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Vision Screening in Children Aged 6 Months to 5 Years
Evidence Report and Systematic Review for the US Preventive Services Task Force

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IMPORTANCE Preschool vision screening could allow detection and treatment of vision abnormalities during a critical developmental stage, preserving function and quality of life.

OBJECTIVE To review the evidence on screening for and treatment of amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years to inform the US Preventive Services Task Force.

DATA SOURCES MEDLINE, Cochrane Library, CINAHL, and trial registries through June 2016; references; and experts, with surveillance of the literature through June 7, 2017.

STUDY SELECTION English-language randomized clinical trials (RCTs) or prospective cohort studies that evaluated screening, studies evaluating test accuracy, RCTs of treatment vs inactive controls, and cohort studies or case-control studies assessing harms.

DATA EXTRACTION AND SYNTHESIS Dual review of abstracts, full-text articles, and study quality; qualitative synthesis of findings. Studies were not quantitatively pooled because of clinical and methodological heterogeneity.

MAIN OUTCOMES AND MEASURES Visual acuity, amblyopia, school performance, functioning, quality of life, test accuracy, testability, and harms.

RESULTS Forty studies were included (N = 34 709); 34 evaluated test accuracy. No RCTs compared screening with no screening, and no studies evaluated school performance, function, or quality of life. Studies directly assessing earlier or more intensive screening were limited by high attrition. Positive likelihood ratios were between 5 and 10 for amblyopia risk factors or nonamblyogenic refractive error in most studies of test accuracy and were greater than 10 in most studies evaluating combinations of clinical tests. Inability to cooperate may limit use of some tests in children younger than 3 years. Studies with low prevalence (<10%) of vision abnormalities showed high false-positive rates (usually >75%). Among children with amblyopia risk factors (eg, strabismus or anisometropia), patching improved visual acuity of the amblyopic eye by a mean of less than 1 line on a standard chart after 5 to 12 weeks for children pretreated with glasses (2 RCTs, 240 participants); more children treated with patching than with no patching experienced improvement of at least 2 lines (45% vs 21%; $P = .003$; 1 RCT, 180 participants). Patching plus glasses improved visual acuity by about 1 line after 1 year (0.11 logMAR [95% CI, 0.05-0.17]) for children not pretreated with glasses (1 RCT, 177 participants). Glasses alone improved visual acuity by less than 1 line after 1 year (0.08 logMAR [95% CI, 0.02-0.15], 1 RCT, 177 participants).

CONCLUSIONS AND RELEVANCE Studies directly evaluating the effectiveness of screening were limited and do not establish whether vision screening in preschool children is better than no screening. Indirect evidence supports the utility of multiple screening tests for identifying preschool children at higher risk for vision problems and the effectiveness of some treatments for improving visual acuity outcomes.

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The most common causes of vision problems in children are amblyopia (a neurodevelopmental disorder that arises from abnormal processing of visual images that leads to a functional reduction of visual acuity) and its associated risk factors (**Table 1**), nonamblyopic strabismus and nonamblyopic refractive error.[9-12] Recent prevalence estimates of amblyopia, strabismus, and anisometropia (a difference in refractive power between the eyes, in which one foveal image is more blurred than the other) among US children younger than 6 years range from 1% to 6%.[12-16]

A variety of vision screening tools are available to evaluate children (**Table 2**). Left untreated, vision abnormalities in young children could lead to problems at school, bullying, reduced function and quality of life, depression and anxiety, and injuries. Vision abnormalities are often treatable, but efficacy can decrease as children age, and visual loss can become irreversible.[20-24] Untreated amblyopia rarely resolves spontaneously.[25,26]

In 2011, the US Preventive Services Task Force (USPSTF) recommended screening children to detect amblyopia or its risk factors at least once between the ages of 3 to 5 years (B recommendation) and concluded that the evidence was insufficient to assess the balance of benefits and harms of vision screening for children younger than 3 years (I statement). To inform an updated recommendation, a review was undertaken of the evidence on benefits and harms of vision screening in children; screening test accuracy; and benefits and harms of treatment of amblyopia, its risk factors, and refractive error.

Methods

Scope of Review

Detailed methods and additional details of results and analyses are reported in the full evidence report available at https://www.uspreventiveservicestaskforce.org/Page/Document/final-evidence-review/vision-in-children-ages-6-months-to-5-years-screening. **Figure 1** shows the analytic framework and key questions (KQs) that guided the review.

Data Sources and Searches

PubMed/MEDLINE, the Cochrane Library, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) were searched for English-language articles published from January 2009 through June 2016. Search strategies are listed in the eMethods in the Supplement. To identify relevant studies published before 2009, all articles included in the 2011 systematic review for the USPSTF were assessed.[28-30] ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry platform were searched for unpublished literature. To supplement electronic searches, the reference lists of pertinent articles, all studies suggested by reviewers, and comments received during public commenting periods were reviewed. Since June 2016, ongoing surveillance was conducted through article alerts and targeted searches of high-impact journals to identify major studies published in the interim that may affect the conclusions or understanding of the evidence and therefore the related USPSTF recommendation. The last surveillance was conducted on June 7, 2017.

Study Selection

Two investigators independently reviewed titles, abstracts, and full-text articles to determine eligibility using prespecified criteria for each KQ (eTable 1 in the Supplement). Disagreements were resolved by discussion. The review included English-language studies of children aged 6 months to 5 years conducted in countries categorized as "very high" on the United Nations Human Development Index. Only studies rated as good or fair quality were included.

Data Extraction and Quality Assessment

For each included study, 1 investigator extracted pertinent information about the populations, tests or treatments, comparators, outcomes, settings, and designs, and a second investigator reviewed for completeness and accuracy. To provide a consistent metric for visual acuity outcome measures, results were converted to logarithm of the minimal angle of resolution (logMAR) measurements using established conversion charts.[31] Measures of visual acuity are generally reported as Snellen (eg, 20/20, 20/25, 20/30, 20/40, 20/50) or logMAR scales (eg, 0.00, 0.09, 0.18, 0.30, 0.40). Two independent investigators assessed the quality of studies as good, fair, or poor, using predefined criteria developed by the USPSTF and adapted for this topic (eTables 2-5 in the Supplement).[32] Disagreements were resolved by discussion. Individual study quality ratings are reported in the Supplement (eTables 2-5).

Data Synthesis and Analysis

Findings for each question were summarized in tabular and narrative format. Results of test accuracy studies were not quantitatively pooled because of considerable clinical and methodological heterogeneity (eg, different tests, target condition definitions, populations, and results), and there were too few treatment trials making similar comparisons to attempt quantitative synthesis.

For KQ2, sensitivities, specificities, likelihood ratios (LRs), and predictive values were calculated when articles reported sufficient data. When qualitatively evaluating LRs, positive LRs indicated a minimal (>1-2), small (>2-5), moderate (>5-10), or large (>10) increase in the risk of the condition of interest (eg, amblyopia or its risk factors). Negative LRs indicated a minimal (0.5-<1), small (0.2-<0.5), moderate (0.1-<0.2), or large (<0.1) decrease in the risk of the condition of interest. Likelihood ratios less than 0.1 or greater than 10 provide strong evidence for ruling out (negative LR <0.1) or ruling in (positive LR >10) diagnoses.[33,34]

Definitions for what constitutes a minimal clinically important change in visual acuity in young children vary across studies. Recent studies consider a change of 0.2 logMAR (about 2 lines on the Snellen chart) the minimal clinically important change.[35-39] Others consider smaller changes clinically meaningful, generally between 0.10 logMAR (about 1 line on the Snellen chart) and 0.15 logMAR (between 1 and 2 lines).[40-42] Large treatment studies have calculated sample size requirements based on the ability to detect a change of at least 0.1 logMAR between treatment groups.[43-46] When assessing whether improvement in visual acuity represents a clinically meaningful change, practitioners may also consider that visual impairment associated with amblyopia can become permanent and may limit function for the child's lifetime.[23,47]

The overall strength of the body of evidence was assessed for each KQ as high, moderate, low, or insufficient using methods

Table 1. Risk Factors for Amblyopia[a,b]

Risk Factor[c]	Age, mo		
	12-30	31-48	>48
Astigmatism, diopters	>2.0	>2.0	>1.5
Hyperopia, diopters	>4.5	>4.0	>3.5
Anisometropia, diopters	>2.5	>2.0	>1.5
Myopia, diopters	>−3.5	>−3.0	>−1.5
Manifest strabismus in primary position, prism diopters	>8	>8	>8
Media opacity, mm	>1	>1	>1

[a] Adapted from Donahue et al.[1]

[b] Amblyopia is a neurodevelopmental disorder that arises from abnormal processing of visual images that leads to a functional reduction of visual acuity.[2] It results from conditions that interfere with normal binocular vision. Specific conditions associated with amblyopia are anisometropia (a difference in refractive power between the eyes, in which one foveal image is more blurred than the other), strabismus (ocular misalignment, in which each eye does not have the same image on the fovea), and deprivation (caused by the blockage of the visual pathway, often attributable to cataracts, ptosis, or refractive error due to myopia, hyperopia, and/or astigmatism).[3-7] Strabismic and anisometropic amblyopia can coexist. Strabismus can also inhibit development of normal binocular vision in the absence of amblyopia.[8]

[c] Ptosis has been removed from the list because nearly all amblyopia-related ptosis occurs in the setting of superimposed anisometropia.[1]

Table 2. Screening Tests for Visual Impairment Used in or Available in Primary Care Settings

Category	Screening Test	Description of Test
Visual acuity test	Picture identification tests (eg, LEA Symbols)	Figure identification from various distances (eg, the LEA Symbols test uses a circle, apple, square, and house; symbols gradually decrease in size)
Visual acuity test	HOTV eye test	Identification of letters HOTV; letters gradually decrease in size
Visual acuity test	Snellen	Letter or number identification; letters or numbers gradually decrease in size
Visual acuity test	Tumbling E	Identification of the direction of arms of the letter E; letters gradually decrease in size
Stereoacuity test	Contour stereotests (eg, Frisby, Random Dot E, Randot Stereo Smile, Titmus Fly)	Use of polarized glasses and stereo cards to determine whether a child can correctly identify a 3-dimensional image
Stereoacuity test	Moving dynamic random dot stereosize test[17]	Computer-generated moving stereotest dots
Ocular alignment test	Corneal light reflex test (Hirschberg testing)	Symmetric light reflex in both pupils from light held 2 feet away; can also detect cataracts and tumors
Ocular alignment test	Cover-uncover test (cross cover test)	Alignment changes when covering or uncovering a single focusing eye
Ocular alignment test	Simultaneous red reflex test (Bruckner test)	Equal red reflexes when viewed through ophthalmoscope; can also detect cataracts and tumors
Photoscreening (multiple categories)	Photoscreening[a]	A trained observer evaluates images of corneal light reflexes from a calibrated camera; binocular; can assess ocular alignment, media opacity, and visual acuity
Autorefraction (automated visual acuity test)	Autorefractive screening[b]	Estimates refractive error using an automated device; monocular; does not assess ocular alignment

[a] Photoscreening devices use optical images (photographs) of the eye's red reflex to identify risk factors in both eyes simultaneously. Most photoscreeners can estimate refractive error, media opacity, and ocular alignment.[18] Interpretation of the image is subjective and based on preestablished pass/fail criteria; older devices require a trained interpreter, but newer machines often include computerized interpretation or relay information to a central reading system. Image acquisition takes a few seconds and captures images from both eyes at once, making photoscreeners especially useful for preverbal or developmentally delayed children and children unable to tolerate longer examinations.[18]

[b] Autorefractors are computerized instruments that provide objective refractive status by measuring how light changes as it enters and reflects off the back of the eye. For patients with reduced visual acuity, it determines the lens power required to accurately focus light on the retina. Advantages of autorefractors include ease and time of use, ready availability, and patient tolerance. Handheld autorefractors require only a few seconds of a child's attention, potentially increasing testability rates vs traditional tabletop models, especially among young children.[19] A disadvantage of autorefraction is that it typically measures 1 eye at a time, limiting its ability to detect strabismus without refractive error.[18]

developed for the USPSTF (and the Evidence-based Practice Center program[29,30]), based on the overall quality of studies, consistency of results between studies, precision of findings, and risk of reporting bias.

Results

A total of 40 published studies (described in 46 articles[40,44,48-91]) with 34 709 participants were included (**Figure 2**). The main results for each KQ are summarized below.

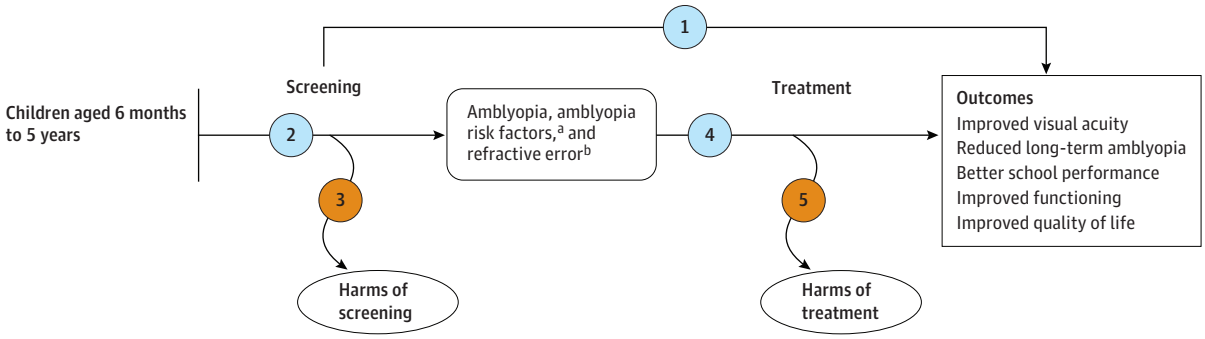
Benefits of Screening

Key Question 1. Does screening for amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years reduce long-term amblyopia or improve visual acuity, school performance, functioning, and/or quality of life?

Key Question 1a. Does the effectiveness of screening in children aged 6 months to 5 years vary among different age groups?

One randomized clinical trial (RCT)[86,89] and 1 cohort study[90] enrolling children from the Avon Longitudinal Study of Parents and Children (ALSPAC) project were included (**Table 3**). The ALSPAC project is a geographically defined birth cohort study enrolling 14 000

Figure 1. Analytic Framework and Key Questions



Key questions

1 Does screening for amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years reduce long-term amblyopia or improve visual acuity, school performance, functioning, and/or quality of life?

a. Does the effectiveness of screening in children aged 6 months to 5 years vary among different age groups?

2 What are the accuracy and reliability of screening tests for amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years?

a. Do the accuracy and reliability of screening tests for amblyopia, its risk factors, and refractive error vary among different age groups?

3 What are the harms of screening for amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years?

4 a. Does treatment of amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years improve visual acuity?

b. Does treatment of amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years reduce long-term amblyopia or improve school performance, functioning, and/or quality of life?

5 What are the harms of treating amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years?

Evidence reviews for the US Preventive Services Task Force (USPSTF) use an analytic framework to visually display the key questions that the review will address to allow the USPSTF to evaluate the effectiveness and safety of a preventive service. The questions are depicted by linkages that relate interventions and outcomes. Further details are available in the USPSTF procedure manual.[27]

[a] Amblyopia risk factors include anisometropia, strabismus, hyperopia, any media opacity, astigmatism, and abnormal visual acuity (which includes substantial isoametropic refractive error).

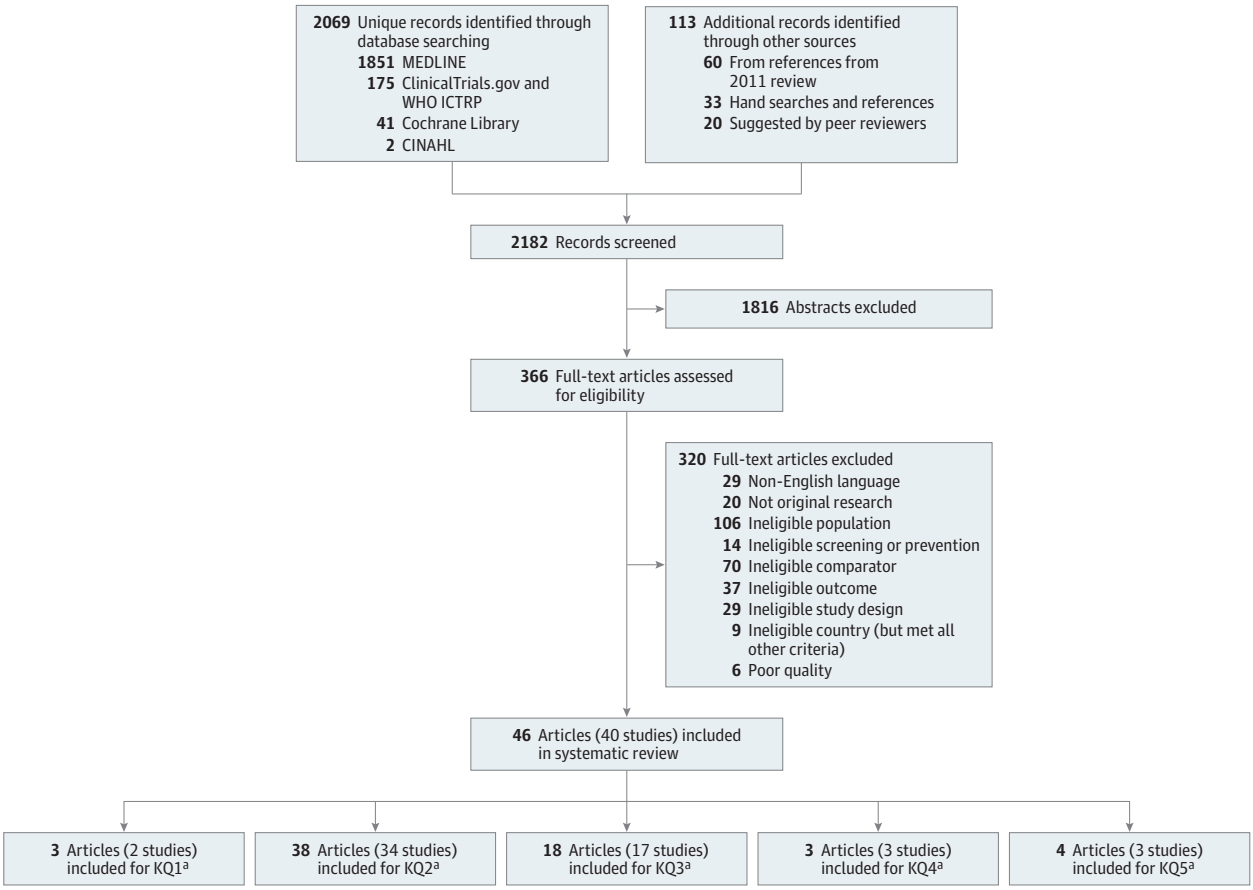
[b] Determination of refractive error is based on age-appropriate standards.

children born in southwest England between April 1991 and December 1992.[86] Both studies reported prevalence of amblyopia at age 7.5 years; neither evaluated school performance, function, or quality of life outcomes. The major methodological shortcoming in both studies was high attrition; around half of children did not have results and were excluded from analyses. In addition, the method of randomization in the (self-described) RCT was inadequate (based on last digit of the mother's day of birth).[86,89]

The RCT (n = 3490) compared intensive orthoptist screening (clinical examination, age-specific visual acuity testing, and cover-uncover testing) before age 3 years (at 8, 12, 18, 25, 31, and 37 months) with 1-time orthoptist screening at age 37 months.[86,89] Baseline data for amblyopia or amblyopia risk factors were not reported. Children in both groups were offered "usual care" in terms of surveillance for visual problems: (1) examination at ages 8 and 18 months by a health visitor (community pediatric nurse), with referrals if a visual problem was suspected[86]; and (2) visual screening at school entry (ages 4-5 years) by a school nurse.[89] The prevalence of amblyopia at 7.5 years was approximately 1% lower in the intensive screening group than in the control group, but the difference was statistically significant for only 1 of their 2 definitions of amblyopia (Table 3).[89] Among those who received patching treatment (n = 40 in each group), presence of residual amblyopia at 7.5 years was more likely in the 1-time screening group than in the intensive-screening group, but the difference was statistically significant for only 1 of the 2 amblyopia definitions, and estimates were imprecise; visual acuity at 7.5 years in the worse eye was better in the intensive-screening group than in the 1-time screening group (Table 3).[89]

The prospective cohort study (n = 6081 completers) compared orthoptist screening at age 3 years in 1 health district with no preschool screening in 2 other health districts.[90] Screening examinations by the orthoptist consisted of a monocular vision test, a cover test, and an assessment of binocularity; failure of any part of the examination resulted in referral for further evaluation. All children in the study area were offered vision screening at school entry (ages 4-5 years).[90] Among participants who attended the examination at age 7.5 years and were not part of the ALSPAC RCT, no statistically significant differences in amblyopia were apparent between groups based on any of the studies' 3 definitions of amblyopia (Table 3).[90]

Figure 2. Summary of Evidence Search and Selection



CINAHL indicates Cumulative Index to Nursing and Allied Health Literature; KQ, key question; WHO ICTRP, World Health Organization International Clinical Trials Registry.

[a] Sum of the numbers of studies or articles per KQ exceeds the total number of included studies or articles because some were included in multiple KQs.

Accuracy of Screening Tests

Key Question 2. What is the accuracy and reliability of screening tests for amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years?

Thirty-four fair-quality studies (described in 38 articles) were included (eTables 6-17 in the Supplement).[48,49,51-62,64-85,88,91] The studies evaluated a variety of test types, including visual acuity tests, stereoacuity tests, ocular alignment tests, autorefractors, photoscreeners, and retinal birefringence scanning. Screening was administered by a variety of personnel across studies (eg, pediatricians, ophthalmologists, nurses, research staff). Sample sizes ranged from 63[75] to 4040.[70,91]

About one-third of the studies included participants younger than 3 years.[48,56,65,66,71,72,75-77,80,81,85,88,91] The included studies reported accuracy of tests for a variety of target conditions, ranging from very specific (eg, astigmatism) to broad (eg, amblyopia risk factors). The prevalence of target conditions was generally much higher in samples from ophthalmology clinics[53,56,57,62,66,68,69,72,75,77,80,81,85,88] than in those from primary care, community, Head Start, or school settings.

Findings from the Vision In Preschoolers (VIP) study, the largest study for this KQ, were reported in multiple manuscripts (up to 4040 participants).[55,60,64,70,78,82,84,91] Phase 1 of the VIP study enrolled 3- to 5-year-olds and compared the accuracy of 11 screening tests.[78] Phase 2 compared the performance of nurse screeners with that of lay screeners for 4 tests.[84] Unlike many of the included studies, the VIP study evaluated accuracy for a broad range of conditions, including significant nonamblyogenic refractive error. The applicability of the VIP study may be limited because it did not enroll a representative spectrum of patients (as demonstrated by the high prevalence of target conditions, ranging from 21%-36%), study participants may have experienced fatigue from the number of tests, and testing was conducted by skilled personnel in a controlled environment (in phase 1).

Detailed results of studies evaluating test accuracy are provided in the eResults and eTables 6 through 17 in the Supplement. Six publications evaluated visual acuity tests,[53,73,74,78,82,84] including 3 from the VIP Study Group.[78,82,84] When screening test cutoffs were set to achieve specificities of 90%, phase 1 of the VIP study found that an abnormal result moderately increased the likelihood of amblyopia, amblyopia risk factors (strabismus, astigmatism, hyperopia, myopia, anisometropia), or significant nonamblyogenic refractive error (positive LR, 6.1 [95% CI,

Table 3. Characteristics and Results of Studies That Evaluated Screening Earlier Compared With Screening Later (Key Question 1)[a]

Source	Study Design	Screening Intervention vs Control	Sample Size	Age	Female, No. (%)[b]	Non-White, No. (%)	Main Results (at Age 7.5 y)
Williams et al,[86] 2001 Williams et al,[89] 2002	RCT	Screening at 8, 12, 18, 25, 31, and 37 mo[c] vs screening at 37 mo[d]	3490 randomized (2029 intensive screening, 1490 1-time screening) 1914 analyzed	Initially tested at 8-37 mo and followed up to age 7.5 y	924 (48)	96 (5)	Amblyopia A: 1.5% (16/1088) vs 2.7% (22/826); RR, 0.55 (95% CI, 0.29-1.04)[e] Amblyopia B: 0.6% (69/1088) vs 1.8% (15/876); RR, 0.35 (95% CI, 0.15-0.86)[f] Residual amblyopia A among children treated with occlusion: 25% (10/40) vs 8% (3/40); OR, 1.56 (95% CI, 0.62-3.92) Residual amblyopia B among children treated with occlusion: OR, 4.11 (95% CI, 1.04-16.29) Mean visual acuity in worse eye after patching treatment (adjusted for confounding variables): 0.15 (95% CI, 0.08-0.22) vs 0.26 (95% CI, 0.17-0.35); $P < .0001$
Williams et al,[90] 2003	Cohort	Screening at 37 mo vs no preschool screening[g]	6081 analyzed (1516 screened; 4565 not screened)	Screening offered at 37 mo; tested at 7.5 y	2852 (47)	NR	Amblyopia A: 1.1% (11/1019) vs 2.0% (100/5062); adjusted OR, 0.63 (95% CI, 0.32-1.23)[e,h] Amblyopia B: 0.7% (7/1019) vs 1.3% (65/5062); adjusted OR, 0.72 (95% CI, 0.32-1.60)[f,h] Amblyopia C: 1.9% (19/1019) vs 3.4% (171/5062); adjusted OR, 0.65 (95% CI, 0.38-1.10)[h,i] Mean visual acuity in worse eye after patching treatment (adjusted for confounding variables): 0.14 (95% CI, 0.11-0.18) (n = 25) vs 0.22 (95% CI, 0.20-0.23) (n = 166); $P < .001$

Abbreviations: logMAR, logarithm of the minimum angle of resolution; NR, not reported; OR, odds ratio; RCT, randomized clinical trial; RR, relative risk.

[a] All studies in this table were conducted in community orthoptic clinics and were of fair quality.

[b] No. and percent among those analyzed.

[c] Cover-uncover test; Cardiff cards at ages 8 and 12 months; Cardiff and Kay picture test at ages 18, 25, and 31 months; Kays picture test and HOTV crowded symbols distance visual acuity test at age 37 months; noncycloplegic autorefraction (performed at all visits but only used for referral at age 37 months).

[d] Cover-uncover test; Kays picture test and HOTV test; noncycloplegic autorefraction.

[e] Amblyopia A indicates interocular difference in acuity of 0.2 logMAR (2 lines on standard chart) or greater.

[f] Amblyopia B indicates interocular difference in acuity of 0.3 logMAR or greater.

[g] Kay pictures or Sheridan Gardiner singles visual acuity test, cover-uncover test, and 20-diopter prism or stereopsis test (or both).

[h] Adjusted for sex, highest level of maternal education, birth weight, family history of strabismus or amblyopia, and duration of breastfeeding.

[i] Amblyopia C indicates visual acuity in amblyopic eye of 0.18 logMAR or worse (20/30 or worse on Snellen chart).

4.8-7.6]).[78] A normal result indicated a small decrease in the likelihood (negative LR, 0.43 [95% CI, 0.38-0.50]).

Four fair-quality studies (total, 1854 participants) evaluated a combination of clinical tests, including visual acuity tests, stereoacuity tests, and ocular alignment tests (eTables 6-7 in the Supplement).[52,54,67,80] Three of the 4 found that abnormal results indicated a large increase in the likelihood of amblyopia or its risk factors (positive LRs ranged from 12-17).[52,67,80] The 4 studies found more variability for negative LRs (range, 0.10-0.91).

Sixteen fair-quality studies (16 712 observations) evaluated autorefractors (eTables 6-17 in the Supplement).[49,51,55,57,58,65,66,70,72-74,77,78,84,88,91] Overall, most studies found moderate positive LRs and small negative LRs, although some found large positive and negative LRs.

Eleven fair-quality studies (12 publications, 6187 observations) evaluated photoscreeners (eTables 6-15 in the Supplement).[56,59,67-69,73,75-78,81,85] Overall, most studies found moderate positive LRs and small negative LRs, although some found larger or smaller LRs.

Key Question 2a. Does the accuracy or reliability of screening tests for amblyopia, its risk factors, and refractive error vary among different age groups?

Five studies evaluated whether accuracy varies by age (eTable 13 in the Supplement).[54,66,69,81,82] All 5 evaluated different screening tests and assessed different age stratifications/comparisons. Overall, data were limited and estimates were somewhat imprecise, but studies did not find any clear differences in test accuracy when results were stratified by age.

Many included studies reported testability information, although few reported data stratified by age or for children younger than 3 years. eTable 14 in the Supplement details the proportion unexaminable reported by studies. Overall, testability exceeded 90% in the majority of studies. Few studies reported testability rates less than 80%, but all that did included children younger than 3 years.[48,66,71,77] Some studies demonstrated that testability rates improved somewhat as children age.[53,66,71,77,78,80] One study (n = 1170) found that testability rates were 10% for a visual acuity test at ages 24 months to younger than 30 months and steadily improved to 80% by ages 36 months to younger than 42 months and to 95% by ages 48 months to younger than 54 months.[71]

For autorefractors and photoscreeners, the VIP study found testability rates close to 100% (all participants were 3 years or older).[78] Two studies from ophthalmology clinics and 1 from a primary care practice reported better testability for older preschool children than for younger ones (eResults in the Supplement).[65,66,77]

Harms of Screening

Key Question 3. What are the harms of screening for amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years?

One controlled study that evaluated potential psychosocial effects was included,[87] and 16 studies of test accuracy described in KQ2 were used to calculate false-positive rates.[48,51,52,55,62,65,67,69,75-78,80-82,85] The controlled study used the ALSPAC population-based cohort (n = 4473) to assess bullying by age 8 years.[87] It prospectively compared children who had been offered state-provided preschool screening for amblyopia (at 37 months) with those who had not. Children were asked whether they had repeatedly (≥4 times a month) been bullied. Among the subgroup of patched children, the study showed a lower likelihood of being bullied for children offered screening than for those not offered early screening (25.7% vs 47.1%, $P = .033$; adjusted odds ratio, 0.39 [95% CI, 0.16-0.92], adjusted for sex, paternal socioeconomic class, highest level of maternal education, type of housing).

The most frequently assessed potential harms of screening were false-positive findings (which would lead to unnecessary referrals). In general, studies with a lower prevalence (<10%) of vision abnormalities showed much higher false-positive rates (usually >75%), while those with a high prevalence had lower false-positive rates (usually <35%) (eFigure in the Supplement).

Benefits of Treatment

Key Question 4a. Does treatment of amblyopia, its risk factors, and refractive error in children ages 6 months to 5 years improve visual acuity?

Key Question 4b. Does treatment of amblyopia, its risk factors, and refractive error in children ages 6 months to 5 years reduce long-term amblyopia or improve school performance, functioning, and/or quality of life?

Three trials were included (**Table 4**)[40,44,50]; all evaluated patching for amblyopia or amblyopic risk factors. Two compared patching with no patching (children were pretreated with eyeglasses if indicated in both groups),[44,50] and 1 compared patching plus eyeglasses vs eyeglasses alone vs no treatment.[40] One of the patching vs no patching trials included a run-in phase, during which all participants wore updated eyeglass prescriptions until visual acuity in the amblyopic eye stopped improving[44]; another trial treated children with refractive error with 6 weeks of corrective lenses before allocation.[50] All 3 studies included children based on visual acuity criteria. One of the 3 trials reported enrolling screen-detected children.[40] Two of the trials reported best corrected visual acuity,[40,44] and 1 measured improvement in visual acuity as a secondary outcome (the trial focused primarily on assessing adherence).[50]

Overall, the trials indicated that treatments for amblyopia or its risk factors resulted in small mean improvements in visual acuity (Table 4). In the study with the run-in phase,[44] patching improved visual acuity by a mean of 0.7 of a line on a standard visual acuity chart, and more children treated with patching than with no patching had at least 2 lines of improvement in acuity (45% vs 21%).

Two included trials[40,44] examined treatment outcomes for subgroups defined by baseline visual acuity. First, 1 trial (n = 180) assessed subgroups with either moderate (20/40 to 20/100) or severe (20/125 to 20/400) amblyopia at baseline.[44] Findings for these subgroups were similar to the overall trial results for the primary outcome, visual acuity in the amblyopic eye. Second, the trial that compared patching plus eyeglasses, eyeglasses alone, and no treatment among preschoolers (n = 177) assessed subgroups defined by baseline visual acuity abnormalities.[40] The authors assessed children with mild (0.18-0.30 logMAR) and moderate or worse (≥0.48 logMAR) refractive error at baseline and examined differences between treatment groups. For children with moderate refractive error at baseline, patching plus eyeglasses resulted in much greater improvement than no treatment at 1 year (0.27 logMAR [95% CI, 0.14-0.39], compared with

Table 4. Characteristics and Main Results of Randomized Trials That Evaluated Treatment of Amblyopia, Its Risk Factors, and Refractive Error (Key Question 4 and Key Question 5)

Source	Duration	Age, Mean (Range), y	Diagnoses	Baseline Mean Acuity	Country (Setting)	Intervention vs Control	Main Results for Amblyopic Eye
Good Quality							
Wallace et al,[44] 2006 (PEDIG) n = 180	5 wk of treatment (up to 52 wk follow-up)	5.2 (3-7)	Strabismus, 23%; anisometropia, 47%; strabismus and anisometropia, 30%	0.56 logMAR (≈Snellen equivalent 20/75)	United States (46 clinical sites)	Patching for 2 h/d (with ≥1 h of near activities) vs no patching Continued use of eyeglasses if needed, regardless of randomization group	Mean logMAR acuity: 0.44 (SD, 0.22) vs 0.51 (SD, 0.28)[a] Mean difference in logMAR acuity, adjusted for baseline acuity: 0.07 (95% CI, 0.02 to 0.12) Mean improvement in lines at 5 wk: 1.1 (SD, 1.6) vs 0.5 (SD, 1.7) Mean improvement in lines, best measured acuity (from 5-52 wk): 2.2 (SD, 1.8) vs 1.3 (SD, 1.4) Difference in mean best logMAR acuity, adjusted for baseline acuity (up to week 52): 0.10 (95% CI, 0.05 to 0.14) Proportion of children with ≥2 lines of improvement in acuity: 38/85 (45%) vs 18/88 (21%), *P* = .003
Clarke et al,[40] 2003 n = 177	1 y of treatment (78 wk follow-up)	4 (3-5)	Anisometropia, 72%	0.36 logMAR (≈Snellen 20/45)	United Kingdom (8 eye clinics)	Patching + eyeglasses vs eyeglasses only vs no treatment	Mean best corrected logMAR acuity at 1 y: 0.19 (SD, 0.12) vs 0.22 (SD, 0.17) vs 0.30 (SD, 0.20) Mean difference from no treatment, patching + eyeglasses: 0.11 (95% CI, 0.05 to 0.17)[b] Eyeglasses only: 0.08 (95% CI, 0.02 to 0.15)[b] Among the subgroup with moderate acuity loss at baseline (n = 63), mean difference from no treatment, patching + eyeglasses: 0.27 (95% CI, 0.14 to 0.39) Eyeglasses only: 0.11 (95% CI, −0.03 to 0.24)
Fair Quality							
Awan et al,[50] 2005 n = 60	12 wk	4.6 (up to 8)	Strabismus, 45%; mixed amblyopia, 42%	0.63, 0.69, and 0.59 logMAR (≈Snellen 20/85, 20/100, and 20/80)	United Kingdom (ophthalmology and orthoptic clinics)	Patching for 3 h/d vs patching for 6 h/d vs no treatment[c]	Mean improvement in logMAR acuity: 0.29 (SD, 0.14) vs 0.34 (SD, 0.19) vs 0.24 (SD, 0.17), *P* = .11[d] Approximate mean Snellen equivalents, lines of improvement: 1.9 (SD, 1.0) vs 2.3 (SD, 1.2) vs 1.6 (SD, 0.12)

Abbreviations: logMAR, logarithm of the minimum angle of resolution; PEDIG, Pediatric Eye Disease Investigator Group.

[a] Equivalent to 20/50 vs 20/63 on standard Snellen chart.

[b] Between-group differences in acuity were not significant at 6 months posttrial, after all groups had received treatment (after the 1-year follow-up visit, children in the no-treatment and glasses-only groups received treatment following the same protocol as those in the combined-treatment group).

[c] Eyeglasses were prescribed for all who needed them (all groups).

[d] Although the difference was not statistically significant, the point estimates of the effect were in favor of the patching groups, adherence was suboptimal (participants wore patching for 58% of the prescribed time in the 3-hour group [mean, 103 minutes] and for 41% in the 6-hour group [mean, 153 minutes]), and the study was underpowered to find a small difference between groups.

improvement for all participants of 0.11 logMAR [95% CI, 0.05-0.17]); the difference between eyeglasses alone and no treatment did not reach statistical significance. For children with mild refractive error at baseline, neither treatment was significantly different than no treatment at the end of the trial.

Harms of Treatment

Key Question 5. What are the harms of treatment of amblyopia, its risk factors, and refractive error in children aged 6 months to 5 years?

Three trials (described in 4 articles) were included (Table 4).[40,44,50,63] Overall, the trials provided limited evidence but suggest that patching may have some psychological harms.

One trial comparing patching with no patching (n = 180) found that worsening visual acuity in the nonamblyopic eye was not significantly different between groups at 5 weeks (2.4% vs 6.8%, respectively; *P* = .28).[44] Among children with no ocular deviation at baseline (n = 118), 5 patients in the patching group and 3 patients in the no-patching group were noted to have a new small-angle strabismus, and 1 patient in the no-patching group was noted to have a new large-angle strabismus.

The trial comparing patching plus eyeglasses, eyeglasses alone, and no treatment found no statistically significant difference between treatment groups at 1-year follow-up in the proportion of children whose uncorrected visual acuity in the amblyopic eye worsened (change >0.1 logMAR) for those with baseline mild acuity loss (9.7% vs 6.5% vs 13.3%, respectively, *P* = .28) or for those with baseline moderate acuity loss (15.0% vs 11.1% vs 23.8%, *P* = .13).[40]

A substudy[63] of the trial[40] that compared patching plus eyeglasses, eyeglasses alone, and no treatment examined the emotional status of children undergoing treatment; in the substudy, 144 of 177 parents of participants completed questionnaires at baseline (all participants), 3 months after beginning treatment (participants in active treatment only), and 2 years after recruitment (all participants). They found no significant differences between treatment groups with regard to being happy, cooperative, or good tempered; teasing; problems at preschool; or in emotional and behavioral problems, but found that children were more upset by patching plus eyeglasses than by eyeglasses alone (85% vs 29% at age 4 years, *P* = .03; 62% vs 26% at age 5 years, *P* = .005). Although the study reported some negative effects of glasses or patching for the child (difficulty wearing patch or glasses, upset, coping with treatment) and parent (worry about treatment, upset by treatments, arguments about treatment), it did not report a comparison with the no-treatment group for these outcomes.

One trial (n = 60) comparing no treatment, patching for 3 hours daily, or patching for 6 hours daily reported that no patients experienced an adverse event, such as inverse amblyopia or patch allergy.[50]

Discussion

The summary of findings is presented in **Table 5**. No eligible RCTs directly compared screening with no screening. For the overarching question (KQ1), the strength of evidence was graded as low because of unknown consistency (with a single study making each comparison), imprecision, and methodological limitations. One cohort study showed a reduction in harm (ie, less school-aged bullying) among patched children screened in preschool compared with patched children not screened in preschool.[87] In theory, although both glasses and patching have been reported to increase the risk of being bullied,[92] preschool screening may allow for treatment before school starts, thus avoiding potential bullying and psychosocial distress.

Harms of preschool vision screening might include unnecessary referrals from false-positive screens, overdiagnosis, and unnecessary treatment. Studies of test accuracy show that screening tests are associated with high false-positive rates among populations with a low prevalence of vision abnormalities. A large (n = 102 508) retrospective study from a statewide photoscreening program found that 19.5% (174/890) of those with false-positive test results were prescribed glasses (ie, unnecessary treatments).[93] The study was not eligible for this systematic review because it did not attempt to perform the reference standard in all participants or a random sample of participants.

Regarding test accuracy, estimates for all tests suggest utility for identifying children at higher risk for amblyopia risk factors or other visual conditions. Positive LRs were in the moderate range (>5-10) for most studies, and most studies that evaluated combinations of clinical tests found high (>10) positive LRs. The VIP study, the largest to directly compare multiple tests, generally found similar accuracy across tests. The strength of evidence was graded as low, because of imprecision and methodological limitations of the individual studies. Findings are applicable to a variety of settings and screening personnel.

Accuracy did not clearly differ for preschool children in different age groups. However, unlike studies of photoscreeners, most studies of clinical test accuracy did not enroll children younger than 3 years. Data were relatively limited and estimates were somewhat imprecise, but studies did not find any clear differences in accuracy of tests when results were stratified according to age. Testability may limit the utility of some screening tests, especially clinical tests, in children younger than 3 years. Although relatively few studies assessed changes in testability by age, those that did generally found better testability in children 3 years or older, and some reported low testability rates for visual acuity and stereoacuity tests for those younger than 3 years. In contrast, some data suggest that photoscreeners have high testability rates for children as young as 1 year.[94]

The review found evidence of moderate strength supporting the effectiveness of some treatments for improving visual acuity outcomes, although mean improvements were small. No studies evaluated potential effectiveness of treatments for reducing long-term amblyopia or for improving school performance, functioning, or quality of life, and no eligible studies evaluated atropine or vision therapy. The included trials all enrolled children 3 years or older, and applicability to those younger than 3 years is unclear. The trials varied somewhat in the populations (with amblyopic risk factors and pretreated with glasses or with amblyopic risk factors but not pretreated with glasses) and interventions compared (2 evaluated patching vs no patching; 1 compared patching plus glasses vs glasses alone vs no treatment). The trial that compared patching plus eyeglasses, eyeglasses alone, and no treatment enrolled screen-detected children, demonstrating the applicability of findings to the main population of interest for this review.[40]

Table 5. Summary of Evidence for Vision Screening in Children

No. of Studies (Study Design)	No. of Participants	Summary of Main Findings (Including Consistency and Precision)	Quality	Limitations (Including Reporting Bias)	Strength of Evidence	Applicability
KQ1: Benefits of Screening						
2 (1 RCT and 1 prospective cohort study)	7995 (analyzed)	School performance, function, or QOL: NR Prevalence of amblyopia at 7.5 y: In the RCT, approximately 1% lower for intensive screening (at 8, 12, 18, 25, 31, and 37 mo) than for screening at 37 mo; difference was statistically significant for 1 of 2 definitions of amblyopia.[a] In cohort study, no statistically significant difference between screened (at 37 mo) and nonscreened groups for any definition of amblyopia.[b] Consistency of findings is unknown, and findings were imprecise.	Fair	Studies had high overall attrition (approximately 50%) and compared different screening strategies; RCT did not use a valid randomization method. Reporting bias not detected.	Low	Healthy preschool children who receive vision screening at ages 4 to 5 y by a school nurse as part of usual care. Trained orthoptists conducted screening examinations.
KQ2: Test Accuracy						
34 (studies of test accuracy)	45 588 observations[c]	Estimates for all tests suggest utility for identification of children at higher risk for amblyopia risk factors or other visual conditions, with positive LRs most commonly in the moderate range (>5-10). Evidence suggests that combinations of clinical tests have higher positive LRs (>10). The VIP study, the largest to directly compare multiple tests, generally found similar LRs across tests. Accuracy did not clearly differ for children stratified according to age. Findings were mostly consistent but were imprecise.	Fair	Many studies recruited from specialty clinics or enrolled populations with high prevalence; heterogeneity of populations, settings, and target conditions evaluated; common shortcomings included high (or NR) rates of uninterpretable results or noncompliance with tests, not reporting whether uninterpretable results or noncompliance were included in analyses, lacking a representative spectrum, and lacking a random or consecutive sample. Reporting bias not detected.	Low	Most studies of clinical tests did not include children <3 y; however, most studies of photoscreeners and 5 of 16 studies of autorefractors included them. Applicable to a variety of settings and screening personnel, although only 1 study was conducted completely in a primary care setting and another was described as conducted partly in primary care.
KQ3: Harms of Screening						
17 (1 cohort study and 16 observational studies of test accuracy)	14 196	One cohort reported lower likelihood of being bullied for the subgroup of patched children offered screening at 37 mo than those not screened (25.7% vs 47.1%, $P = .033$; adjusted OR, 0.39 [95% CI, 0.16-0.92]).[d] Studies of test accuracy with a lower prevalence (<10%) of vision abnormalities had higher false-positive rates (1 – PPV) than studies with higher prevalence (usually >75% vs usually <35%). Evidence on bullying was imprecise. For false-positive rates, findings were reasonably consistent (for studies of similar prevalence) and reasonably precise.	Fair	Medium risk of selection bias and confounding in the cohort study that reported bullying. Studies did not assess psychological effects or other harms of the false-positive findings. Reporting bias not detected.	Low for bullying, moderate for false-positive rates, insufficient for other harms	Children (<6 y) being screened for amblyopia or its risk factors.

(continued)

Table 5. Summary of Evidence for Vision Screening in Children (continued)

No. of Studies (Study Design)	No. of Participants	Summary of Main Findings (Including Consistency and Precision)	Quality	Limitations (Including Reporting Bias)	Strength of Evidence	Applicability
KQ4: Benefits of Treatment						
3 (RCTs)	417	Patching vs no patching: on average, <1 line (on Snellen chart) improvement after 5-12 wks for visual acuity of amblyopic eye; more children experienced improvement of ≥2 lines (45% vs 21%, *P* = .003) in the one study reporting it. Patching + glasses vs glasses alone vs no treatment: on average, improvement of about 1 line on Snellen chart after 1 y for patching + glasses vs no treatment, logMAR, 0.11 (95% CI, 0.05-0.17) and <1 line for glasses alone; magnitude of improvement was greater for those with worse baseline acuity. Findings were consistent and precise.	2 good 1 fair	Adherence to treatment was low in the fair-quality study; the fair-quality study was focused on adherence and underpowered to find a small difference between groups in visual acuity. Reporting bias not detected.	Moderate for improved visual acuity	For patching vs no patching: children aged ≥3 y with amblyopic risk factors pretreated with glasses. For patching + glasses vs glasses alone vs no treatment: children aged ≥3 y with amblyopic risk factors.
KQ5: Harms of Treatment						
3 (RCTs)	417	Worsening visual acuity in the nonamblyopic eye: risk not increased with patching vs no patching at 5 wk (2.4% vs 6.8%, *P* = .28). Loss of visual acuity in the amblyopic eye: No significant difference between patching + glasses, glasses alone, and no treatment at 1 y.[e] Child happiness or behavior problems: No difference between patching + glasses, glasses alone, and no treatment. Child or parent upset or worry about treatment: Greater with patching than with glasses alone. Consistency was unknown (single study reported each outcome), and findings were imprecise.	2 good 1 fair	Overall sparse evidence on harms of treatment; no included studies examined atropine; assessment did not compare glasses and patching with the no-treatment group for the psychological harms identified (eg, child difficulty coping, upset, parental worry). Reporting bias not detected.	Low	Children receiving treatment for amblyopia or its risk factors with eyeglasses or patching

Abbreviations: KQ, key question; logMAR, logarithm of the minimum angle of resolution; LR, likelihood ratio; NR, not reported; OR, odds ratio; PPV, positive predictive value; QOL, quality of life; RCT, randomized clinical trial; VIP, Vision In Preschoolers.

[a] Amblyopia A: 1.5% vs 2.7% (RR, 0.55 [95% CI, 0.29-1.04]); amblyopia B: 0.6% vs 1.8% (RR, 0.35 [95% CI, 0.15-0.86]). See Table 3 notes for definitions of amblyopia A and B.

[b] Amblyopia A: adjusted OR, 0.63 (95% CI, 0.32-1.23); amblyopia B: adjusted OR, 0.72 (95% CI, 0.32-1.60); amblyopia C: adjusted OR, 0.65 (95% CI, 0.38-1.10). See Table 3 notes for definitions of amblyopia A, B, and C. All ORs adjusted for sex, highest level of maternal education, birth weight, family history of strabismus/amblyopia, and duration of breastfeeding.

[c] Some study participants contributed multiple observations (eg, if they were evaluated with multiple tests)

[d] The effects were observed in children who received patches but not those prescribed only glasses.

[e] Values were 9.7% vs 6.5% vs 13.3% (*P* = .28) for those with mild baseline acuity loss and 15.0% vs 11.1% vs 23.8% (*P* = .13) for those with moderate baseline acuity loss, respectively, for patching plus eyeglasses, eyeglasses alone, and no treatment.

Taken together, the treatment trials provide evidence of moderate strength that (1) patching improves visual acuity of the amblyopic eye by a mean of less than 1 line on an eye chart after 5 to 12 weeks compared with no patching for children with amblyopic risk factors pretreated with glasses, (2) patching plus glasses improves visual acuity by about 1 line after 1 year compared with no treatment for children with amblyopic risk factors not pretreated with glasses, and (3) glasses alone improve visual acuity by less than 1 line after 1 year compared with no treatment for children with amblyopic risk factors. The magnitude of improvement for patching plus glasses or glasses alone was greater for those with worse baseline visual acuity. Few of the trials reported binary outcomes that may help determine how many participants achieved a clinically meaningful change, although 1 trial reported that more children treated with patching than with no patching experienced improvement of at least 2 lines.[44]

The review has several limitations. First, for studies of test accuracy conducted in ophthalmology settings, details about the study participants were sometimes limited, making it difficult to determine whether participants had known impaired visual acuity or obvious symptoms of impaired visual acuity. Thus, the review may have included some studies that would not meet eligibility criteria if additional description of the study populations was available. Second, the review did not include comparative effectiveness (ie, head-to-head) studies, such as those comparing atropine with patching. The previous review for the USPSTF described head-to-head trials that compared different patching regimens (eg, 2-hour vs 6-hour patching), different atropine regimens (daily atropine vs weekend atropine), and patching with atropine.[43,45,46,95-97] It concluded that the trials found no differences in visual acuity improvement in the amblyopic eye between the treatments. Third, studies published in languages other than English and those conducted in countries not categorized as very high on the Human Development Index were excluded.

Conclusions

Studies directly evaluating the effectiveness of screening were limited and do not establish whether vision screening in preschool children is better than no screening. Indirect evidence supports the utility of multiple screening tests for identifying preschool children at higher risk for vision problems and the effectiveness of some treatments for improving visual acuity outcomes.

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Author Contributions: Dr Jonas had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Jonas, Amick, Wallace, Feltner.
Acquisition, analysis, or interpretation of data: Jonas, Amick, Wallace, Feltner, Vander Schaaf, Brown, Baker.
Drafting of the manuscript: Jonas, Amick, Wallace, Vander Schaaf, Brown, Baker.
Critical revision of the manuscript for important intellectual content: Jonas, Amick, Feltner, Vander Schaaf, Brown.
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Editorial Disclaimer: This evidence report is presented as a document in support of the accompanying USPSTF Recommendation Statement. It did not undergo additional peer review after submission to *JAMA*.

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