

Vision Screening in Children Aged 6 Months to 5 Years

US Preventive Services Task Force

Recommendation Statement

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IMPORTANCE One of the most important causes of vision abnormalities in children is amblyopia (also known as “lazy eye”). Amblyopia is an alteration in the visual neural pathway in a child’s developing brain that can lead to permanent vision loss in the affected eye. Among children younger than 6 years, 1% to 6% have amblyopia or its risk factors (strabismus, anisometropia, or both). Early identification of vision abnormalities could prevent the development of amblyopia.

SUBPOPULATION CONSIDERATIONS Studies show that screening rates among children vary by race/ethnicity and family income. Data based on parent reports from 2009-2010 indicated identical screening rates among black non-Hispanic children and white non-Hispanic children (80.7%); however, Hispanic children were less likely than non-Hispanic children to report vision screening (69.8%). Children whose families earned 200% or more above the federal poverty level were more likely to report vision screening than families with lower incomes.

OBJECTIVE To update the 2011 US Preventive Services Task Force (USPSTF) recommendation on screening for amblyopia and its risk factors in children.

EVIDENCE REVIEW The USPSTF reviewed the evidence on the accuracy of vision screening tests and the benefits and harms of vision screening and treatment. Surgical interventions were considered to be out of scope for this review.

FINDINGS Treatment of amblyopia is associated with moderate improvements in visual acuity in children aged 3 to 5 years, which are likely to result in permanent improvements in vision throughout life. The USPSTF concluded that the benefits are moderate because untreated amblyopia results in permanent, uncorrectable vision loss, and the benefits of screening and treatment potentially can be experienced over a child’s lifetime. The USPSTF found adequate evidence to bound the potential harms of treatment (ie, higher false-positive rates in low-prevalence populations) as small. Therefore, the USPSTF concluded with moderate certainty that the overall net benefit is moderate for children aged 3 to 5 years.

CONCLUSIONS AND RECOMMENDATIONS The USPSTF recommends vision screening at least once in all children aged 3 to 5 years to detect amblyopia or its risk factors. (B recommendation) The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of vision screening in children younger than 3 years. (I statement)

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The US Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific preventive care services for patients without obvious related signs or symptoms.

It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.

The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.

Summary of Recommendations and Evidence

The USPSTF recommends vision screening at least once in all children aged 3 to 5 years to detect amblyopia or its risk factors (B recommendation) (Figure 1).

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of vision screening in children younger than 3 years. (I statement)

Rationale

Importance

One of the most important causes of vision abnormalities in children is amblyopia (also known as “lazy eye”). Amblyopia is an alteration in the visual neural pathway in a child’s developing brain that can lead to permanent vision loss in the affected eye.^{1,2} It usually occurs in 1 eye but can occur in both. Risk factors associated with the development of amblyopia include strabismus (ocular misalignment); vision deprivation caused by media opacity (eg, cataracts); high, uncorrected refractive errors (eg, myopia, hyperopia, and astigmatism); and anisometropia (Table 1). Other common causes of vision abnormalities are nonamblyopic strabismus and nonamblyopic refractive error.¹ Among children younger than 6 years, 1% to 6% have amblyopia or its risk factors (strabismus, anisometropia, or both), which, if left untreated, could lead to amblyopia.^{1,3-7} Early identification of vision abnormalities could prevent the development of amblyopia.

Detection

The USPSTF found adequate evidence that vision screening tools are accurate in detecting vision abnormalities, including refractive errors, strabismus, and amblyopia. The USPSTF found inadequate evidence to compare screening accuracy across age groups (<3 vs ≥3 years). Many studies of clinical accuracy did not enroll children younger than 3 years.

Benefits of Early Detection and Treatment

The USPSTF found adequate evidence that treatment of amblyopia or its risk factors in children aged 3 to 5 years leads to improved visual acuity. The USPSTF determined that the magnitude of improvement in visual acuity is of moderate benefit. The USPSTF found inadequate evidence that treatment reduced the incidence of long-term amblyopia or improved school performance, functioning, or

quality of life. Limited evidence suggests that screening can potentially reduce psychosocial harms. The USPSTF found inadequate evidence that treatment of amblyopia or its risk factors in children younger than 3 years leads to improved vision outcomes (ie, visual acuity) or other benefits.

Harms of Early Detection and Treatment

The USPSTF found adequate evidence to assess harms of vision screening tests in children aged 3 to 5 years, including higher false-positive rates in low-prevalence populations. False-positive screening results may lead to overdiagnosis or unnecessary treatment. Limited evidence suggests that eye patching in children aged 3 to 5 years does not worsen visual acuity in the nonamblyopic eye but may be associated with psychological harms, such as child or parental upset or concern. The USPSTF found adequate evidence to bound the potential harms of vision screening and treatment in children aged 3 to 5 years as small, based on the nature of the interventions. The USPSTF found inadequate evidence on the harms of treatment in children younger than 3 years.

USPSTF Assessment

The USPSTF concludes with moderate certainty that vision screening to detect amblyopia or its risk factors in children aged 3 to 5 years has a moderate net benefit. The USPSTF concludes that the benefits of vision screening to detect amblyopia or its risk factors in children younger than 3 years are uncertain, and that the balance of benefits and harms cannot be determined for this age group.

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to children aged 6 months to 5 years (Figure 2).

Risk Factors Associated With Amblyopia

Although all children aged 3 to 5 years are at risk of vision abnormalities and should be screened, there are certain risk factors that increase risk. Risk factors for amblyopia include strabismus; high, uncorrected refractive errors (eg, myopia, hyperopia, and astigmatism); anisometropia; and media opacity.¹⁻³ Additional risk factors associated with amblyopia, strabismus, or refractive errors include family history in a first-degree relative, prematurity, low birth weight, maternal substance abuse, maternal smoking during pregnancy, and low levels of parental education.^{1,8-13}

Screening Tests

A variety of screening tests are used to identify vision abnormalities in children in primary care settings (Table 2). Visual acuity tests screen for visual deficits associated with amblyopia and refractive error. Ocular alignment tests screen for strabismus. Stereoacuity tests assess depth perception.^{1,14} For children younger than 3 years, screening may include the fixation and follow test (for visual acuity), the red reflex test (for media opacity), and the corneal light reflex test (for strabismus).^{1,14} Instrument-based vision screening (ie, with autorefractors and photoscreeners) may be used in very young children, including infants. Autorefractors are computerized instruments that detect refractive errors; photoscreeners detect amblyopia risk factors (ocular alignment and media opacity) and refractive errors.^{1,15} Vision

Figure 1. US Preventive Services Task Force (USPSTF) Grades and Levels of Certainty

What the USPSTF Grades Mean and Suggestions for Practice		
Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the Clinical Considerations section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit	
Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as the number, size, or quality of individual studies. inconsistency of findings across individual studies. limited generalizability of findings to routine primary care practice. lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of the limited number or size of studies. important flaws in study design or methods. inconsistency of findings across individual studies. gaps in the chain of evidence. findings not generalizable to routine primary care practice. lack of information on important health outcomes. More information may allow estimation of effects on health outcomes.
The USPSTF defines certainty as “likelihood that the USPSTF assessment of the net benefit of a preventive service is correct.” The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.	

screening in children older than 3 years may include the red reflex test, the cover-uncover test (for strabismus), the corneal light reflex test, visual acuity tests (eg, Snellen, Lea Symbols [Lea-Test], and HOTV [Precision Vision] charts), autorefractors and photo-screeners, and stereoacuity tests.^{1,14} Children with positive findings should be referred for a complete eye examination to confirm the presence of vision problems and for further treatment.

Screening Interval

The USPSTF did not find adequate evidence to determine the optimal screening interval in children aged 3 to 5 years.

Treatment

Treatment depends on the specific condition and includes correction of any underlying refractive error with the use of corrective lenses, occlusion therapy for amblyopia (eg, eye patching, atropine eye drops, or Bangert occlusion foils), or surgical interventions for some causes of refractory strabismus.

Suggestions for Practice Regarding the I Statement

Potential Preventable Burden

Untreated amblyopia is not likely to spontaneously resolve.^{1,16,17} Treatment efficacy decreases with age, with a risk of irreversible

Table 1. Definitions

Condition	Description
Amblyopia	Functional reduction in visual acuity characterized by abnormal processing of visual images; established by the brain during a critical period of vision development
Strabismus	Ocular misalignment; one of the most common causes of amblyopia
Anisometropia	Asymmetric refractive error between the 2 eyes that causes image suppression in the eye with the larger error
Astigmatism	Blurred vision at any distance due to abnormal curvature of the cornea or lens
Hyperopia	Farsightedness; visual images come to focus behind the retina
Myopia	Nearsightedness; visual images come to focus in front of the retina

Figure 2. Clinical Summary: Vision Screening in Children Aged 6 Months to 5 Years

Population	Children aged 3 to 5 y	Children younger than 3 y
Recommendation	Screen at least once to detect amblyopia or its risk factors Grade: B	No recommendation. Grade: I (insufficient evidence)
Risk Assessment	All children aged 3 to 5 years are at risk of vision abnormalities and should be screened; specific risk factors include strabismus, refractive errors, and media opacity. Additional risk factors associated with amblyopia, strabismus, or refractive errors include family history in a first-degree relative, prematurity, low birth weight, maternal substance abuse, maternal smoking during pregnancy, and low levels of parental education.	
Screening Tests	Various screening tests are used in primary care to identify vision abnormalities in children, including the red reflex test, the cover-uncover test, the corneal light reflex test, visual acuity tests (such as Snellen, LEA Symbols, and HOTV charts), autorefractors and photoscreeners, and stereoacuity tests.	
Treatments	Primary treatment includes correction of any underlying refractive error with the use of corrective lenses, occlusion therapy for amblyopia (eye patching, atropine eye drops, or Bangert occlusion foils), or a combination of treatments.	
Balance of Benefits and Harms	The USPSTF concludes with moderate certainty that vision screening to detect amblyopia or its risk factors in children aged 3 to 5 y has a moderate net benefit.	The USPSTF concludes that the benefits of vision screening to detect amblyopia or its risk factors in children younger than 3 y are uncertain and that the balance of benefits and harms cannot be determined.

For a summary of the evidence systematically reviewed in making this recommendation, the full recommendation statement, and supporting documents, please go to <https://www.uspreventiveservicestaskforce.org>.



vision loss.^{1,18-20} Untreated vision abnormalities can result in short- and long-term physical and psychological harms, such as accidents and injuries, experiencing bullying behaviors, poor visual motor skills, depression and anxiety, poor self-esteem, and problems at school and work.²¹⁻²⁵

Current Practice

Vision screening is routinely offered in most primary care settings. Screening rates among children aged 3 years are approximately 40% and increase with age.^{1,26} One survey reported that 3% of pediatricians began vision screening at age 6 months.^{1,27} Typical components of vision screening include assessments of visual acuity and strabismus. Younger children (<3 years) are often unable to cooperate with some of the clinical screening tests performed in clinical practice, such as visual acuity testing, which may result in false-positive results. Some clinical practice guidelines now recommend using handheld autorefractors and photoscreeners as alternative approaches to screening in children 6 months and older because of improved child cooperation and improved accuracy.^{1,28} One potential disadvantage of using some types of photoscreeners

is the need for external interpretation of screening results. Children with positive findings should be referred for a complete eye examination to confirm the presence of vision abnormalities and for further treatment.

Other Considerations

Research Needs and Gaps

The USPSTF identified several gaps in the evidence. Well-designed trials are needed to better understand the effects of screening vs no screening, the optimal age for initiation of screening, and appropriate screening intervals. Additional studies are needed to determine the best screening approach and most favorable combinations of screening tests in primary care. There is also a need for studies that examine the benefits and harms of vision screening and treatment in children younger than 3 years and the long-term benefits and harms of preschool vision screening on health outcomes, such as quality of life, school performance, developmental trajectory, and functioning.

Table 2. Primary Care Screening Tests for Vision Abnormalities

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

Discussion

Burden of Disease

The prevalence of amblyopia, strabismus, and anisometropia ranges from 1% to 6% among children younger than 6 years in the United States.^{1,3-7} Strabismus is the most common cause of amblyopia among children younger than 3 years; among children aged 3 to 6 years, strabismus and anisometropia contribute equally.¹⁸ Studies show that screening rates among children vary by race/ethnicity and family income.^{1,29} Medical Expenditure Panel Survey data from 2009-2010 reported identical screening rates among black non-Hispanic children and white non-Hispanic children (80.7%); however, Hispanic children were less likely than non-Hispanic children to report vision screening (69.8%). Children whose families earned 200% or more above the federal poverty level were more likely to report vision screening than families with lower incomes.^{1,29}

Among children younger than 6 years, 4% have myopia (nearsightedness, ie, visual images focus in front of the retina) and up to 20% have hyperopia (farsightedness, ie, visual images focus behind the retina). Among preschool-aged children, 5% to 10% have astigmatism.^{1,19-21} Amblyopia may significantly increase the risk of severe vision abnormalities or vision loss in the nonamblyopic eye.^{1,30,31} The estimated lifetime risk of vision loss in persons with amblyopia is 1.2% or greater.^{1,30,31}

Scope of Review

The USPSTF commissioned a systematic evidence review¹ to update its 2011 recommendation³² on screening for amblyopia and its risk factors in children. The review examined the evidence on the accuracy of vision screening tests to detect amblyopia, its risk factors, or both and the benefits and harms of vision screening and treatment. Surgical interventions for refractory strabismus, cataracts, ptosis, or other conditions were considered to be out of scope for this review. General eye examination to detect ocular abnormalities not typically detected by vision screening was also considered to be out of scope for this review.

Accuracy of Screening Tests

The USPSTF found 34 fair-quality studies (n = 45 588 observations) that assessed the accuracy of various screening tests: visual

acuity tests (6 studies), stereoaquity tests (4 studies), ocular alignment tests (1 study), combinations of clinical tests (4 studies), autorefractors (16 studies), photoscreeners (11 studies), and retinal birefringence scanning (1 study).¹

Fourteen studies recruited participants from ophthalmology clinics and 17 studies recruited from Head Start, community, or school settings; 2 studies were conducted in primary care settings, and 1 study did not report its setting. Across the studies, screening was administered by diverse personnel such as pediatricians, orthoptists, ophthalmologists, nurses, and Head Start staff.¹

More than half of the studies (19 studies) were conducted in the United States. The remaining studies took place in Canada (5 studies), Europe (7 studies), and New Zealand or Australia (3 studies). Study sample sizes ranged from 63 to 4040 participants. The age of study participants ranged from 6 months to 6 years. About one-third of study participants were younger than 3 years; most were 3 years and older.¹ Many of the studies evaluating photoscreeners (n = 6187 observations) included children younger than 3 years; 5 of the 16 studies evaluating autorefractors (n = 16 712 observations) included children younger than 3 years.¹

The Vision In Preschoolers (VIP) study (n ≤ 4040) provided data for several publications. The VIP study evaluated the accuracy of multiple screening tests for a wide range of vision conditions. It preferentially enrolled children aged 3 to 5 years from Head Start with amblyopia, amblyopia risk factors, reduced visual acuity, or strabismus.^{1,33} Phase 1 of the study compared the accuracy of 11 screening tests.³³ Testing was conducted in specially equipped vans that provided a standard environment with minimal distractions. Phase 2 of the study compared screening performed by nurses vs lay staff and focused on 4 of the 11 screening tests.³⁴ The VIP study evaluated the accuracy of screening for a broader range of vision conditions than most other studies, including significant nonamblyogenic refractive error.

Visual Acuity Tests

Six fair-quality studies evaluated visual acuity tests (Lea Symbols or HOTV). Three publications from the VIP study (n = 6019) assessed the accuracy of Lea Symbols for identifying amblyopia risk factors or clinically significant nonamblyogenic refractive error.¹ In phase 1 of the VIP study, visual acuity testing with Lea Symbols was associated

with a positive likelihood ratio (LR) of 6.1 (95% CI, 4.8-7.6)³³ for detecting amblyopia risk factors or significant nonamblyogenic refractive error; among the 3-, 4-, and 5-year-old age groups, it ranged from 5.95 to 7.39.¹ The overall negative LR was 0.43 (95% CI, 0.38-0.50); among the 3-, 4-, and 5-year-old age groups, it ranged from 0.39 to 0.47. In phase 2 of the VIP study, positive LRs were 4.9 (95% CI, 4.0-6.0) and 3.7 (95% CI, 3.0-4.7) for screening performed by nurse and lay staff, respectively. Negative LRs were 0.57 (95% CI, 0.52-0.62) and 0.70 (95% CI, 0.65-0.76), respectively.^{1,34}

Three additional studies (n = 773) assessed the accuracy of Lea Symbols for detecting amblyopia risk factors, significant refractive error, or astigmatism. Positive LRs ranged from 1.6 to 5.7 and negative LRs ranged from 0.05 to 0.21.¹

The VIP study (n = 3121) found that the HOTV test was associated with an overall positive LR of 4.9 (95% CI, 3.9-6.1) for detecting amblyopia risk factors or significant nonamblyogenic refractive error.^{1,33} Among the 3-, 4-, and 5-year-old age groups, positive LRs ranged from 3.76 to 6.83.¹ Overall, the negative LR was 0.52 (95% CI, 0.46-0.58); among the 3-, 4-, and 5-year-old age groups, it ranged from 0.47 to 0.62.^{1,33}

Stereoacuity Tests

Four fair-quality studies (n = 7801) evaluated stereoacuity tests.¹ Most of the studies reported positive LRs ranging from 3.6 to 4.9. Negative LRs were in the minimal range for detecting amblyopia risk factors or significant nonamblyogenic refractive error and in the moderate range for detecting refractive error or strabismus.¹

Ocular Alignment Tests

In phase 1 of the VIP study (n = 3121), the cover-uncover test was associated with a positive LR of 7.9 (95% CI, 4.6-14.0) and a negative LR of 0.73 (95% CI, 0.15-0.85).^{1,33}

Combinations of Clinical Tests

Four fair-quality studies (n = 1854) assessed combinations of tests of visual acuity, stereoacuity, and ocular alignment.¹ Three of the 4 studies reported positive LRs ranging from 12 to 17.¹ The fourth study, which reported a smaller positive LR of 4.8 (95% CI, 2.8-8.4), was the smallest (n = 141) of the studies. The 4 studies reported negative LRs ranging from 0.10 to 0.91.¹

Autorefractors

Sixteen fair-quality studies (16 712 observations; n = 80-4040) evaluated autorefractors.¹ Most studies reported moderate positive LRs and small negative LRs; some studies reported large positive LRs and negative LRs.¹ Five of the 16 studies evaluating autorefractors enrolled children younger than 3 years.

Photoscreeners

Eleven fair-quality studies (6187 observations; n = 63-3121) assessed photoscreeners. Generally, most studies reported moderate positive LRs and small negative LRs.¹ Many of the studies evaluating photoscreeners enrolled children younger than 3 years.

Retinal Birefringence Scanning

One fair-quality study (n = 102) evaluated the Pediatric Vision Scanner (REBIScan). The positive LR was 10.4 (95% CI, 5.6-19.4) and the negative LR was 0.0.¹

Direct Comparisons of Different Screening Tests

Phase 1 of the VIP study compared 11 screening tests among children aged 3 to 5 years. The Lea Symbols and HOTV visual acuity tests and the Retinomax (Nikon), SureSight (Welch Allyn), and Power Refractor (Plusoptix) autorefractors had higher sensitivity for identifying any visual condition compared with the Random Dot E stereoacuity test (StereoOptical), Randot Stereo Smile Test II (StereoOptical), iScreen photoscreener (iScreen), and MTI photoscreener (Medical Technologies). However, LRs were similar. Positive LRs were generally in the moderate range and negative LRs were in the small to minimal range, with overlapping confidence intervals.^{1,33}

Age and Testability

Five studies evaluated whether the accuracy of different screening tests (including visual acuity tests, a combination of clinical tests, an autorefractor, and 2 photoscreeners) varies by age.¹ Data were limited and estimates were imprecise. Most studies of test accuracy (n = 45 588 observations) did not enroll children younger than 3 years. Accuracy did not clearly differ among preschool-aged children by age group.¹

Testability (the ability to complete the screening test) may limit the usefulness of some clinical screening tests in children younger than 3 years. Testability was reported in many of the included studies; however, few reported data stratified by age or for children younger than 3 years. Testability generally exceeded 80% to 90% in children aged 3 years, with small increases through age 5 years. Studies that evaluated testability found better testability rates in older children (≥ 3 years); visual acuity and stereoacuity tests had low testability rates in children younger than 3 years.¹ Some data suggest that photoscreeners have high testability rates in children as young as 1 year.¹ The VIP study found testability rates near 100% (in children aged ≥ 3 years) for autorefractors and photoscreeners.^{1,33}

Effectiveness of Early Detection and Treatment

No eligible randomized clinical trials directly compared screening vs no screening. No available studies evaluated school performance, other functional outcomes, or quality of life. No eligible studies evaluated atropine eye drops or vision therapy.¹

The USPSTF evaluated 2 fair-quality studies; a nested, randomized trial within a population-based cohort study (Avon Longitudinal Study of Parents and Children [ALSPAC]) and the ALSPAC cohort study. The studies assessed prevalence of amblyopia at age 7.5 years (using visual acuity testing); school performance, function, or quality of life outcomes were not evaluated.^{1,35,36} The ALSPAC nested trial (n = 3490) compared earlier, more intensive screening (at ages 8, 12, 18, 25, 31, and 37 months) vs 1-time screening at age 37 months.^{1,35} Periodic screening (including clinical examination, a visual acuity test, and the cover-uncover test) from ages 8 to 37 months was associated with a 1% decrease in the prevalence of amblyopia at age 7.5 years compared with 1-time screening at age 37 months; however, the difference was only statistically significant for 1 of 2 definitions of amblyopia (interocular difference in acuity ≥ 0.2 logMAR [logarithm of the minimum angle of resolution], 1.5% vs 2.7%; relative risk, 0.55 [95% CI, 0.29-1.04]; and interocular difference in acuity ≥ 0.3 logMAR, 0.6% vs 1.8%; relative risk, 0.35 [95% CI, 0.15-0.86]).^{1,35} The ALSPAC cohort study (n = 6081) compared screening at age 37 months vs no

screening and found no statistically significant difference in the prevalence of amblyopia at age 7.5 years for 3 definitions of amblyopia.^{1,36}

ALSPAC had several limitations. A major limitation was the high overall attrition rate (about 55%) in both studies. Additional limitations included inadequate randomization and the inability to parse out the effects of earlier screening vs repeated screening. As a result, the USPSTF did not consider ALSPAC to be adequate direct evidence.^{1,35,36}

One fair-quality trial and 2 good-quality trials (n = 417) of older preschool-aged children (mean age, 4-5 years) assessed the benefits of eye patching for the treatment of amblyopia or its risk factors.^{1,37-39} There were no trials in children younger than 3 years. Two trials compared patching vs no patching (children were pretreated with eyeglasses if indicated in both groups).^{1,38,39} One trial compared patching plus eyeglasses vs eyeglasses alone vs no treatment.^{1,37} Study sample sizes ranged from 60 to 180 participants.¹ One of the 3 trials (evaluating patching plus eyeglasses vs eyeglasses alone vs no treatment) enrolled screen-detected children.^{1,37} Treatment duration was 5 weeks, 12 weeks, and 1 year; follow-up duration was 1 year, 12 weeks, and 1.5 years, respectively.^{1,37} Trials were conducted in the United States or the United Kingdom.^{1,37-39} The trials reported best corrected visual acuity and improvement in visual acuity (secondary outcome).^{1,37-39} Results could not be pooled, due to differences in study populations (eg, eligibility criteria and baseline visual acuity), outcome measures, comparisons, and length of follow-up.¹

Patching improved visual acuity in the amblyopic eye by an average of less than 1 line on the Snellen chart after 5 to 12 weeks among children with amblyopia risk factors who were pretreated with eyeglasses.¹ More children treated with patching experienced improvement of at least 2 lines on the Snellen chart than did children with no patching (45% vs 21%; $P = .003$). Patching plus eyeglasses improved visual acuity by about 1 line on the logMAR chart after 1 year (0.11 logMAR [95% CI, 0.05-0.17]) among children with amblyopia risk factors not pretreated with eyeglasses.¹ Eyeglasses alone improved visual acuity by less than 1 line on the logMAR chart after 1 year (0.08 logMAR [95% CI, 0.02-0.15]) among children with amblyopia risk factors. Benefits were greater for children with more severe vision impairment at baseline. Children with worse baseline visual acuity had greater improvement with patching plus eyeglasses or eyeglasses alone.¹

Potential Harms of Screening and Treatment

Potential harms of vision screening in preschool-aged children include psychosocial effects such as labeling and anxiety, unnecessary referrals due to false-positive results, overdiagnosis, and unnecessary use of corrective lenses or treatments to prevent amblyopia. Studies of screening test accuracy (n = 9723) found higher false-positive rates (usually >75%) in populations with a lower prevalence (<10%) of vision abnormalities, whereas studies in populations with a higher prevalence of vision abnormalities found lower false-positive rates (usually <35%).¹ No studies reported measures of psychosocial distress, labeling, or anxiety. The ALSPAC prospective cohort study (n = 4473) evaluated bullying behaviors among 8-year-olds in a subgroup of children treated with eye patching. The likelihood of experiencing bullying behaviors was lower among patched children offered screening at age 37 months than among

those not screened (25.7% vs 47.1%; $P = .033$; adjusted odds ratio, 0.39 [95% CI, 0.16-0.92]).^{1,36}

Potential harms of treatment include loss of visual acuity in the amblyopic eye, psychological harms (eg, effects on child happiness, behavioral problems, and parental concern or upset), inverse amblyopia, and patch allergy. One fair-quality trial and 2 good-quality trials (n = 417) assessed treatment harms.^{1,37-40} and did not report similar outcomes. There were no trials in children younger than 3 years. None of the included studies evaluated treatment with atropine eye drops. One trial compared patching (n = 87) vs no patching (n = 93) and found that worsening visual acuity in the nonamblyopic eye did not differ between groups at 5 weeks (2.4% vs 6.8%; $P = .28$).^{1,38} One trial compared patching plus eyeglasses (n = 59) vs eyeglasses alone (n = 59) vs no treatment (n = 59) and found no significant difference in loss of visual acuity in the amblyopic eye among treatment groups at 1 year.^{1,37} In a subanalysis of 1 trial (patching plus eyeglasses vs eyeglasses alone vs no treatment), the psychological harms of treatment were evaluated in 144 of 177 study participants.^{1,37,40} Few differences in child happiness or behavioral problems were observed between the treatment groups. More children were upset about treatment with patching than with eyeglasses alone (85% vs 29% at age 4 years, $P = .03$; 62% vs 26% at age 5 years, $P = .005$).^{1,40} The study did not compare the eyeglasses and patching group with the nontreatment group for the psychological harms identified.^{1,40} No participants experienced an adverse event (eg, inverse amblyopia or patch allergy) in 1 trial (n = 60) comparing patching vs no patching.^{1,39}

Estimate of Magnitude of Net Benefit

The USPSTF found adequate evidence that vision screening tools are accurate in detecting vision abnormalities. Accuracy did not clearly differ among preschool-aged children by age group. Treatment of amblyopia is associated with moderate improvements in visual acuity in children aged 3 to 5 years, which are likely to result in permanent improvements throughout life. The USPSTF concluded that the benefits are moderate because untreated amblyopia results in permanent, uncorrectable vision loss, and the benefits of screening and treatment potentially can be experienced over a child's lifetime. The USPSTF found adequate evidence on harms of screening (ie, higher false-positive rates in low-prevalence populations). The USPSTF found adequate evidence to bound the potential harms of treatment as small. Therefore, the USPSTF concludes with moderate certainty that the overall net benefit is moderate for children aged 3 to 5 years.

Trials that examined the benefits and harms of treatment did not enroll children younger than 3 years. The USPSTF found inadequate evidence that treatment of amblyopia or its risk factors in children younger than 3 years leads to improved vision outcomes or other benefits. The USPSTF found inadequate evidence on the harms of treatment in children younger than 3 years. Therefore, the USPSTF concludes that the benefits of screening to detect amblyopia or its risk factors in children younger than 3 years are uncertain, and that the balance of benefits and harms cannot be determined for this age group.

How Does Evidence Fit With Biological Understanding?

Amblyopia is a functional reduction in visual acuity characterized by abnormal processing of visual images by the brain. It is associated

with conditions that affect binocular vision, such as strabismus, anisometropia, and media opacity. The loss in visual acuity is unlikely to resolve spontaneously if left untreated. Therefore, screening in preschool-aged children seems to be consistent with the current biological understanding of amblyopia and the importance of detecting it during a critical period in children's development.

Response to Public Comment

A draft version of this recommendation statement was posted for public comment on the USPSTF website from February 28 to March 27, 2017. Some comments expressed concern about the scope of the review for screening. The USPSTF added language to clarify that the general eye examination to detect ocular abnormalities was not in scope for this review, and further clarified the language about screening tests in the Clinical Considerations section. Other comments expressed concern about the lack of information on health disparities. In response, the USPSTF added language about health disparities to the Clinical Considerations section. Some comments did not agree with delaying screening until the age of 3 years. The USPSTF added more language about the lack of evidence regarding screening and treatment in children younger than 3 years to the Discussion section. Last, some comments requested information about the effects of screening on learning and quality of life outcomes. The USPSTF revised the Research Needs and Gaps section, which discusses these gaps in the evidence on outcomes.

Update of Previous USPSTF Recommendation

This recommendation is an update of the USPSTF 2011 recommendation,³² in which the USPSTF recommended vision screening for amblyopia and its risk factors in children aged 3 to 5 years

(B recommendation). The USPSTF concluded that the evidence was insufficient to assess the balance of benefits and harms of vision screening in children younger than 3 years (I statement). The current recommendation reaffirms the previous recommendation.

Recommendations of Others

In 2016, the American Academy of Pediatrics, American Association for Pediatric Ophthalmology and Strabismus, American Academy of Certified Orthoptists, and American Academy of Ophthalmology released a joint clinical report recommending preschool vision screening.⁴¹ The joint report recommends vision assessment in children aged 6 months to 3 years with physical examination (eg, external inspection, the fixation and follow test, the red reflex test, and pupil examination). Instrument-based vision screening (with autorefractors or photoscreeners) may be used, when available, in children aged 1 to 3 years. Visual acuity screening may be attempted at age 3 years using HOTV or Lea Symbols charts; children aged 4 to 5 years should have visual acuity assessed using HOTV or Lea Symbols charts, the cover-uncover test, and the red reflex test.^{1,41}

The American Academy of Family Physicians recommends vision screening in all children at least once between the ages of 3 and 5 years to detect amblyopia or its risk factors; it concluded that the current evidence is insufficient to assess the balance of benefits and harms of vision screening in children younger than 3 years.⁴²

The American Optometric Association recommends initial vision screening in infants at birth. Regular comprehensive eye examinations should occur at age 6 months, 3 years, and prior to entry into first grade; eye examinations should then occur at 2-year intervals unless children are considered at high risk for vision abnormalities.⁴³

ARTICLE INFORMATION

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