**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0055

**Measure Title**: Comprehensive Diabetes Care: Eye Exam (retinal) performed

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 4/9/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: retinal exam in patients with diabetes

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Adults with diabetes (type 1 or 2) >>> Eye exam (retinal) is performed>>> Eye exam results are evaluated>>>Eye exam results are positive for diabetic retinopathy>>>Health provider determines treatment>>>Control of diabetic retinopathy and improvement in quality of life (desired outcome).

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

N/A

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Table 1. American Diabetes Association (ADA) Guidelines

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  American Diabetes Association. (2018). Standards of Medical Care in Diabetes – 2018. Diabetes Care 2018; 41(Suppl. 1): S105-S118; doi: 10.2337/dc18-S010  Guideline available from:  <http://care.diabetesjournals.org/content/41/Supplement_1>  2013 Submission  American Diabetes Association. (2013). Standards of Medical Care in Diabetes – 2013. Diabetes Care 2013; 36:S1-e4; doi: 10.2337/dc13-S001  Guideline available from:  <http://care.diabetesjournals.org/content/36/Supplement_1/S11> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 2018 Submission  “Screening   * Adults with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes (B) * Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of the diabetes diagnosis (B) * If there is no evidence of retinopathy for one or more annual eye exam and glycemia is well controlled, then exams every 1–2 years may be considered. If any level of diabetic retinopathy is present, subsequent dilated retinal examinations should be repeated at least annually by an ophthalmologist or optometrist. If retinopathy is progressing or sight threatening, then examinations will be required more frequently. (B) * While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam (E) * Women with preexisting type 1 or type 2 diabetes who are planning pregnancy or who are pregnant should be counseled on the risk of development and/or progression of diabetic retinopathy (B) * Eye examination should occur before pregnancy in the first trimester in patients with preexisting type 1 or type 2 diabetes, and then patients should be monitored every trimester and for 1 year postpartum as indicated by the degree of retinopathy (B)   2013 Submission  “Screening   * Adults and children aged ≥10 years with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 years after the onset of diabetes. (B) * Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes. (B) * Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less frequent exams (every 2–3 years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing.(B) * High-quality fundus photographs can detect most clinically significant diabetic retinopathy. Interpretation of the images should be performed by a trained eye care provider. While retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam, which should be performed at least initially and at intervals thereafter as recommended by an eye care professional. (E) * Women with pre-existing diabetes who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum. (B) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  Level of evidence and description:   * B:   Supportive evidence from well-conducted cohort studies, including:   * + Evidence from a well-conducted prospective cohort study or registry   + Evidence from a well-conducted meta-analysis of cohort studies   Supportive evidence from a well-conducted case-control study   * E:   Expert consensus or clinical experience  2013 Submission  Same as above |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  Level of Evidence & Description:   * A:   Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:   * + Evidence from a well-conducted multicenter trial   + Evidence from a meta-analysis that incorporated quality ratings in the analysis   Compelling nonexperimental evidence, i.e., “all or none” rule developed by the Centre for Evidence-Based Medicine at Oxford  Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:   * + Evidence from a well-conducted trial at one or more institutions   + Evidence from a meta-analysis that incorporated quality ratings in the analysis * C   Supportive evidence from poorly controlled or uncontrolled studies   * + Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results   + Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls)   + Evidence from case series or case reports   Conflicting evidence with the weight of evidence supporting the recommendation  2013 Submission  Same as above |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The ADA does not provide information on the systematic review conducted to support its 2018 or 2013 guideline and the recommendations mentioned above. In lieu of the ADA systematic review, we provide information on two other systematic reviews that support the ADA’s recommendations in Table 4. |
| Estimates of benefit and consistency across studies | See Table 4 below |
| What harms were identified? | See Table 4 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

Table 2. American Academy of Ophthalmology (AAO) Guidelines

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern Guidelines. Diabetic Retinopathy. American Academy of Ophthalmology. 2017. 1-63  URL: <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp-updated-2017>  2013 Submission  American Academy of Ophthalmology Retina Panel. Preferred Practice Pattern Guidelines. Diabetic Retinopathy. American Academy of Ophthalmology. 2008. 1-43  **URL**: <http://www.eyenet.com.cn/upfiles/2015-06/20150626160757_6751.pdf> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 2018 Submission  Pg. 10  “Examination   * Visual acuity (III; Good; Strong) * Slit-lamp biomicroscopy (III; Good; Strong) * Intraocular pressure (IOP) (III; Good; Strong) * Gonioscopy before dilation, when indicated. Iris neovascularization is best recognized prior to dilation. When neovascularization of the iris is present or suspected, or if the IOP is elevated, undilated gonioscopy can be used to detect neovascularization in the anterior chamber angle. (III; Good; Strong) * Pupillary assessment for optic nerve dysfunction * Thorough funduscopy including stereoscopic examination of the posterior pole (III; Good; Strong) * Examination of the peripheral retina and vitreous (III; Good; Strong)   A dilated pupil is preferred to ensure optimal examination of the retina, because only 50% of eyes are correctly classified for the presence and severity of retinopathy through undilated pupils.   * Slit-lamp biomicroscopy is the recommended method to evaluate retinopathy in the posterior pole and midperipheral retina. (III; Good; Strong) * Examination of the peripheral retina is best performed using indirect ophthalmoscopy or slit-lamp biomicroscopy. (III; Good; Strong)   Because treatment is effective in reducing the risk of visual loss, a detailed examination is indicated to assess for the following features that often lead to visual impairment:   * Macular edema (III; Good; Strong) * Signs of severe NPDR (extensive retinal hemorrhages/microaneurysms, venous beading, and IRMA) (III; Good; Strong) * Optic nerve head neovascularization and/or neovascularization elsewhere (III; Good; Strong) * Vitreous or preretinal hemorrhage (III, Good; Strong)   Page 9 -Table 3 Recommended Eye Examination for Patients with Diabetes Mellitus and No Diabetic Retinopathy   |  |  |  | | --- | --- | --- | | Diabetes Type | Recommended Initial Evaluation | Recommended Follow up\* | | Type 1 | 5 years after diagnosis (II++;Good, Strong) | Yearly (III; Good; Strong) | | Type 2 | At time of diagnosis (II+; Good Strong) | Yearly (III; Good; Strong) | | Pregnancy (type 1 or type 2) | Soon after conception and early in the first trimester (III; Good; Strong) | No retinopathy to mild or moderate NPDR: every 3-12 months (III, Good, Strong)  Severe NPDR or worse: every 1-3 months (III, Good, Strong) |   NPDR= nonproliferative diabetic retinopathy  \*Abnormal findings may dictate more frequent follow up examinations”  2013 Submission  Pg. 23  “Examination   * Visual acuity (A: I) * Slit-lamp biomicroscopy (A:III) * Intraocular pressure (A:III) * Gonioscopy when indicated (A:III) * Dilated funduscopy including stereoscopic examination of posterior pole (A:I) * Examination of the peripheral retina and vitreous (A:III) * A dilated pupil is necessary to ensure optimal examination of the retina, because only 50% of eyes are correctly classified for the presence and severity of retinopathy through undilated pupils (A:I). Slit-lamp biomicroscopy with accessory lenses is the recommended method to evaluate retinopathy in the posterior pole and midperipheral retina (A:III). The examination of the peripheral retina is best performed with indirect ophthalmoscopy or with slit-lamp biomicroscopy, combined with a contact lens (A:III).   Table A2-1 Recommended Eye Examination Schedule for Patients with Diabetes Mellitus   |  |  |  | | --- | --- | --- | | Diabetes Type | Recommended Time of First Examination | Recommended Follow up\* | | Type 1 | 3-5 years after diagnosis (A:II) | Yearly (A:II) | | Type 2 | At time of diagnosis (A:II) | Yearly (A:II) | | Prior to pregnancy (type 1 or type 2) | Prior to conception and early in the first trimester (A:I) | No retinopathy to mild or moderate NPDR: every 3-12 months (A:I)  Severe NPDR or worse: every 1-3 months (A:I) |   NPDR= nonproliferative diabetic retinopathy  \*Abnormal findings may dictate more frequent follow up examinations” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  To rate individual studies, a scale based on Scottish Intercollegiate Guideline Network (SIGN) is used. The definition and levels of evidence to rate individual studies are as follows:   |  |  | | --- | --- | | II++ | High-quality systematic reviews of case-control or cohort studies  High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal | | II+ | Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal | | III | Nonanalytic studies (e.g., case reports, case series) |   Recommendations for care are formed based on the body of the evidence. The body of evidence quality ratings are defined by GRADE as follows:   |  |  | | --- | --- | | Good quality | Further research is very unlikely to change our confidence in the estimate of effect |   Key Recommendations for care are defined by GRADE as follows:   |  |  | | --- | --- | | Strong recommendation | Used when the desirable effects of an intervention clearly outweigh the undesirable effects or clearly do not |   2013 Submission  Care Process Ratings:   * Level A: Most important to the care process   Strength of Evidence Ratings:   * Level I: includes evidence from at least one properly conducted, well-designed, randomized controlled trial. It could include meta-analyses of randomized controlled trials * Level II: includes evidence obtained from the following:   + Well-designed controlled trials without randomization   + Well-designed cohort or case -control analytic studies, preferably from more than one center   + Multiple-time series with or without the intervention * Level III: include evidence obtained from one of the following:   + Descriptive studies   + Case reports   + Reports of expert committees/organizations |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  To rate individual studies, a scale based on Scottish Intercollegiate Guideline Network (SIGN) is used. The definition and levels of evidence to rate individual studies are as follows:   |  |  | | --- | --- | | I++ | High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias | | I+ | Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias | | I- | Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias | | II- | Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal |   Recommendations for care are formed based on the body of the evidence. The body of evidence quality ratings are defined by GRADE as follows:   |  |  | | --- | --- | | Moderate quality | Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate | | Insufficient quality | Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate  Any estimate of effect is very uncertain |   Key Recommendations for care are defined by GRADE as follows:   |  |  | | --- | --- | | Discretionary recommendation | Used when the trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced |   2013 Submission  Care Process Ratings:   * Level B: Moderately important to the care process * Level C: Relevant but not critical to the care process |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The AAO does not summarize the details of the systematic review conducted to support its guideline and the recommendations mentioned above. In lieu of the AAO systematic review, we provide information on two other systematic reviews that support the AAO’s recommendations in Table 4. |
| Estimates of benefit and consistency across studies | See Table 4 below |
| What harms were identified? | See Table 4 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

Table 3. American Geriatrics Society (AGS) Guidelines

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  American Geriatrics Society (AGS). 2013. Guidelines Abstracted from the American Geriatrics Society Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 Update. American Geriatrics Society Panel on the Care for Older Adults with Diabetes Mellitus. Journal of American Geriatric Society. 2013 November; 61 (11): 2020-2026. Doi:10.1111/jgs.12514  URL: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4064258/pdf/nihms583558.pdf>  2013 Submission  American Geriatrics Society (AGS). 2003. Guidelines for Improving the Care of the Older Person with Diabetes Mellitus. California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with Diabetes. American Geriatrics Society. May 2013; 51, Suppl 5, JAGS  URL: |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | 2018 Submission  “1. Older adults with new-onset DM should have an initial screening dilated-eye examination with funduscopy performed by an eye care specialist.” (Level I, Grade B)  “2. Older adults with DM and who are at high risk for eye disease (symptoms of eye disease present; evidence of retinopathy, glaucoma, or cataracts on an initial dilated-eye examination or subsequent examinations during the prior 2 years; A1C ≥ 8.0%; type 1 DM; or blood pressure ≥ 140/80) on the prior examination should have a screening dilated-eye examination performed by an eye-care specialist with funduscopy training at least annually. Persons at lower risk or after one or more normal eye examinations may have a dilated-eye examination at least every 2 years.” (Level II, Grade B)  2013 Submission  Page S272  “1. The older adult who has new-onset DM should have an initial screening dilated-eye examination performed by an eye-care specialist with funduscopy training.” (Level I, Grade B)  “2. The older adult who has DM and who is at high risk for eye disease (symptoms of eye disease present; evidence of retinopathy, glaucoma, or cataracts on an initial dilated-eye examination or subsequent examinations during the prior 2 years; A1C ≥ 8.0%; type 1 DM; or blood pressure ≥ 140/80) on the prior examination should have a screening dilated-eye examination performed by an eye-care specialist with funduscopy training at least annually. Persons at lower risk may have a dilated-eye examination at least every 2 years.” (Level III, Grade B) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  Quality of Evidence   * Level I: Evidence from at least one properly randomized controlled trial * Level II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytical studies, from multiple time-series, or from dramatic results in uncontrolled experiments   Strength of Evidence   * B: Moderate evidence to support the use of a recommendation clinicians “should do this most of the time”   2013 Submission  Quality of Evidence   * Level I: Evidence from at least one properly randomized controlled trial * Level III: Evidence from respected authorities, based on clinical experience, descriptive studies, or reports of expert committee   Strength of Evidence   * B: Moderate evidence to support the use of a recommendation; clinicians should do this most of the time |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  Quality of Evidence   * Level III: Evidence from respected authorities based on clinical experience, descriptive studies, or reports of expert committees   Strength of Evidence   * A: Good evidence to support the use of a recommendation; clinicians should do this all the time * C: Poor evidence to support or to reject the use of a recommendation; clinicians may or may not follow the recommendation * D: Moderate evidence against the use of a recommendation; clinicians should not do this * E: Good evidence against the use of a recommendation; clinicians should not do this   2013 Submission   * Level II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, or from multiple time-series studies, or from dramatic results in uncontrolled experiments * A: Good evidence to support the use of a recommendation; clinicians should do this all the time * C: Poor evidence to support or to reject the use of a recommendation; clinicians may or may not follow the recommendation * D: Moderate evidence against the use of a recommendation; clinicians should not do this * E: Good evidence against the use of a recommendation; clinicians should not do this |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The AGS does not provide information on the systematic review conducted to support its guideline and the recommendations mentioned above. In lieu of the AGS systematic review, we provide information on two other systematic reviews that support the AGS’s recommendations in Table 4. |
| Estimates of benefit and consistency across studies | See Table 4 below |
| What harms were identified? | See Table 4 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

Table 4. Additional Systematic Reviews

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| **Citations** | AACE Diabetes Care Plan Guidelines. Endocrine Practice. 2011. Vol 17, Suppl 2: 1-53  **URL:** http://journals.aace.com/doi/abs/10.4158/EP.17.S2.1 | Li R, Zhang P, Barker LE, Chowdhury FM, Zhang X. Cost-effectiveness of interventions to prevent and control diabetes mellitus: a systematic review. Diabetes Care. 2010. 33(8):1872-1894.  **URL:** <http://care.diabetesjournals.org/content/33/8/1872.full.pdf+html> |
| **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?** | The measure is based on guidelines and evidence that support the use of regular eye exams for individuals with diabetes. The evidence reviews for diabetic retinopathy describe a two-step approach to detect diabetic retinopathy early and delay visual impairments. Evidence includes recommendations for the timing of eye exams, appropriate eye tests, and appropriate providers for referrals. | |
| **Grade assigned for the quality of the quoted evidence with definition of the grade** | |  |  | | --- | --- | | Numerical descriptor (evidence level) | Semantic descriptor  (reference methodology) | |  |  | | 1 | Randomized controlled trials (RCT) | | 2 | Meta-analysis of nonrandomized prospective or case-controlled trials (MNRCT) | |  |  | | 2 | Prospective cohort study (PCS) | |  |  | | 3 | Cross-sectional study (CSS) | | 3 | Surveillance study (registries, surveys, epidemiologic study, retrospective chart  review, mathematical modeling of database) (SS) | | 4 | No evidence (theory, opinion, consensus, review, or preclinical study) (NE) |   1=strong evidence; 2=intermediate evidence; 3=weak evidence; and 4=no evidence. | Randomized controlled trials in this review follow the American Diabetes Association guidelines. Per the ADA guidelines, grades assigned to the evidence varied from A - C.  Level of Evidence & Description:  A Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:   * Evidence from a well-conducted multicenter trial * Evidence from a meta-analysis that incorporated quality ratings in the analysis   Compelling nonexperimental evidence, i.e., the “all or none” rule developed by the Centre for Evidence-Based Medicine at Oxford  Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:   * Evidence from a well-conducted trial at one or more institutions * Evidence from a meta-analysis that incorporated quality ratings in the analysis   B Supportive evidence from well-conducted cohort studies, including:   * Evidence from a well-conducted prospective cohort study or registry * Evidence from a well-conducted meta-analysis of cohort studies * Supportive evidence from a well-conducted case-control study   C Supportive evidence from poorly controlled or uncontrolled studies, including:   * Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results * Evidence from observational studies with high potential for bias (such as case series with comparison to historical controls) * Evidence from case series or case reports   Conflicting evidence with the weight of evidence supporting the recommendation |
| **Provide all other grades and associated definitions of the evidence in the grading system** | 2 Nonrandomized controlled trial (NRCT) | Level of Evidence & Description:  E Expert consensus or clinical experience |
| **What is the time period covered by the body of evidence?** | 1984-2006 | 1994-2003 |
| **Quantity and Quality of Body of Evidence** | * Timing of Eye Exams: 1 Cross sectional study (CSS), 1 Surveillance study (SS), 1 Prospective cohort study (PCS) * Referral to appropriate providers: 1 Meta-analysis of nonrandomized case-controlled study (MNRCT) * Appropriate eye tests: 1 Surveillance study (SS) * Preventive diabetic retinopathy methods: 2 Randomized controlled trials (RCT), 2 Prospective cohort study (PCS) * Diabetic Retinopathy Treatments: 1 Randomized controlled trial (RCT), 2 Review/no evidence (NE) | The systematic review included six studies that examined the cost effectiveness of preventing eye complications in diabetics and treating retinopathy. Four of these studies focused on the timing of eye examinations (i.e. every 6 months, annually, every 2 years, every 3 years, etc.). These studies included a literature review, cross sectional, longitudinal, and epidemiological studies. One epidemiological study focused on the type of eye test and one randomized prospective clinical trial on the treatment of retinopathy. |
| **What is the overall quality of evidence across studies in the body of evidence?** | Overall, the quality of evidence supporting the guidelines and this measure is medium to strong. While there are seven studies that examine the timing of eye examinations, there were no RCTs for this area. More RCTs were available when examining referrals to providers. | |
| **Estimates of benefit and consistency across studies in body of evidence – what are the estimates of benefits?** | The evidence supports the early identification of diabetic retinopathy and eye care to reduce visual impairments in diabetic patients. Early detection of retinopathy also improves the quality of life in diabetics and reduces financial burdens that stem from poor visual health. Some studies report a decline in diabetic retinopathy due to improvements in diabetic eye care and diabetic control. One study also suggests that timely eye exam screenings and treatment in diabetics can prevent 75% of new blindness cases. | |
| **What harms were studied and how do they affect the net benefit (benefits over harms)?** | Overall, there are minimal harms associated with receiving dilated eye examinations. Minor discomforts may stem from having the eyes dilated. One additional harm may include the misclassification of the level of diabetic retinopathy due to possible false negative exam results. These harms can be mitigated with regular subsequent eye exams based on the guidelines. These potential harms do not outweigh the benefits of having regular eye examinations to provide early detection of diabetic retinopathy. | |
| **Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?** | Numerous studies have been conducted since the systematic reviews we cite in this table, none of which change the conclusion that routine eye exams for individuals with diabetes are appropriate. Below we list two additional studies that support this measure.  Nathan DM, Bebu I, Hainsworth D, et al.; DCCT/EDIC Research Group. Frequency of evidence-based screening for retinopathy in type 1 diabetes. N Engl J Med 2017;376:1507–1516  Agardh E, Tababat-Khani P. Adopting 3-year screening intervals for sight-threatening retinal vascular lesions in type 2 diabetic subjects without retinopathy. Diabetes Care 2011;34:1318–1319 | |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

N/A

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

N/A

**1a.4.2 What process was used to identify the evidence?**

N/A

**1a.4.3.** **Provide the citation(s) for the evidence.**

N/A