metaanalysis [tw]) OR ((review [pt] OR guideline [pt] OR consensus [ti] OR guideline* [ti] OR literature [ti] OR overview [ti] OR review [ti] OR Decision Support Techniques [mh]) AND ((Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])) OR (handsearch* [tw] OR search* [tw] OR searching [tw]) AND (hand [tw] OR manual [tw] OR electronic [tw] OR bibliographi* [tw] OR database* OR (Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw]))))) OR ((synthesis [ti] OR overview [ti] OR review [ti] OR survey [ti]) AND (systematic [ti] OR critical [ti] OR methodologic [ti] OR quantitative [ti] OR qualitative [ti] OR literature [ti] OR evidence [ti] OR evidence-based [ti]))) BUTNOT (case report [mh] OR case* [ti] OR report [ti] OR editorial [pt] OR comment [pt] OR letter [pt]) → 38,865 MEDLINE records

[**] Randomised [ti] OR Randomized [ti] OR Controlled [ti] OR intervention [ti] OR evaluation [ti] OR impact [ti] OR effectiveness [ti] OR Evaluation [ti] OR Studies [ti] OR study [ti] Comparative [ti] OR Feasibility [ti] OR Program [ti] OR Design [ti] OR Clinical Trial [pt] OR Randomized Controlled Trial [pt] OR Epidemiologic Studies [mh] OR Evaluation Studies [mh] OR Comparative Study [mh] OR Feasibility Studies [mh] OR Intervention Studies [mh] OR Program Evaluation [mh] OR Epidemiologic Research Design [mh] —> 2,551,486 MEDLINE records

[††] N Engl J Med [ta] OR JAMA [ta] OR Ann Intern Med [ta] OR Am J Med [ta] OR Arch Intern Med [ta] OR J Gen Intern Med [ta] OR BMJ [ta] OR Lancet [ta] OR CMAJ [ta] OR Clin Invest Med [ta] OR Arch Fam Med [ta] OR J Fam Pract [ta] OR Fam Pract [ta] OR Ann Med [ta] OR Br J Gen Pract [ta] OR J Intern Med [ta] OR Med J Aust [ta] OR South Med J [ta] OR West J Med [ta] OR Aust N Z J Med [ta] OR Med Care [ta] OR Health Serv Res [ta] OR Inquiry [ta] OR Milbank Q [ta] OR Health Aff (Millwood) [ta] OR Health Care Financ Rev [ta] OR Med Care Res Rev [ta] OR eff clin pract [ta] OR eval health prof [ta] OR Jt Comm J Qual Improv [ta] OR Qual Saf Health Care [ta] OR Int J Qual Health Care [mh] OR Qual Health Care [ta] OR Qual Health Res [ta] OR Rep Med Guidel Outcomes Res [ta] OR Am J Manag Care [ta] OR Am J Med Qual [ta] OR J Contin Educ Health Prof [ta] OR Prev Med [ta] OR Am J Prev Med [ta] OR Patient Educ Couns [ta] OR Ann Behav Med [ta] OR J Hum Hypertens [ta] OR Hypertension [ta] OR Am J Hypertens [ta] OR Clin Exp Hypertens [ta] OR J Clin Hypertens [ta] OR J Hypertens [ta] OR Am J Cardiol [ta] OR Am Heart J [ta] OR circulation [ta] OR J AM Coll Cardiol [ta] OR Can J Cardiol [ta] OR Heart Lung [ta]

#14	Additional yield of author search	(#8 AND author search[‡‡]) BUTNOT (#13 OR editorial [pt] OR comment [pt] OR letter [pt]) [Limited to English, 1980]	29
#14			3,070 references total (322 of these were same as in the Diabetes search)

[‡‡] (Berwick D [au] OR berlowitz d [au] OR davis d [au] OR kiefe c [au] OR wagner e [au] OR glasgow r [au] OR boddenheimer t [au] OR Hulscher M [au] OR grol r [au] OR grimshaw j [au] OR haynes b [au] OR haynes rb [au] OR sackett d [au] OR goldberg h [au] OR Hirsch I [au] OR nash d [au] OR roper w [au] OR weingarten s [au]) --> 6,401

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Appendix C: Article Review Triage Forms (Exemplar: Diabetes)

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Appendix C: Article Review Triage Forms (Exemplar: Diabetes)

Note: Items in *Italics* are topic-specific

Diabetes Triage Forms

Stage 1:

1. Does the article report or evaluate the results of an intervention (whether performed by the investigators or not)?
   - o Yes
   - o No **<exclusionary answer>**
   - o Can't Tell

2. Does the article involve quality improvement or a QI strategy?
   - o Yes - involves quality improvement or a QI strategy
   - o Yes - systematic review of evaluations of a QI strategy
   - o No **<exclusionary answer>**
   - o Can't Tell

Stage 2:

1. Should this article proceed to article abstraction stage for this topic?
   - o Yes - evaluates a QI strategy involving diabetes
   - o *No - focused on diabetes in pregnancy, Type I DM only, screening for/preventing diabetes, hospital care only* **<exclusionary answer>**
   - o No - but involves other EPC topic(s) **<exclusionary answer>**
   - o No - not an evaluation or not QI **<exclusionary answer>**
   - o Can't tell - need article
   - o No - but useful background article **<exclusionary answer>**

2. What type of study design was used?
   - o RCT or quasi-RCT
   - o Prospective clinical trial, CBA* or ITS **
   - o Cohort study; before-after or time series not meeting CBA* or ITS** definitions **<exclusionary answer for this topic>**
   - o Observational (e.g., cross-section, case-control) **<exclusionary answer>**
   - o Can't tell (need article)
   - o Systematic review or meta-analysis
   - o Economic or decision analysis, modeling **<exclusionary answer>**
   - o Non-research (commentary, review, news) **<exclusionary answer>**
   - o Qualitative research (e.g., focus groups) **<exclusionary answer>**
   - o Guideline or consensus statement **<exclusionary answer>**

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Appendix D: Full Article Review Abstraction Forms Stages 3 and 4 (Exemplar: Diabetes)

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Appendix D: Full Article Review Abstraction Forms Stages 3 and 4 (Exemplar: Diabetes)

Note: Items in *Italics* are topic-specific

Stage 3:

1. Does this article merit abstraction at Level 3?
   - Yes
   - No – not QI or not an evaluation of a QI strategy **<exclusionary answer>**
   - No – study design below Level 2 **<exclusionary answer>**
   - *No - excluded topic (focused only on pregnancy, Type I DM, or screening)* **<exclusionary answer>**
   - No – no eligible outcomes* **<exclusionary answer>**

*Eligible outcomes include measure of disease control, provider adherence, or patient adherence. Excluded are: measures of provider or patient understanding, satisfaction, self-efficacy; costs and resource use. Also excluded are articles reporting no outcomes specifically related to diabetes (e.g. smoking only).

2. Does this article present data overlapping with another article?
   - Exclude this article as a duplicate publication (identify included citation being duplicated) **<exclusionary answer>**
   - Include this article, but obtain listed citation to help with abstraction (e.g., separate methods paper; identify required citation)
   - No or N/A

3. What category of study question is addressed by the article?
   - *Can screening for or awareness of diabetes be improved?*
   - *Can provider treatment of diabetes be improved? (e.g., increased adherence to recommended care)?*
   - *Can patient glycemic control or diabetic complications be improved?*
   - *Can patient adherence, education or self management be improved?*
   - Not sure or Other (describe)
   - N/A

4. Describe the QI strategy used and its salient features.

5. Did the QI strategy involve a provider reminder system* or facilitated relay of clinical data ** back to providers?
   - Chart based reminder system* for providers
   - Computer based reminder* or decision support for providers
   - Facilitated relay of clinical data to providers**
   - Not sure
   - No or N/A

* Patient or provider encounter specific information, provided verbally, on paper or on a computer screen, which is intended to prompt provider to recall information (e.g., the last time the patient had a HbA_{1c} checked and its value, the last time the patient underwent screening colonoscopy and the result).

** Clinical information collected directly from patients and given to the provider using some format other than the conventional chart system.

6. Did the QI strategy involve provider audit and feedback*?
   - Confidential feedback to individual provider
   - Non-confidential feedback to provider and colleagues in same clinic or institution
   - Public reporting of performance data
   - Benchmarking**
   - Not sure or other
   - No or N/A

*Any summary of clinical performance of health care over a specified period of time. E.g., the percentage of a provider's patients who have achieved or have not achieved some clinical target (e.g., BP or HbA_{1c} in certain range), have or have not been offered some diagnostic test.

**Benchmarking refers to the provision of performance data from institutions or providers regarded as "leaders in the field." These data provide targets for other providers and institutions to emulate.

7. Did the QI strategy involve provider education?
   - o Educational workshops, meetings (e.g., traditional CME), lectures (live or computer based)
   - o Educational outreach visits (Use of a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice)
   - o Distribution of educational materials (Distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications)
   - o Not sure or other
   - o No or N/A

8. Did the QI strategy involve patient education or promote self-management?
   - o In-person patient education individually or as a part of a group or community
   - o Distribution of printed or audio-visual educational materials
   - o Patient reminders (e.g., to keep appointments or comply with other aspect of care)
   - o Provision of clinical data back to the patient *(e.g., your most recent HbA1c or lipid panel was such and such)*
   - o Distribution of materials or access to a resource that enhances patients' ability to manage their condition
   - o Not sure or other
   - o No or N/A

9. Did the QI strategy involve organizational change?
   - o Case management, disease management --coordination of assessment, treatment and arrangement for referrals by a person or multidisciplinary team in collaboration with or supplementary to the primary care provider
   - o Adding new members to team *(e.g., adding a diabetes nurse, clinical pharmacist, or nutritionist to clinic)* or creating multidisciplinary teams (creation of a new team of health professionals of different disciplines or additions of new members to the team who work together to care for patients)
   - o Communication and case discussion between distant health professionals (e.g., telemedicine)
   - o TQM/CQI - cycles of measurement of quality problems, design of interventions, implementation and re-measurement
   - o Changes in medical records systems -- e.g. changing from paper to computerized records, patient tracking systems
   - o Revision of professional roles ('professional substitution', 'boundary encroachment') - the shifting of roles among health professionals (e.g., nurse midwives providing obstetrical care)
   - o Increased staffing without changes in roles (e.g., adding more nurses)
   - o Skill mix changes (changes in types or qualifications of personnel - e.g., changing from LVN to RN or RN to NP, but also changing from GP to specialist)
   - o Not sure or other
   - o No or N/A

10. Did the QI strategy involve financial, regulatory or legislative incentives or actions?
    - o Positive or negative financial incentives directed at providers
    - o Positive or negative financial incentives directed at patients
    - o System-wide changes in reimbursement (e.g., capitation, prospective payment, shift from fee for service to salary)
    - o Changes to provider licensure requirements
    - o Changes to institutional accreditation requirements
    - o Not sure or other
    - o No or N/A

11. Did a clinical information system play a role in design or implementation of intervention (regardless of QI strategy type)?
    - o Identification and/or group allocation of eligible patients or providers
    - o Reminders generated by existing clinical information system
    - o Decision support at point of care (e.g., for provider order entry)
    - o Facilitated communication between providers (e.g., generated emails between members of care team)
    - o Audit data gathered from clinical information system to design QI strategy (e.g., audit and feedback, TQM, provider education, financial incentives)
    - o Not sure or Other
    - o No or N/A

12. Who or what was targeted by the intervention?
    - o Patients
    - o Providers (i.e., individual clinicians)
    - o Ambulatory clinics or practices

- o Inpatient units or hospitals
- o Public health systems, healthcare delivery systems, policy makers
- o Not sure or Other
- o N/A

13. Among the target group, what was the number of participants? (i.e., study size)

14. What type of study design was used?
    - o RCT or quasi-RCT
    - o Prospective clinical trial, CBA* or ITS**
    - o Cohort study, retrospective before-after, or time series not meeting ITS definition** **<exclusionary answer for this topic>**
    - o Not sure or other
    - o N/A

*Controlled Before After (CBA) requires contemporaneous observation periods for control and intervention groups AND judgment that control represents a comparable group or setting

** Interrupted time series (ITS) requires statement of well-defined time period for intervention implementation AND at least three time points both before and after

15. What were the outcome types?
    - o Measure of disease control (clinical outcomes, *HbA1c, glucose control, lipids*)
    - o Provider adherence (adherence to a guideline or recommended practice)
    - o Patient adherence
    - o Patient or provider understanding, self-efficacy, empowerment **<exclusionary answer for this topic>**
    - o Not sure or other
    - o N/A

16. What specific measures of disease control were used?
    - o *Serum glucose values (mean or percent of patients in certain range) HbA1c (mean or percent of patients in certain range)*
    - o *Cardiovascular risk factor modification (hyperlipidemia, hypertension, smoking cessation)*
    - o *Microvascular complications (retinopathy, neuropathy, microalbuminuria, foot ulcers)*
    - o *Macrovascular complications (MI, stroke, renal failure, amputation)*
    - o Not sure or other
    - o None or N/A

17. For studies reporting measures of clinician adherence, what specific measures were used?
    - o *Adherence to guideline targets for assessment of glycemic control (e.g., measuring HbA1c at certain intervals)*
    - o *Adherence to recommended screening practices for ophthalmologic complications (e.g., performance of or referral for dilated retinal exam)*
    - o *Adherence to recommended screening practices for renal complications (e.g., checking urine microalbumin)*
    - o *Adherence to recommended screening practices for neuropathy or foot complications (e.g., performance of or referral for foot examination)*
    - o *Adherence to treatment choices for achieving glycemic control (e.g., medication choices)*
    - o *Adherence to guideline targets for managing blood pressure or cardiovascular disease*
    - o *Adherence to recommendations for patient education or counseling re: diet, exercise, smoking, or other lifestyle factors*
    - o Not sure or other
    - o N/A

18. For studies reporting measures of patient adherence, how was adherence assessed?
    - o Laboratory confirmation (e.g., detection of drug or metabolite in blood or urine; including biochemical assays for smoking cessation)
    - o Pharmacy data (e.g., filled or refilled prescriptions)
    - o Specially designed dispensers that record medication use
    - o Home medication counts
    - o Office medication counts (e.g., patients bring in bottles with unused pills)
    - o Patient self report (via interview or survey)
    - o Not sure or other
    - o N/A

Stage 4:

1. Does abstraction of this study require information from methods or results reported in other citations.
   - o Yes (specify)
   - o No

2. Does the article report data for more than one comparison (i.e., should it be abstracted as more than one study)?
   - o Yes (specify which comparison is being abstracted here and which others will be abstracted elsewhere)
   - o No

A) Study Setting and Participants

3. In what country did the study take place?
   - o US only
   - o Non-US (specify)

4. Were the dates of the study period reported?
   - o Yes – give dates exactly as indicated in paper
   - o No – indicate duration of study in month or years if reported.

5. In what setting did the study intervention take place?
   - o Primary care clinic
   - o Specialist clinic (e.g. diabetes or endocrinology practice)
   - o Community
   - o Multiple or Other (describe)
   - o Not stated or not clear

6. Were INCLUDED patients selected on the basis of any of the following?
   - o *Poor compliance with medications or clinic attendance (describe)*
   - o *Poor glycemic control (describe)*
   - o *Presence of specific comorbid conditions or illnesses (specify/describe – e.g., HTN, hyperlipidemia, coronary artery disease, obesity, tobacco use)*
   - o *Presence of specific diabetic complications (specify/describe – e.g., renal failure, albuminuria, neuropathy, retinopathy)*
   - o Other (explain)
   - o None of above
   - o Not applicable (no patient involvement in study – e.g., study of provider-based intervention and provider outcomes only).

7. What type of care was provided to the control population?
   - o No intervention or usual care
   - o Some form of low intensity intervention (describe)
   - o No true control – just two or more different types of intervention (discuss with other reviewers; study may need to be excluded)

B) Study Design

8. What was the study design?
   - o Randomized trial – state method of randomization if described and any descriptive phrases (e.g., “randomly assigned”)
   - o Quasi randomly trial – state basis for treatment allocation (e.g., alternating patients, calendar date, even or odd identification numbers)
   - o Controlled before-after study

9. Did the study have a cross over design? (Patients randomized to a sequence of interventions such as treatment A followed by treatment B in one group B in one group and treatment B followed by treatment A in the other group).
   - o Yes (describe)
   - o No
   - o Not sure – clarify with other review

10. What was the unit of randomization or treatment allocation?
   - o Patient
   - o Episode of care
   - o Clinic day
   - o Provider
   - o Practice
   - o Firm (describe)

- o Institution
- o Community
- o Other

11. For the unit of treatment allocation (above), state sample size in each group (If sample size differs for outcomes, detail differences in "Not stated or not clear" text box):
    - o Control group
    - o Intervention group
    - o Not stated or not clear (explain)

12. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient outcomes analyzed, state sample size in each group: (Use text box for "Not applicable" if sample size for any outcomes reported is different-give details)
    - o Control group
    - o Intervention group
    - o Not stated or not clear

13. If unit of analysis differed from unit of treatment allocation, did authors acknowledge this issue and/or make appropriate adjustments?
    - o Yes (describe)
    - o No
    - o Not applicable (unit of analysis did not differ from unit of treatment allocation)

14. Was the adequate concealment of treatment allocation?
    - o Yes – (unit of allocation was institution, team or professional and any random process explicitly described, e.g., use of random number tables, OR unit of allocation was patient or episode of care and some form of centralized randomization scheme or sealed, opaque, serially numbered envelopes used)
    - o Not clear (only partially meets above criteria) or not stated – specify which
    - o No – inadequate concealment (enrollment of patient in alternation or through use of even/odd identifying numbers OR unit of allocation was patient or episode of care and reported use of any allocation process that is entirely transparent before assignment (e.g., open list of random numbers) OR allocation was altered by investigators, professionals or patients)

15. Were patients blind to intervention/treatments allocation?
    - o Yes
    - o No
    - o Not sure (explain)
    - o Not applicable (patients not actively involved in study – e.g., provider-focused intervention with patient level data obtained retrospectively from charts)

16. Were providers blind to intervention/treatment allocation?
    - o Yes
    - o No
    - o Not sure (explain)
    - o Not applicable – (explain)

17. Do any methodologic aspects of the study design not captured above seriously undermine appropriateness of inclusion?
    - o Yes (explain)
    - o No (use text box to document any non-fatal, but still noteworthy methodological features)

C) Quality Improvement Attributes of Intervention

18. Did the study involve PATIENT Education?
    - o Yes (describe what was taught, where it occurred, duration and frequency of sessions)
    - o No

19. Did the intervention include access to a resource or provision of a device that promoted Patient Self-Management? (excluding patient reminder systems)
    - o Yes (describe)
    - o No

20. Did the intervention involve a PATIENT REMINDER system?
    - o Yes (specify target of reminder – appointments, compliance with meds or recommendations for self-care)
    - o No

21. Did the intervention involve PROVIDER education?
    - o Yes (describe nature of education, who administered the education, how often did it occur, etc)
    - o No

22. Did the intervention involve a PROVIDER REMINDER system?
    - o Yes (describe content of reminders and how delivered)
    - o No

23. Did the intervention involve a Facilitated Relay of clinical information to providers?
    - o Yes (describe type of information – e.g., recent glucose or HbA1c, and method of relaying information)
    - o No

24. Did the intervention involve provider AUDIT and FEEDBACK?
    - o Yes (describe what was fed back, how often, etc)
    - o No

25. Did the intervention involve ORGANIZATIONAL Change (e.g., disease or case management, creation of multidisciplinary teams or expansion of professional roles, TQM/CQI, telemedicine, change in medical record system)?
    - o Yes
    - o No

26. If the intervention involved Disease Management or Case Management, which of the following apply?
    - o Intervention specifically described as involving "case management" or "disease management"
    - o Someone other than physician actively participated in ongoing patient management using guidelines or systematic approach to care (protocols/algorithms to guide practitioner and patient decisions in specific clinical circumstances (specify type of person playing role of case manager)
    - o Person or system actively tracked, scheduled and coordinated patients' appointments
    - o Other basis for describing intervention as disease/case management (describe)
    - o Not applicable – no component of disease/case management

27. Did intervention involve changes to make up of healthcare team or roles of providers?
    - o Yes – Creation of multidisciplinary team, addition of new team member, expansion of roles, automatic referral for periodic visit with specific provider type (e.g., podiatrist or ophthalmologist)
    - o *Revision/expansion of roles or "shared care" (e.g., nurse or pharmacist operated actively managed medications without consulting physician)*
    - o Other (describe)
    - o No changes to team/personnel

28. Did the intervention involve changes to medical records systems?
    - o Change from paper to computerized records
    - o Implementation of computerized provider order entry (CPOE)
    - o New patient tracking system
    - o Other (describe)
    - o Not applicable – No change to medical record system

29. Did intervention involve any type of organizational change not captured by above questions?
    - o Yes (describe)
    - o No

30. Did a clinical information system play a role in design or implementation of intervention?
    - o Identification and/or group allocation of eligible patients or providers
    - o Reminders generated by existing clinical information system
    - o Decision support at point of care (e.g., for provider order entry)
    - o Facilitated communication between providers (e.g., generated emails between members of care team)
    - o Audit data gathered from clinical information system to design QI strategy (e.g., audit and feedback, TQM, provider education, financial incentives)
    - o Other
    - o No role for a clinical information system

D) Results

31. For unit of treatment allocation (e.g., clinics, providers, patients), were results reported for at least 80% of participants?
    - o Yes (state %)
    - o No (state %)
    - o Not stated

32. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient level outcomes analyzed), were results reported for at least 80% of participants?
    - Yes (state %)
    - No (state %)
    - Not stated or not clear
    - Not applicable (unit of analysis same as unit of treatment allocation)

Measures of Disease Control

33. Did the study report outcomes involving measures of disease control?
    - *Yes*
    - *No*

34. Did one measure of disease control involve HbA1c reported as mean and standard deviation in intervention and control groups?
    - *Yes*
    - *No*

35. For the outcome of disease control involving mean HbA1c, provide the following information for patients in CONTROL group; indicate not reported by typing "NR"
    - *Mean HbA1c before intervention*
    - *Standard deviation for HbA1c before intervention*
    - *Mean HbA1c after intervention*
    - *Mean difference between pre- and post-intervention HbA1c values*
    - *Standard deviation for difference between pre- and post-intervention HbA1c values*
    - *Not applicable (no measure of HbA1c)*

36. For the outcome of disease control involving mean HbA1c, provide the following information for INTERVENTION group; indicate not reported by typing "NR"
    - *Mean HbA1c value before intervention*
    - *Standard deviation for HbA1c before intervention*
    - *Mean HbA1c value after intervention*
    - *Standard deviation for HbA1c after intervention*
    - *Mean difference between pre- and post-intervention HbA1c values*
    - *Standard deviation for difference between pre- and post-intervention HbA1c values*
    - *Not applicable (no measure of HbA1c)*

37. Did study report any measures of disease control involving HbA1c outcomes not captured above (e.g. median HbA1c or % of patients with HbA1c in certain range)?
    - *Yes (describe)*
    - *No*

38. For articles reporting changes in SYSTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in CONTROL group (indicate not reported by typing NR)
    - *pre-intervention SBP (state mean and standard deviation)*
    - *post-intervention SBP (state mean and standard deviation)*
    - *difference between pre- and post-intervention values (state mean and SD)*
    - *Not applicable - no disease control outcomes involving SBP as mean and SD*

39. For articles reporting changes in SYSTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in INTERVENTION group (indicate not reported by typing NR)
    - *pre-intervention SBP (state mean and standard deviation)*
    - *post-intervention SBP (state mean and standard deviation)*
    - *difference between pre- and post-intervention values (state mean and SD)*
    - *Not applicable - no disease control outcomes involving SBP as mean and SD*

40. For articles reporting changes in DIASTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in the CONTROL group (indicate not reported by typing NR)
    - *pre-intervention DBP (state mean and standard deviation)*
    - *post-intervention DBP (state mean and standard deviation)*
    - *difference between pre- and post-intervention values (state mean and SD)*
    - *Not applicable - no disease control outcomes involving DBP as mean and SD*

41. *For articles reporting changes in DIASTOLIC BLOOD PRESSURE using mean and standard deviation, provide the following information for patients in INTERVENTION group (indicate not reported by typing NR)*
    - *pre-intervention DBP (state mean and standard deviation)*
    - *post-intervention DBP (state mean and standard deviation)*
    - *difference between pre- and post-intervention values (state mean and SD)*
    - *Not applicable - no disease control outcomes involving DBP as mean and SD*

42. *Did study report any measures of disease control involving blood pressure outcomes not captured above (e.g. median SBP/DBP or % patients with BP in certain range)?*
    - *Yes (describe)*
    - *No*

43. *Indicate results for measures of disease control no captured above:*
    - *Serum blood glucose*
    - *Other CV risk factor (e.g. total cholesterol, HDL-C, LDL-C, triglyceride, lipid, smoking, weight)*
    - *Microalbuminuria or renal failure*
    - *Other microvascular complications (e.g. foot lesions, retinopathy, neuropathy)*
    - *Clinical outcomes (e.g. mortality, MI, stroke, amputation)*
    - *Other (explain)*
    - *Not applicable - no other outcomes of disease control*

Measures of clinician adherence

44. *Did the study report outcomes related to clinician adherence?*
    - *Yes*
    - *No – none reported or none in usable form (explain)*

ADHERENCE TO GUIDELINES FOR ASSESSING GLYCEMIC CONTROL USING HBA1C

45. *Did one of the outcomes of clinician adherence involve proportion of patient with HbA1c measure at least once during a certain time period?*
    - *Yes*
    - *No – none reported or none in usable form (explain)*

46. *For the adherence outcome involving measurement of HbA1c, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with HbA1c checked according to stated definition); indicate not reported by typing NR*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving measurement of HbA1c in this format*

47. *For the adherence outcome involving measurement of HbA1c, indicate all that were reported or calculable for intervention group:*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving measurement of HbA1c in this format*

48. *Did study report any outcomes of clinician adherence involving checking HbA1c that are not captured above?*
    - *Yes (describe; give results)*
    - *No*

ADHERENCE TO OTHER GUIDELINES INVOLVING PERFORMANCE OF LABORATORY TESTS

49. *Did the article report outcomes for change in clinician adherence to a guideline for obtaining any lab measurements other than HbA1c?*
    - *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
    - *No - none reported or none in usable form*

50. *For the adherence outcome involving measurement of other lab values, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with other lab values checked according to stated definition); indicate not reported by typing NR*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*

- *difference between pre- and post-intervention values (% patients)*
- *Not applicable - no adherence outcome involving measurement of other lab values in this format*

51. *For the adherence outcome involving measurement of other lab values, indicate all that were reported or calculable for intervention group:*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving measurement of other lab values in this format*

52. *Were there any adherence outcomes for obtaining lab measurements not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)*
    - *Yes (list)*
    - *No*

ADHERENCE TO GUIDELINES FOR ASSESSMENT OR MANAGEMENT OF HYPERTENSION AND/OR CORONARY ARTERY DISEASE

53. *Did the article report outcomes for change in clinician adherence to a guideline for assessment or management of HTN and/or CAD?*
    - *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
    - *No - none reported or none in usable form*

54. *For the adherence outcome involving assessment or management of HTN and/or CAD, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with stated guideline performed); indicate not reported by typing NR*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving assessment or management of HTN and /or CAD in this format*

55. *For the adherence outcome involving assessment or management of HTN and/or CAD, indicate all that were reported or calculable for intervention group:*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving assessment or management of HTN and /or CAD in this format*

56. *Were there any adherence outcomes for assesment or management of HTN and/OR CAD not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)*
    - *Yes (list)*
    - *No*

ADHERENCE TO GUIDELINES FOR ASSESSMENT OF DIABETIC COMPLICATIONS INVOLVING THE EYE OR FOOT

57. *Did the article report outcomes for change in clinician adherence to a guideline for referral for or performance of foot exam?*
    - *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
    - *No - none reported or none in usable form*

58. *For the adherence outcome involving referral for or performance of foot exam, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with feet checked according to stated definition); indicate not reported by typing NR*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving referral for or performance of foot exam in this format*

59. *For the adherence outcome involving referral for or performance of foot exam, indicate all that were reported or calculable for intervention group:*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving referral for or performance of foot exam in this format*

60. *Were there any adherence outcomes for referral for or performance of foot exam not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)*
    - *Yes (describe)*
    - *No*

61. *Did the article report outcomes for change in clinician adherence to a guideline for referral for or performance of eye exam?*
    - *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
    - *No - none reported or none in usable form*

62. *For the adherence outcome involving referral for or performance of eye exam, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group with eyes checked according to stated definition); indicate not reported by typing NR*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving referral for or performance of eye exam in this format*

63. *For adherence outcome involving referral for or performance of eye exam, indicate all that were reported or calculable for intervention group:*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving referral for or performance of eye exam in this format*

64. *Were there any adherence outcomes for referral for or performance of eye exam not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)*
    - *Yes (describe)*
    - *No*

ADHERENCE TO GUIDELINES FOR PATIENT COUNSELING OR DELIVERY OF PATIENT EDUCATION

65. *Did the article report outcomes for change in clinician adherence to a guideline for patient counseling or delivering of patient education?*
    - *Yes - specify definition (if more than one, report below for outcome with median effect attributable to intervention)*
    - *No - none reported or none in usable form*

66. *For the adherence outcome involving patient education or counseling, indicate all that were reported or calculable for control group (All results should reflect % patients in designated group counseled or educated according to stated definition); indicate not reported by typing NR*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving patient education or counseling in this format*

67. *For the adherence outcome involving patient education or counseling, indicate all that were reported or calculable for intervention group:*
    - *pre-intervention adherence (% patients)*
    - *post-intervention adherence (% patients)*
    - *difference between pre- and post-intervention values (% patients)*
    - *Not applicable - no adherence outcome involving patient education or counseling in this format*

68. *Were there any adherence outcomes for patient education or counseling not captured above? (If you had to choose outcome with median effect, use textbox for "Yes" answer to list the other adherence outcomes.)*
    - *Yes*
    - *No*

69. Did the article report outcomes for change in clinician adherence to any OTHER guideline?

- *Yes (describe and give results)*
- *No*

Patient compliance outcomes

70. Describe results for any outcomes involving patient compliance

- *Compliance with self-care measures (e.g. self-monitoring of blood glucose), complying with diet or exercise, keeping appointments*
- *Compliance with medications*
- *Other (describe)*
- *No patient compliance outcomes*
- *Not sure (explain)*

71. Use textbox to state any important study features or results not captured above.

72. Has a senior reviewer checked this Level 4 abstraction?

- Yes - completely (indicate which senior reviewer)
- Partially (indicate where re-review was left off, i.e. question #)
- No (indicate any important questions/comments for senior reviewer)
- Not applicable (first reviewer is a senior reviewer)