Amblyopia
Secretary for Quality of Care
Anne L. Coleman, MD, PhD

Academy Staff
Nancy Collins, RN, MPH
Doris Mizuiri
Jessica Ravetto
Flora C. Lum, MD

Medical Editor: Susan Garratt
Design: Socorro Soberano

Approved by: Board of Trustees
September 15, 2012

Copyright © 2012 American Academy of Ophthalmology®
All rights reserved

AMERICAN ACADEMY OF OPHTHALMOLOGY and PREFERRED PRACTICE PATTERN are registered trademarks of the American Academy of Ophthalmology. All other trademarks are the property of their respective owners.

This document should be cited as follows:

Preferred Practice Pattern® guidelines are developed by the Academy’s H. Dunbar Hoskins Jr., M.D. Center for Quality Eye Care without any external financial support. Authors and reviewers of the guidelines are volunteers and do not receive any financial compensation for their contributions to the documents. The guidelines are externally reviewed by experts and stakeholders before publication.
PED paAtrIC OP THERALMOLOGY/ STRABISMUS PREFERRED PRACTICE PATTERN DEVELOPMENT PROCESS AND PARTICIPANTS

The Pediatric Ophthalmology/Strabismus Preferred Practice Pattern® Panel members wrote the Amblyopia Preferred Practice Pattern® guidelines ("PPP"). The PPP Panel members discussed and reviewed successive drafts of the document, meeting in person twice and conducting other review by e-mail discussion, to develop a consensus over the final version of the document.

Pediatric Ophthalmology/Strabismus Preferred Practice Pattern Panel 2011–2012
C. Gail Summers, MD, Chair
Stephen P. Christiansen, MD
Alex R. Kemper, MD, MPH, MS, American Academy of Pediatrics Representative
Katherine A. Lee, MD, PhD
Graham E. Quinn, MD
Michael X. Repka, MD, MBA
David K. Wallace, MD, MPH, American Association for Pediatric Ophthalmology & Strabismus Representative
Susannah G. Rowe, MD, MPH, Methodologist

The Preferred Practice Patterns Committee members reviewed and discussed the document during a meeting in March 2012. The document was edited in response to the discussion and comments.

Preferred Practice Patterns Committee 2012
Christopher J. Rapuano, MD, Chair
David F. Chang, MD
Robert S. Feder, MD
Stephen D. McLeod, MD
Timothy W. Olsen, MD
Bruce E. Prum, Jr., MD
C. Gail Summers, MD
David C. Musch, PhD, MPH, Methodologist

The Amblyopia PPP was then sent for review to additional internal and external groups and individuals in June 2012. All those returning comments were required to provide disclosure of relevant relationships with industry to have their comments considered. Members of the Pediatric Ophthalmology/Strabismus Preferred Practice Pattern Panel reviewed and discussed these comments and determined revisions to the document. The following organizations and individuals returned comments.

Academy Reviewers
Board of Trustees and Committee of Secretaries Council
General Counsel
Ophthalmic Technology Assessment Committee
Pediatric Ophthalmology/Strabismus Panel
Basic and Clinical Science Course Subcommittee
Practicing Ophthalmologists Advisory Committee for Education

Invited Reviewers
American Academy of Pediatrics
American Association for Pediatric Ophthalmology and Strabismus
American Association of Certified Orthoptists
American Board of Ophthalmology
American Uveitis Society
Canadian Association of Pediatric Ophthalmology
European Paediatric Ophthalmological Society
National Eye Institute
Sean P. Donahue, MD
FINANCIAL DISCLOSURES

In compliance with the Council of Medical Specialty Societies’ Code for Interactions with Companies (available at www.cmss.org/codeforinteractions.aspx), relevant relationships with industry are listed. The Academy has Relationship with Industry Procedures to comply with the Code (available at http://one.aao.org/CE/PracticeGuidelines/PPP.aspx). A majority (87%) of the members of the Pediatric Ophthalmology/Strabismus Preferred Practice Pattern Panel 2011–2012 had no financial relationship to disclose.

**Pediatric Ophthalmology/Strabismus Preferred Practice Pattern Panel 2011–2012**
- Stephen P. Christiansen, MD: No financial relationships to disclose
- Alex R. Kemper, MD, MPH, MS: No financial relationships to disclose
- Katherine A. Lee, MD, PhD: No financial relationships to disclose
- Graham E. Quinn, MD: No financial relationships to disclose
- Michael X. Repka, MD, MBA: No financial relationships to disclose
- Susannah G. Rowe, MD: No financial relationships to disclose
- C. Gail Summers, MD: No financial relationships to disclose
- David K. Wallace, MD, MPH: Allergan, Inc. – Consultant/Advisor

**Preferred Practice Patterns Committee 2012**
- David F. Chang, MD: Allergan, Inc. – Lecture fees
- Robert S. Feder, MD: No financial relationships to disclose
- Stephen D. McLeod, MD: No financial relationships to disclose
- David C. Musch, PhD, MPH: No financial relationships to disclose
- Timothy W. Olsen, MD: No financial relationships to disclose
- Bruce E. Prum, Jr., MD: Allergan, Inc. – Consultant/Advisor
- Christopher J. Rapuano, MD: Allergan, Inc. – Consultant/Advisor, Lecture fees
- C. Gail Summers, MD: No financial relationships to disclose

**Secretary for Quality of Care**
- Anne L. Coleman, MD, PhD: No financial relationships to disclose

**Academy Staff**
- Nancy Collins, RN, MPH: No financial relationships to disclose
- Susan Garratt, Medical Editor: No financial relationships to disclose
- Flora C. Lum, MD: No financial relationships to disclose
- Doris Mizuiri: No financial relationships to disclose
- Jessica Ravetto: No financial relationships to disclose

The disclosures of relevant relationships to industry of other reviewers of the document from January to August 2012 are available online at www.aao.org/ppp.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>OBJECTIVES OF PREFERRED PRACTICE PATTERN GUIDELINES</td>
<td>2</td>
</tr>
<tr>
<td>METHODS AND KEY TO RATINGS</td>
<td>3</td>
</tr>
<tr>
<td>HIGHLIGHTED FINDINGS &amp; RECOMMENDATIONS FOR CARE</td>
<td>4</td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td>5</td>
</tr>
<tr>
<td>Disease Definition</td>
<td>5</td>
</tr>
<tr>
<td>Strabismic Amblyopia</td>
<td>5</td>
</tr>
<tr>
<td>Refractive Amblyopia</td>
<td>5</td>
</tr>
<tr>
<td>Visual Deprivation Amblyopia</td>
<td>5</td>
</tr>
<tr>
<td>Patient Population</td>
<td>6</td>
</tr>
<tr>
<td>Clinical Objectives</td>
<td>6</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>6</td>
</tr>
<tr>
<td>Prevalence and Risk Factors</td>
<td>6</td>
</tr>
<tr>
<td>Natural History</td>
<td>6</td>
</tr>
<tr>
<td>Rationale for Treatment</td>
<td>7</td>
</tr>
<tr>
<td>CARE PROCESS</td>
<td>7</td>
</tr>
<tr>
<td>Patient Outcome Criterion</td>
<td>7</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>7</td>
</tr>
<tr>
<td>History</td>
<td>7</td>
</tr>
<tr>
<td>Examination</td>
<td>8</td>
</tr>
<tr>
<td>Criteria for Diagnosis</td>
<td>12</td>
</tr>
<tr>
<td>Management</td>
<td>13</td>
</tr>
<tr>
<td>Prevention</td>
<td>13</td>
</tr>
<tr>
<td>Choice of Therapy</td>
<td>14</td>
</tr>
<tr>
<td>Follow-up Evaluation</td>
<td>17</td>
</tr>
<tr>
<td>Provider and Setting</td>
<td>19</td>
</tr>
<tr>
<td>Counseling and Referral</td>
<td>19</td>
</tr>
<tr>
<td>Socioeconomic Considerations</td>
<td>19</td>
</tr>
<tr>
<td>APPENDIX 1. QUALITY OF OPHTHALMIC CARE CORE CRITERIA</td>
<td>21</td>
</tr>
<tr>
<td>APPENDIX 2. INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS (ICD) CODES</td>
<td>23</td>
</tr>
<tr>
<td>APPENDIX 3. VISUAL ACUITY TESTING CHARTS</td>
<td>24</td>
</tr>
<tr>
<td>APPENDIX 4. PEDIATRIC EYE DISEASE INVESTIGATOR GROUP CLINICAL TRIALS</td>
<td>28</td>
</tr>
<tr>
<td>SUGGESTED READING</td>
<td>31</td>
</tr>
<tr>
<td>RELATED ACADEMY MATERIALS</td>
<td>31</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>32</td>
</tr>
</tbody>
</table>
OBJECTIVES OF PREFERRED PRACTICE PATTERN® GUIDELINES

As a service to its members and the public, the American Academy of Ophthalmology has developed a series of Preferred Practice Pattern® guidelines that identify characteristics and components of quality eye care. Appendix 1 describes the core criteria of quality eye care.

The Preferred Practice Pattern® guidelines are based on the best available scientific data as interpreted by panels of knowledgeable health professionals. In some instances, such as when results of carefully conducted clinical trials are available, the data are particularly persuasive and provide clear guidance. In other instances, the panels have to rely on their collective judgment and evaluation of available evidence.

These documents provide guidance for the pattern of practice, not for the care of a particular individual. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these PPPs will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients’ needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.

Preferred Practice Pattern® guidelines are not medical standards to be adhered to in all individual situations. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.

References to certain drugs, instruments, and other products are made for illustrative purposes only and are not intended to constitute an endorsement of such. Such material may include information on applications that are not considered community standard, that reflect indications not included in approved U.S. Food and Drug Administration (FDA) labeling, or that are approved for use only in restricted research settings. The FDA has stated that it is the responsibility of the physician to determine the FDA status of each drug or device he or she wishes to use, and to use them with appropriate patient consent in compliance with applicable law.

INnovation in medicine is essential to ensure the future health of the American public, and the Academy encourages the development of new diagnostic and therapeutic methods that will improve eye care. It is essential to recognize that true medical excellence is achieved only when the patients’ needs are the foremost consideration.

All Preferred Practice Pattern® guidelines are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly. To ensure that all PPPs are current, each is valid for 5 years from the “approved by” date unless superseded by a revision. Preferred Practice Pattern guidelines are funded by the Academy without commercial support. Authors and reviewers of PPPs are volunteers and do not receive any financial compensation for their contributions to the documents. The PPPs are externally reviewed by experts and stakeholders, including consumer representatives, before publication. The PPPs are developed in compliance with the Council of Medical Specialty Societies’ Code for Interactions with Companies. The Academy has Relationship with Industry Procedures (available at http://one.aao.org/CE/PracticeGuidelines/PPP.aspx) to comply with the Code.

Appendix 2 contains the International Statistical Classification of Diseases and Related Health Problems (ICD) codes for the disease entities that this PPP covers. The intended users of the Amblyopia PPP are ophthalmologists.
METHODS AND KEY TO RATINGS

Preferred Practice Pattern® guidelines should be clinically relevant and specific enough to provide useful information to practitioners. Where evidence exists to support a recommendation for care, the recommendation should be given an explicit rating that shows the strength of evidence. To accomplish these aims, methods from the Scottish Intercollegiate Guideline Network1 (SIGN) and the Grading of Recommendations Assessment, Development and Evaluation2 (GRADE) group are used. GRADE is a systematic approach to grading the strength of the total body of evidence that is available to support recommendations on a specific clinical management issue. Organizations that have adopted GRADE include SIGN, the World Health Organization, the Agency for Healthcare Research and Policy, and the American College of Physicians.3

- All studies used to form a recommendation for care are graded for strength of evidence individually, and that grade is listed with the study citation.
- To rate individual studies, a scale based on SIGN1 is used. The definitions and levels of evidence to rate individual studies are as follows:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I++</td>
<td>High-quality meta-analyses, systematic reviews of randomized controlled trials (RCTs), or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>I+</td>
<td>Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>I-</td>
<td>Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>II++</td>
<td>High-quality systematic reviews of case-control or cohort studies</td>
</tr>
<tr>
<td></td>
<td>High-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</td>
</tr>
<tr>
<td>II+</td>
<td>Well-conducted case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>II-</td>
<td>Case-control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>III</td>
<td>Nonanalytic studies (e.g., case reports, case series)</td>
</tr>
</tbody>
</table>

- Recommendations for care are formed based on the body of the evidence. The body of evidence quality ratings are defined by GRADE2 as follows:

<table>
<thead>
<tr>
<th>Quality</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Good</td>
<td>Further research is very unlikely to change our confidence in the estimate of effect</td>
</tr>
<tr>
<td>Moderate</td>
<td>Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate</td>
</tr>
<tr>
<td>Insufficient</td>
<td>Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate</td>
</tr>
<tr>
<td></td>
<td>Any estimate of effect is very uncertain</td>
</tr>
</tbody>
</table>

- Key recommendations for care are defined by GRADE2 as follows:

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong</td>
<td>Used when the desirable effects of an intervention clearly outweigh the undesirable effects or clearly do not</td>
</tr>
<tr>
<td>Discretionary</td>
<td>Used when the trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced</td>
</tr>
</tbody>
</table>

- The Highlighted Findings and Recommendations for Care section lists points determined by the PPP Panel to be of particular importance to vision and quality of life outcomes.
- Literature searches to update the PPP were undertaken in March 2011 in PubMed and the Cochrane Library and were updated in March 2012. Complete details of the literature search are available at www.aao.org/ppp.
Treatment of refractive error alone can improve visual acuity in children who have untreated anisometropic and strabismic amblyopia. Visual acuity of children who have bilateral refractive amblyopia also can substantially improve with refractive correction alone.  (strong recommendation, good evidence)

Most children who have moderate amblyopia respond to initial treatment consisting of at least 2 hours of daily patching or weekend atropine.  
(strong recommendation, good evidence for treatment of amblyopia)  
(discretionary recommendation, good evidence for dosage [amount of time] of treatment)

Patching may be effective in older children and teenagers particularly if they have not previously been treated.  (good evidence)

Children who have amblyopia require continued monitoring, because about one-fourth of children successfully treated for amblyopia experience a recurrence within the first year after treatment has been discontinued.  (strong recommendation, good evidence)

Successful amblyopia treatment may have its greatest impact in later life, when fellow eyes can be injured or affected by diseases of the macula or optic nerve.  (insufficient evidence)
INTRODUCTION

DISEASE DEFINITION

Amblyopia is a unilateral or, less commonly, bilateral reduction of best-corrected visual acuity that occurs in the setting of an otherwise normal eye, or a structural abnormality involving the eye or visual pathway, with reduction in visual acuity that cannot be attributed only to the effect of the structural abnormality. Amblyopic eyes may also have deficits in contrast sensitivity and accommodation. Often the fellow eye is not normal but has subtle deficits.

Amblyopia is caused by an abnormal visual experience early in life. It has traditionally been classified in terms of the disorder or combination of the disorder or combination of disorders that may be responsible for its occurrence, as follows:4

- Strabismic
- Refractive
  - Anisometropic
  - High bilateral refractive errors
- Visual deprivation

Strabismic Amblyopia

Constant, non-alternating or unequally alternating tropias (typically esodeviations) are likely to cause amblyopia. Strabismic amblyopia is thought to result from competitive or inhibitory interaction between neurons carrying the non-fusible inputs from the two eyes, which leads to domination of cortical vision centers by the fixating eye and chronically reduced responsiveness to input by the nonfixing eye.

Refractive Amblyopia

Amblyopia may develop as a result of untreated unilateral or bilateral refractive errors. Anisometropic amblyopia develops when unequal refractive error in the two eyes causes the image on one retina to be chronically more defocused than the fellow eye. This form of amblyopia may occur in combination with strabismus. Purely ametropic amblyopia is thought to result partly from the direct effect of image blur on the development of visual acuity in the involved eye and partly from interocular competition or inhibition similar (but not necessarily identical) to that responsible for strabismic amblyopia. Greater degrees of anisometropia or astigmatism result in increased risk and severity of amblyopia.5

Bilateral refractive (isoametropic or ametropic) amblyopia is a less common form of refractive amblyopia that results in a bilateral reduction in acuity in both eyes of a young child. Its mechanism involves the effect of blurred retinal images alone. Uncorrected bilateral astigmatism in early childhood may result in loss of resolving ability limited to the chronically blurred meridian (meridional amblyopia).6,8

Visual Deprivation Amblyopia

Visual deprivation amblyopia is caused by complete or partial obstruction of the ocular media, resulting in a blurred image on the retina. The most common cause is a congenital or early-onset cataract, but corneal opacities, infectious or noninfectious intraocular inflammation, vitreous hemorrhage, and ptosis are also associated with visual deprivation amblyopia. Deprivation amblyopia is the least common form of amblyopia but the most severe and difficult to treat. Amblyopic visual loss resulting from a unilateral obstruction within the pupil tends to be worse than that produced by bilateral deprivation of similar degree because interocular competition adds to the direct developmental impact of severe image degradation. Even in bilateral cases, however, visual acuity can be 20/200 or worse. Newborns with visually
threatening unilateral cataracts have a better prognosis when the cataract is removed and optical correction is in place by 1 to 2 months of age.9,11

In children younger than 6 years, dense congenital cataracts that occupy the central 3 mm or more of the lens should be considered likely to cause severe amblyopia. Similar lens opacities acquired after age 6 years are generally less harmful. Small polar cataracts, around which retinoscopy can be performed readily, and lamellar cataracts, through which a reasonably good view of the fundus can be obtained, may cause mild to moderate amblyopia or may have no effect on visual development.

Occlusion amblyopia is a specific form of deprivation amblyopia that may be seen after therapeutic patching or defocus with cycloplegia. This type is also termed “reverse amblyopia.”

Vision loss in the setting of a structural abnormality of the eye (e.g., optic nerve hypoplasia, retinopathy of prematurity, uveitis) may have a component of treatable amblyopia.12,13

Subtle or unrecognized abnormalities of the retina or optic nerve in amblyopic eyes may also contribute to vision loss.14

PATIENT POPULATION
Children with amblyopia or who are at risk for amblyopia

CLINICAL OBJECTIVES
- Identify children at risk for amblyopia
- Examine and diagnose the child with amblyopia or risk factors for amblyopia at the earliest possible stage
- Inform the patient and/or family/caregiver, as appropriate, and primary care provider of the diagnosis, treatment options, care plan, and prognosis
- Treat infants and children who have amblyopia in order to improve visual function, and reduce the likelihood of vision-related disability15,16
- Re-evaluate the child and adjust the treatment plan as necessary

BACKGROUND

PREVALENCE AND RISK FACTORS
Amblyopia is an important public health problem because of its prevalence among children, and because visual impairment from amblyopia is lifelong and can be profound.17 Both amblyopia and its treatment can have a substantial impact on quality of life.18-20 Prevalence estimates range from 0.8% to 3.3% depending on the population studied and the definition used.21-30

Unilateral amblyopia is associated with strabismus in 50% of cases and with anisometropia in a somewhat smaller percentage of cases.31,32 Approximately 50% of children with esotropia have amblyopia at the time of initial diagnosis.33,34 Amblyopia is at least four times more common in children who were premature, small for gestational dates,35-40 or who have a first-degree relative with amblyopia.41,42 The prevalence of amblyopia in children with developmental delay is sixfold greater than in healthy, full-term infants.43,44 Environmental factors including maternal smoking and drug or alcohol use during pregnancy may be associated with an increased risk of amblyopia or strabismus.45-49

NATURAL HISTORY
With rare exceptions, amblyopia results in lifelong visual loss if it is untreated or incompletely treated in early childhood.50,51 It appears that the potential for successful treatment of amblyopia is greatest in young children, though recent studies show that treatment in older children can improve visual acuity.50-54
Deprivation amblyopia due to significant media opacities through the first 3 postnatal months produces profound and permanent reductions in high contrast (e.g., grating or optotype) acuity, typically to less than or equal to 20/200 in the affected eye(s). Similar deprivation acquired after 3 months of age but before 30 months can lead to less profound visual acuity reduction, still in the range of 20/200 or less. Visual deprivation early in life needs only to be brief to cause amblyopia. Early deprivation is strongly associated with development of sensory nystagmus in bilateral cases and strabismus in both unilateral and bilateral cases. Deprivation commencing between the ages of 30 months and 8 years differs only in that vision is lost at a slower rate and is more likely to respond to subsequent therapy.

Similar but less severe visual acuity deficits are seen in children who have untreated refractive or strabismic amblyopia. In these cases, reduced acuity in one or both eyes may be evident as early as the fourth to sixth month of life. When the onset of defocus or strabismus occurs after the age of 3 years, the risk of amblyopia is reduced.

Amblyopia is a risk factor for the development of strabismus and reduction of binocularity, and strabismus is a risk factor for the development of amblyopia. In young children, amblyopia treatment may diminish the visual deficit and may foster the redevelopment of binocular vision.

RATIONALE FOR TREATMENT
Timely treatment of amblyopia improves visual acuity and binocularity and decreases the likelihood of severe visual handicap if there is loss of vision in the fellow eye later in life. It is also cost-effective. The lifelong risk of bilateral visual impairment is approximately doubled for patients with amblyopia. A retrospective study found that vision loss originating from the fellow eye was more likely to occur in children who have amblyopia when compared with children who do not have amblyopia. Accidental trauma with injury of the fellow eye was associated with more than one-half of the cases of total vision loss. In older subjects, loss of visual acuity in the fellow eye is usually related to retinal abnormalities such as retinal vein occlusion, age-related macular degeneration, and other macular disorders.

Untreated or insufficiently treated amblyopia may have an impact when the patient is considering a potential career choice. There are specific visual acuity and binocularity requirements for a variety of career fields, such as military service, aviation, and stereoscopic surgery. However, it has not been proven that amblyopia is an impediment to education or career performance. Maintenance of good vision in each eye with appropriate amblyopia treatment is an important part of successful management of strabismus. All children with amblyopia should be offered an attempt at treatment regardless of age.

CARE PROCESS

PATIENT OUTCOME CRITERION
- Improved visual function

DIAGNOSIS
The initial amblyopia evaluation includes a comprehensive ophthalmic evaluation, with attention to risk factors for amblyopia such as strabismus, anisometropia, a positive family history for strabismus or amblyopia, and the presence of a media opacity or structural defects.

History
Although a history generally includes the following items, the exact composition varies with the child’s particular problems and needs:
- Demographic data, including gender, date of birth, and identity of parent/caregiver
- The identity of the historian and relationship of patient
Amblyopia PPP:

Examination

- The identity of health care providers involved in the child’s care
- The chief complaint and reason for the eye evaluation
- Current eye problems
- Ocular history, including prior eye problems, diseases, diagnoses, and treatments
- Systemic history, birth weight, gestational age, prenatal and perinatal history that may be pertinent (e.g., alcohol, tobacco, and drug use during pregnancy), past hospitalizations and operations, and general health and development. In particular, note the presence of developmental delay or cerebral palsy.
- Current medications and allergies
- Family history of ocular conditions and relevant systemic conditions
- Review of systems

Examination

The eye examination consists of an assessment of the physiological function and the anatomic status of the eye and visual system. Documentation of the child’s level of cooperation with the examination can be useful in interpreting the results and in making comparisons among examinations over time. In general, the examination may include the following elements:

- Binocular red reflex (Brückner) test
- Binocularity/stereoacuity testing
- Assessment of fixation pattern and visual acuity
- Binocular alignment and ocular motility
- Pupillary examination
- External examination
- Anterior segment examination
- Cycloplegic retinoscopy/refraction with subjective refinement when indicated
- Funduscopic examination

Binocular Red Reflex (Brückner) Test

In a darkened room, the direct ophthalmoscope light should be directed toward both eyes of the child simultaneously from approximately 18 to 30 inches (45 to 75 centimeters). To be considered normal, a symmetric red reflex should be observed from both eyes. Opacities in the red reflex, a markedly diminished reflex, the presence of a white or yellow reflex, or asymmetry of the reflexes are all considered abnormal. The red reflex varies based on retinal pigmentation and, thus, varies by race/ethnicity. Significant hyperopia will present as an inferiorly placed brighter crescent in the red reflex. Significant myopia presents as a superiorly placed brighter crescent.

Binocularity/Stereoacuity Testing

Binocularity, or binocular vision, consists of several different components, including sensory fusion, stereopsis, fusional vergence (motor fusion), and other coordinated binocular eye movements. These types of binocular vision are sensitive to disruption by amblyopia, strabismus, refractive error, and deprivation, but each can be affected to different degrees depending on the underlying diagnosis. Tests to evaluate each of these components of binocular vision include the Worth 4-dot Test (sensory fusion), the Randot test (stereopsis), and vergence testing with a prism bar or rotary prism (fusional vergence). Assessment of stereoacuity is an important component of binocular alignment testing because high-grade stereoacuity is associated with normal alignment. Testing of sensory function should be performed before any dissociating examination techniques (e.g., covering an eye to check monocular visual acuity, cover testing to assess alignment) are done. Binocular alignment testing should be done before cycloplegia.
Assessment of Fixation Pattern and Visual Acuity

**Fixation**

Visual acuity measurement of the infant and toddler involves a qualitative assessment of fixation and tracking (following) movements of the eyes. Fixation and following are assessed by drawing the child’s attention to the examiner or caregiver’s face (infants under 3 months) or to a hand-held light, toy, or other accommodative fixation target and then slowing moving the target. Fixation behavior can be recorded for each eye as “fixes and follows” or “central, steady, and maintained.”

Fixation preference can be assessed by observing the vigor with which the child objects to occlusion of one eye relative to the other: children resist covering an eye when the fellow eye has limited vision. Grading schemes can be used to describe fixation preference. For strabismic patients, fixation pattern is assessed binocularly by determining the length of time that the nonpreferred eye holds fixation. Fixation pattern can be graded by whether the nonpreferred eye will not hold fixation, holds momentarily, holds for a few seconds (or to or through a blink), or by observation of spontaneous alternation of fixation. For children with small-angle strabismus or no strabismus, the induced tropia test is typically done by holding a 10 to 20 prism diopter base-down prism over one eye and then the other eye and noting fixation behavior.

Qualitative assessment of visual acuity should be replaced with a visual acuity test based on optotypes (letters, numbers, or symbols) as soon as the child can perform this task.

**Visual Acuity**

Recognition visual acuity testing, which involves identifying optotypes, including letters, numbers, or symbols, is preferred for assessment of visual acuity to detect amblyopia. The optotypes may be presented on a wall chart, computer screen, or hand-held card. Visual acuity is routinely tested at distance (10 to 20 feet or 3 to 6 meters) and at near (14 to 16 inches or 35 to 40 centimeters). Under ideal circumstances, visual acuity testing conditions should be standardized so that results obtained over a series of visits can be readily compared. High-contrast charts with black optotypes on a white background should be used for standard visual acuity testing.

A child’s performance on a visual acuity test will be dependent on the choice of chart and the examiner’s skills and rapport with the child. To reduce errors, the environment should be quiet. Younger children may benefit from a pretest on optotypes presented at near, either at the start of testing or in a separate session. Before monocular testing, the examiner should ensure that the child is able to perform the test reliably. Allowing children to match optotypes on the chart to those found on a hand-held card will enhance performance, especially in young, shy, or cognitively impaired children. Visual acuity testing of children with special needs can provide quantitative information about visual impairment and reduce concerns of parents/caregivers about the child’s vision. A shorter testing distance or flip chart can also facilitate testing in younger children.

Visual acuity testing should be performed monocularly and with refractive correction in place. Ideally the fellow eye is covered with an adhesive patch or tape. If such occlusion is not available or tolerated by the child, care must be taken to prevent the child from peeking and using the “covered” eye. Sometimes the child will not allow any monocular occlusion, in which case binocular visual acuity should be measured. Monocular visual acuity testing for patients with nystagmus requires special techniques such as blurring of the fellow eye with plus lenses or a translucent occluder rather than using opaque occlusion. Binocular visual acuity testing can also be performed for these patients to provide additional information about typical visual performance.
The choice and arrangement of optotypes on an eye chart can significantly affect the visual acuity score obtained.88-90 Optotypes should be clear, standardized, of similar characteristics, and should not reflect a cultural bias.85 LEA Symbols (Good-Lite Co., Elgin, IL), a set of four symbol optotypes developed for use with young children, are useful because each optotype blurs similarly as the child is presented with smaller symbols, increasing the reliability that individual symbols will be identified.88,91 Another method for testing the young child uses a chart containing only the letters H, O, T, and V.88,92 Children who cannot name the symbols on the LEA Symbol chart or the letters on the HOTV chart may be able to match them using a hand-held card. Desirable optotypes for older children are LEA numbers and Sloan letters.93 Snellen letters are less desirable because the individual letters are not of equal legibility and the spacing of the letters does not meet World Health Organization standards.85,94-96

Several other symbol charts have serious limitations in testing visual acuity of young children. These include Allen figures,97 the Lighthouse chart, and the Kindergarten Eye Chart.98 In these charts, the optotypes are not standardized to blur equally and/or the optotypes are presented in a culturally biased or confusing fashion.99 The Illiterate or Tumbling E chart is conceptually difficult for young children, leading to high untestability rates.98 Appendix 3 lists the details of design of visual acuity testing charts. Some charts meet recommended criteria,85 although many do not.

<table>
<thead>
<tr>
<th>The choice and arrangement of optotypes (letters, numbers, symbols) on an eye chart can significantly affect the visual acuity score obtained. Preferred optotypes are standardized and validated. (strong recommendation, good evidence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The arrangement of optotypes on the chart is important.99 Optotypes should be presented in a full line of five whenever possible. Children should correctly identify the majority of optotypes on a line to “pass” the line. A similar number of optotypes on each line with equal spacing is preferred. In the setting of amblyopia, visual acuity testing with single optotypes is likely to overestimate acuity because of the crowding phenomenon. In amblyopia, it is easier to discriminate an isolated optotype than one presented in a line of optotypes. Therefore, a more accurate assessment of monocular visual acuity is obtained in amblyopia with the presentation of a line of optotypes. Optotypes should not be covered or masked as the examiner points to each successive symbol in order to preserve the crowding effect of adjacent optotypes. If a single optotype must be used to facilitate visual acuity testing for some children, the optotype should be surrounded (crowded) by bars placed above, below, and on either side of the optotype to account for the crowding phenomenon and not overestimate visual acuity.103-105</td>
</tr>
<tr>
<td>Vision testing with single optotypes is likely to overestimate visual acuity in a patient with amblyopia. A more accurate assessment of monocular visual acuity is obtained with the presentation of a line of optotypes or a single optotype with crowding bars that surround (or crowd) the optotype being identified. (strong recommendation, good evidence)</td>
</tr>
<tr>
<td>The Teller Acuity Cards (Stereo Optical Co., Inc., Chicago, IL) are a test of forced preferential looking and can provide a general assessment of resolution visual acuity in young children and how the patient’s acuity compares with normative data, but this method of testing overestimates recognition visual acuity in children with amblyopia.106,107</td>
</tr>
</tbody>
</table>
Binocular Alignment and Ocular Motility
The corneal light reflection, binocular red reflex (Brückner) test, and cover tests are commonly used to assess binocular alignment. Cover/uncover tests for tropias and alternate cover tests for the total deviation (latent component included) in primary gaze at distance and near should utilize accommodative targets. Cover tests require sufficient visual acuity and cooperation to fix on the desired target. Ocular versions and ductions, including into the oblique fields of gaze, should be tested in all infants and children. Eye movements may be tested using oculocephalic rotation (doll’s head maneuver) or assessed by spontaneous eye movements in the inattentive or uncooperative child. Evaluating oblique muscle function in young children should be attempted when examining a child with strabismus.

Pupillary Examination
The pupils should be assessed for size, symmetry, and shape; for their direct and consensual responses to light; and for presence of a relative afferent defect. Pupillary evaluation in infants and children may be difficult due to hippus, poorly maintained fixation, and rapid changes in accommodative status. Anisocoria greater than 1 mm may indicate a pathological process, such as Horner syndrome, Adie tonic pupil, or a pupil-involving third-cranial-nerve palsy. Irregular pupils may indicate the presence of traumatic sphincter damage, iritis, or a congenital abnormality (e.g., coloboma). A relative afferent pupillary defect of large magnitude is not typically seen in amblyopia108; its presence should warrant a search for compressive or other etiologies of visual impairment (e.g., optic nerve or retinal abnormality).

External Examination
The external examination involves assessment of the eyelids, eyelashes, lacrimal apparatus, and orbit. Components may include assessment of ptosis, amount of ptosis and levator function, presence of lid retraction, and relative position of the globe within the orbit (e.g., proptosis or globe retraction, hypoglobus, or hyperglobus). Older children who have the appearance of proptosis may tolerate measurement using an exophthalmometer. For uncooperative or younger children, proptosis of the globe may be estimated by comparing the position of the globes when viewing from above the head. The anatomy of the face (including the lids, interocular distance, and presence or absence of epicanthal folds), orbital rim, and presence of oculofacial anomalies should be noted. The position of the head and face (including head tilt or turn and chin-up or chin-down head posture) should be recorded. Children who have prominent epicanthal folds and/or a wide, flat nasal bridge and normal binocular alignment often appear to have an esotropia (pseudoesotropia). Distinctive features unusual for the family may suggest the presence of a congenital anomaly and merit an assessment to identify additional physical abnormalities (e.g., ears, hands) that might require further evaluation.

Anterior Segment Examination
The cornea, conjunctiva, anterior chamber, iris, and lens should be evaluated using slit-lamp biomicroscopy, if possible. For infants and young children, anterior segment examination with a direct ophthalmoscope, a magnifying lens such as that used for indirect ophthalmoscopy, or a hand-held slit-lamp biomicroscope may be helpful.

Cycloplegic Retinoscopy/Refraction
Determination of refractive errors is important in the diagnosis and treatment of amblyopia or strabismus. Patients should undergo cycloplegic refraction with retinoscopy and subjective refinement when possible.78 Before cycloplegia, dynamic retinoscopy provides a rapid assessment of accommodation and may be helpful in evaluating a child with asthenopia who has high hyperopia or the child with accommodative insufficiency.109,110
Amblyopia PPP:
Criteria for Diagnosis

Adequate cycloplegia is necessary for accurate retinoscopy in children due to their increased accommodative tone compared with adults. Cyclopentolate hydrochloride is useful because it produces rapid cycloplegia that approximates the effect of topical ophthalmic atropine 1% solution but with a shorter duration of action.\textsuperscript{111} Cyclopentolate 1% solution is typically used in term infants over 6 months old. The dose of cyclopentolate should be determined based on the child’s weight, iris color, and dilation history. In eyes with heavily pigmented irides, repeating the cycloplegic eyedrops or using adjunctive agents such as phenylephrine hydrochloride 2.5% (has no cycloplegic effect) or tropicamide 0.5% or 1.0% may be necessary to achieve adequate dilation to facilitate retinoscopy. Tropicamide and phenylephrine may be used in combination to produce adequate dilation size, but this combination may not be strong enough for adequate cycloplegia in children. A single eyedrop combination of cyclopentolate 0.2% and phenylephrine 1% is safe and effective for infants with dark irides.\textsuperscript{112} In rare cases, topical ophthalmic atropine sulphate 1% solution may be necessary to achieve maximal cycloplegia.\textsuperscript{111} The use of topical anesthetic prior to the cycloplegic reduces the stinging of subsequent eyedrops and promotes its penetration into the eye.\textsuperscript{113} Cycloplegic and dilating agents may be compounded in spray forms that provide similar dilation and cycloplegia with equal or greater patient satisfaction.\textsuperscript{114-116} Short-term side effects of cycloplegic and dilating agents may include hypersensitivity reactions, fever, dry mouth, rapid pulse, nausea, vomiting, flushing, and, rarely, behavioral changes.

**Funduscopic Examination**

The optic disc, macula, retina, vessels, and the choroid should be examined, preferably using an indirect ophthalmoscope and condensing lens after adequate dilation is achieved. It may be impossible to examine the peripheral retina of the awake child. Examination of the peripheral retina with an eyelid speculum and scleral depression may require swaddling, sedation, or general anesthesia.

**CRITERIA FOR DIAGNOSIS**

A diagnosis of amblyopia requires detection of a visual acuity deficit (see Table 1) and identification of the likely cause. Amblyopia in the absence of strabismus, unequal refractive error, media opacity, or structural abnormality is rare.\textsuperscript{117} A careful search for an alternative diagnosis with associated visual loss should be carried out if an obvious cause is not present.

**TABLE 1  ** DIAGNOSTIC CRITERIA FOR AMBLYOPIA

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Finding</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unilateral Amblyopia</strong></td>
<td></td>
</tr>
<tr>
<td>Response to monocular occlusion</td>
<td>Asymmetric objection</td>
</tr>
<tr>
<td>Fixation preference</td>
<td>Failure to initiate or maintain fixation</td>
</tr>
<tr>
<td>Preferential looking</td>
<td>≥2-octave interocular difference*</td>
</tr>
<tr>
<td>Best-corrected visual acuity</td>
<td>≥2-line interocular difference</td>
</tr>
<tr>
<td><strong>Bilateral Amblyopia</strong></td>
<td></td>
</tr>
<tr>
<td>Best-corrected visual acuity</td>
<td>Age ≤3 years: visual acuity worse than 20/50 in either eye</td>
</tr>
<tr>
<td></td>
<td>Age ≥4 years: visual acuity worse than 20/40 in either eye</td>
</tr>
</tbody>
</table>

* A 2-octave difference is a 4-card difference in the full set of Teller Acuity Cards, which is equivalent to multiplying or dividing the visual angle by 4.
MANAGEMENT

Prevention

Vision screening is important to identify factors that predispose to amblyopia. There is consensus that earlier screening is important for both prevention and treatment of amblyopia. The earlier that clinically significant refractive error and strabismus are treated, the greater the likelihood of preventing amblyopia. (See Table 2 for guidelines for refractive correction in infants and young children.) When amblyopia is present, it appears that the potential for successful treatment is greatest in young children, although improvement in visual acuity can reasonably be expected in older children and teenagers. A study of treatment of moderate strabismic and/or anisometropic amblyopia demonstrated that the visual acuity of the amblyopic eye improved in approximately three-quarters of children younger than 7 years to 20/30 or better 6 months after initiating treatment.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Refractive Errors (diopters)</th>
<th>Age &lt;1 year</th>
<th>Age 1–2 years</th>
<th>Age 2–3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoametropia</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(similar refractive error in both eyes)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myopia</td>
<td>−5.00 or more</td>
<td>−4.00 or more</td>
<td>−3.00 or more</td>
<td></td>
</tr>
<tr>
<td>Hyperopia (no manifest deviation)</td>
<td>+6.00 or more</td>
<td>+5.00 or more</td>
<td>+4.50 or more</td>
<td></td>
</tr>
<tr>
<td>Hyperopia with esotropia</td>
<td>+2.50 or more</td>
<td>+2.00 or more</td>
<td>+1.50 or more</td>
<td></td>
</tr>
<tr>
<td>Astigmatism</td>
<td>3.00 or more</td>
<td>2.50 or more</td>
<td>2.00 or more</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anisometropia (without strabismus)*</th>
<th>Refractive Errors (diopters)</th>
<th>Age &lt;1 year</th>
<th>Age 1–2 years</th>
<th>Age 2–3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myopia</td>
<td>−4.00 or more</td>
<td>−3.00 or more</td>
<td>−3.00 or more</td>
<td></td>
</tr>
<tr>
<td>Hyperopia</td>
<td>+2.50 or more</td>
<td>+2.00 or more</td>
<td>+1.50 or more</td>
<td></td>
</tr>
<tr>
<td>Astigmatism</td>
<td>2.50 or more</td>
<td>2.00 or more</td>
<td>2.00 or more</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: These values were generated by consensus and are based solely on professional experience and clinical impressions because there are no scientifically rigorous published data for guidance. The exact values are unknown and may differ among age groups; they are presented as general guidelines that should be tailored to the individual child. Specific guidelines for older children are not provided because refractive correction is determined by the severity of the refractive error, visual acuity, and visual symptoms.

* Threshold for correction of anisometropia should be lower if the child has strabismus. The values represent the minimum difference in the magnitude of refractive error between eyes that would prompt refractive correction.

Children with risk factors for amblyopia should have a comprehensive ophthalmic examination in addition to annual screening. Risk factors include uveitis, ptosis with anisometropic astigmatism; gestational age of less than 30 weeks; a birth weight less than 1500 grams; delayed visual or neurologic maturation of unclear etiology; cerebral palsy; certain conditions such as Down syndrome; and a family history of amblyopia, strabismus, childhood cataract, or childhood glaucoma. In the long term, reduction or prevention of risk factors such as premature birth and prenatal environmental influences (e.g., substance abuse and smoking) may result in a decrease in the incidence of amblyopia.
**Choice of Therapy**

Success rates of amblyopia treatment decline with increasing age. However, an attempt at treatment should be offered to children regardless of age, including those in later childhood. The prognosis for attaining normal vision in an amblyopic eye depends on many factors, including the presumed onset of amblyogenic stimulus; the cause, severity, and duration of amblyopia; the history of previous treatment; adherence to treatment recommendations; and concomitant conditions.

In managing amblyopia, the ophthalmologist strives to improve visual acuity by using one or more of the following strategies. The first is to address causes of visual deprivation. The second is to correct visually significant refractive errors. The third is to promote use of the amblyopic eye by penalizing the fellow eye. While not always achievable, the goal is equal visual acuity between the two eyes. The recommended treatment should be based on the child’s age, visual acuity, and adherence with previous treatment as well as the child’s physical, social, and psychological status.

Initial therapy depends on an understanding of the primary cause of amblyopia. For deprivation amblyopia, the initial treatment should be directed at clearing the ocular media. Optical correction of significant refractive error(s) will typically be required. The following therapies have been used in the treatment of amblyopia.

- Optical correction
- Patching
- Pharmacological penalization
- Optical penalization
- Bangerter filters
- Surgery to treat the cause of the amblyopia
- Acupuncture
- Vision therapy

Appendix 4 shows results from the Pediatric Eye Disease Investigator Group (PEDIG) of completed randomized controlled trials of amblyopia therapy and other pertinent ongoing trials.

**Optical Correction**

Treatment of refractive error alone for 18 weeks can improve visual acuity in the amblyopic eye by 2 or more lines in at least two-thirds of children 3 to 7 years old who have untreated anisometropic amblyopia. A study in older children 7 to 17 years old found that amblyopia improved 2 or more lines with optical correction alone in about one-fourth of the children. In one study, visual acuity of children who had bilateral refractive amblyopia substantially improved with refractive correction. Even children who had strabismus experienced substantial improvement in the amblyopic eye with optical correction alone.

In general, eyeglasses are tolerated well by children, especially when there is improvement in visual function. Obtaining an accurate fit and maintaining proper adjustment facilitate acceptance. Head straps or flexible single-piece frames may be useful in babies; cable temples and spring hinges are helpful in keeping eyeglasses on active young children. Polycarbonate lenses provide greater safety and are preferable for children, especially if they are amblyopic.

---

| Treatment of refractive error alone can improve visual acuity in children who have untreated anisometropic and strabismic amblyopia. Visual acuity of children who have bilateral refractive amblyopia also can substantially improve with refractive correction alone. |
| (strong recommendation, good evidence) |
Patching

Patching for amblyopia in infants and young children improves visual acuity and may improve strabismus in some children.\textsuperscript{73,147} The physiologic benefit of patching is likely related to the associated decrease in neural signals from the fellow or nonamblyopic eye, as demonstrated by recordings from the visual cortex in experimental animals.\textsuperscript{148,149} Patching is best administered by applying an opaque adhesive patch directly to the skin surrounding the fellow eye. Prescribed eyeglasses are worn over the patch. A less preferred alternative is a cloth patch mounted on the eyeglass frame, because children can easily look around or peek over the cloth patch.

It has been thought that full-time occlusion (all waking hours) of the fellow eye may improve visual acuity more rapidly than part-time patching (6 hours or less per day). However, a recent randomized clinical trial has shown that 6 hours of prescribed daily patching produces an improvement in visual acuity that is similar in magnitude to occlusion therapy for all but 1 waking hour when treating severe amblyopia (20/100 to 20/125) in children under 7 years of age (see Appendix 4).\textsuperscript{150} In children who have moderate amblyopia (20/40 to 20/80), initial therapy of 2 hours of prescribed daily patching produces an improvement in visual acuity that is similar in magnitude to the improvement produced by 6 hours of prescribed daily patching.\textsuperscript{130} The treatment benefit achieved by the patching appears stable through at least 10 years of age.\textsuperscript{133}

Several untoward effects of occlusion therapy should be considered in children.

Children treated with patching may develop occlusion amblyopia or strabismus in the previously better-seeing eye.\textsuperscript{73,147,150} Conversely, patching improves strabismus for some children.\textsuperscript{73,147} Mild skin irritation from the adhesive is common with patching (41\% of a treatment cohort); the irritation is moderate or severe in an additional 6\%,\textsuperscript{60} but it can be minimized by switching to a different patch or applying skin lotions to irritated areas when the child is not wearing the patch. The parent/caregiver should be advised that children wearing a patch should be monitored carefully to avoid accidents.

Patching may be effective in older children and teenagers particularly if they have not previously been treated. \textit{(good evidence)}

Most children who have moderate amblyopia respond to initial treatment consisting of at least 2 hours of daily patching or weekend atropine. \textit{(strong recommendation, good evidence for treatment of amblyopia)} \textit{(discretionary recommendation, good evidence for dosage [amount of time] of treatment)}

Pharmacological Penalization

Pharmacological penalization may be used to treat amblyopia if the nonamblyopic eye is hyperopic. The treatment optically defocuses the nonamblyopic eye by using cycloplegia, most often with atropine 1\% solution (off-label use). This technique may be considered for children with mild to moderate amblyopia, occlusion nystagmus, occlusion failure, or for maintenance treatment.\textsuperscript{60,151}

Atropine 1\% ophthalmic solution administered to the nonamblyopic or fellow eye is an effective method of treatment for mild to moderate amblyopia in children ages 3 to 10 years.\textsuperscript{59,60,129-132} The long-term durability of pharmacologic treatment for amblyopia due to strabismus, anisometropia, or both combined has been demonstrated.\textsuperscript{133}
Penalization therapy has been administered using a variety of dosage schemes to the fellow eye. Traditionally daily dosing has been prescribed and has been as effective as patching for initial treatment. Atropine 1% given on two consecutive days was as effective as once daily atropine 1% for moderate amblyopia, treated for 4 months. Modest improvement of 4.5 lines (95% CI, 3.2–5.8 lines) from twice weekly dosing has been reported for children with severe amblyopia. The value of increasing the blur with the prescription of a plano lens for the fellow hyperopic eye for children who have stopped improving with atropine 1% is currently being studied. (See Appendix 4.)

Pharmacologic therapy for amblyopia may have side effects that warrant consideration. Pharmacologic treatment has been associated with transient reduction of visual acuity in the nonamblyopic eye, especially when used in combination with reduced hyperopic correction. Transient reduction of visual acuity in the fellow eye is reported more often with atropine therapy compared with patching for amblyopia management. Monitoring the visual acuity of each eye of a child being treated is essential. Fellow eye acuity can be assessed more accurately when atropine is discontinued at least 1 week before testing. In a few cases, atropine 1% has been associated with the development or resolution of strabismus. Atropine 1% solution has been reported to cause photosensitivity in 18% of children and conjunctival irritation in 4%. Photosensitivity may limit the use of atropine in areas that have high sun exposure. Adverse systemic effects include dryness of the mouth and skin, fever, delirium, and tachycardia. Use of atropine 1% for amblyopia in children younger than 3 years has not been studied in clinical trials, and this age group may be more likely to experience toxicity.

Applying direct digital pressure over the lacrimal sac and puncta for 20 to 30 seconds may reduce systemic absorption and toxicity when using atropine and other cycloplegic agents. Atropine 1% should be used with caution during the first year of life because of the greater potential for systemic side effects.

**Optical Penalization (Eyeglass Lens)**

Altering the refractive correction of the fellow eye has been used to treat amblyopia. However, the effectiveness of this technique has been variable and has not been evaluated in randomized clinical trials.

**Bangerter Filters**

An option for mild amblyopia is the use of Bangerter filters or foils (Ryser Optik AG, St. Gallen, Switzerland). A translucent filter is placed on the eyeglass lens of the fellow eye. These filters have been used mostly as maintenance treatment after initial treatment with either patching or atropine. The effectiveness of the filters as primary treatment for amblyopia compared with 2 hours per day of patching was the subject of a randomized controlled trial. On average, the patching and filter groups had similar improvement in visual acuity for moderate amblyopia.

**Surgery**

Surgery is recommended when the cause of the amblyopia can be attributed to an opacification of the media, such as cataract, nonclearing vitreous opacity, corneal opacities, or blepharoptosis, which are severe enough to prevent successful amblyopia therapy without surgical correction. Although strabismus surgery may facilitate amblyopia management in selected cases, it usually does not eliminate the need for amblyopia treatment.

Opacification of the posterior segment from hemorrhage or inflammatory debris may produce deprivation amblyopia and necessitate vitrectomy. Vitrectomy has a higher incidence of a cataract developing; therefore, vision and lens clarity need to be monitored closely in these patients. If subluxation of a clear lens causes significant optical defocus that is not correctable with eyeglasses or contact lenses, a lensectomy with subsequent optical rehabilitation may be necessary.
The role of refractive surgery in treating anisometropic amblyopia is controversial. Keratorefractive surgery for children is an off-label use of an FDA-approved device. Studies have shown that photorefractive keratectomy can be safely performed for children with anisometropic amblyopia who are noncompliant with refractive correction. Visual acuity and stereopsis improved in most eyes, even in older children. Photorefractive keratectomy and other refractive procedures may have a future role in the management of amblyopia in certain children who fail conventional treatment.

Acupuncture

Acupuncture has been used for amblyopia treatment in two clinical trials. The first study found acupuncture over a 15-week period to be as effective as occlusion for 88 children 7 to 12 years old who had anisometropic amblyopia. In this randomized controlled trial, children had 20/40 to 20/125 best-corrected visual acuity and no strabismus. The second study examined the effect of adding acupuncture to refractive correction for 83 children 3 to 7 years old who had untreated anisometropic amblyopia (20/40 to 20/200). At 15 weeks, there was more improvement in visual acuity with refractive correction with acupuncture compared with refractive correction alone. In both studies, the acupuncture technique consisted of five acupuncture needles placed and manipulated for 15 minutes five times a week for 15 weeks. Acupuncture for amblyopia requires further investigation, including an evaluation of cost-effectiveness. The mechanism of action for acupuncture in the treatment of amblyopia is unknown.

Vision Therapy

Other eye exercises or forms of vision therapy have been promoted for the treatment of amblyopia as an adjunct to patching. However, there are insufficient cohort studies or randomized clinical trials to make a recommendation to use these techniques.

Follow-up Evaluation

The purpose of the follow-up evaluation is to monitor the response to therapy and adjust the treatment plan as necessary. Determining the visual acuity of the amblyopic eye is the primary goal of the follow-up evaluation, but it is also important to include interval history, especially adherence to the treatment plan, side effects of the treatment, and visual acuity in the fellow eye. Visual acuity measurement is often difficult in children, and it helps to maintain a consistent care team and testing environment over the follow-up period. Using similar charts in a setting comfortable for the child enhances the ability to obtain reliable results at follow-up visits. Visual acuity results in either eye can vary because of changes in refractive error, poor test reliability, reverse amblyopia, and persistent cycloplegia in an atropine-treated eye.

In general, a follow-up examination should be arranged in 2 to 3 months after initiation of treatment, but timing will vary according to the intensity of the treatment and the age of the child. Based on the outcome of the follow-up examination and an assessment of adherence to treatment, the treatment regimen may need to be adjusted as follows:

- **If the visual acuity in both eyes is unchanged, consider increasing treatment intensity or changing treatment modality, if appropriate.** For example, if currently patching the fellow eye 2 hours per day, consider increasing to 6 hours per day or switching to pharmacologic penalization.
- **If the visual acuity in the amblyopic eye is improved and the fellow eye is stable, continue the same treatment regimen.**
- **If the visual acuity in the amblyopic eye is decreased and the fellow eye is stable, recheck the refractive status, retest visual acuity, retest the pupillary examination, and assess adherence in greater depth.** Some children fail to demonstrate improvement in visual acuity despite adherence to the treatment regimen. In these cases, the ophthalmologist should consider an alternative diagnosis, such as optic nerve hypoplasia, subtle macular abnormalities, or other anterior visual pathway disorders.
If the visual acuity in the fellow eye is decreased, consider the diagnosis of reverse amblyopia and again recheck the refractive status of both eyes, retest visual acuity, and consider alternative diagnoses. If the diagnosis of reverse amblyopia is made, the treatment should be interrupted and follow-up should take place within a few weeks. The visual acuity should be retested to determine whether it has returned to the pretreatment level prior to resuming amblyopia therapy.

Consensus suggestions for adjusting patching dosage during treatment are detailed in Table 3. The value of increasing patching dosage for children who have stopped improving is currently being studied (see Appendix 4). Alternatively, some clinicians intensify treatment by adding topical atropine penalization. One study found no benefit to increasing treatment intensity by adding atropine to the patching regimen for a child who has stabilized on 6 hours per day of patching.157

<table>
<thead>
<tr>
<th>Indication to Change</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual acuity is not improved after one or two treatment intervals</td>
<td>Maintain or increase patching or penalization, or consider alternative therapy</td>
</tr>
<tr>
<td>Severe skin irritation develops with patching</td>
<td>Select alternative therapy</td>
</tr>
<tr>
<td>Visual acuity is not improved with high percentage occlusion for three follow-up intervals</td>
<td>Taper or terminate treatment</td>
</tr>
<tr>
<td>Treatment is futile (e.g., organic lesion)</td>
<td>Taper or terminate treatment</td>
</tr>
<tr>
<td>Strabismus and/or diplopia develop</td>
<td>Temporarily stop treatment and monitor</td>
</tr>
<tr>
<td>Visual acuity decreases in the fellow eye</td>
<td>Temporarily stop treatment, review diagnosis, and monitor</td>
</tr>
<tr>
<td>Visual acuity is stabilized at normal or near normal for child &lt;12 years old</td>
<td>Taper therapy</td>
</tr>
</tbody>
</table>

NOTE: These recommendations are generated by consensus based on professional experience and clinical impressions.

When the ophthalmologist is convinced that maximal visual acuity for the child has been obtained, treatment intensity can be tapered to maintenance therapy.158 Maintenance methods include part-time occlusion, full- or part-time optical penalization, use of Bangerter foils, or part-time cycloplegic penalization. If visual acuity in the amblyopic eye is maintained as therapy is tapered, the treatment may be stopped but with follow-up still planned, because approximately one-fourth of children successfully treated for amblyopia experience a recurrence within the first year off treatment.129,135 For children treated with 6 or more hours of daily patching, data suggest that the risk of recurrence is greater when patching is stopped abruptly rather than when it is reduced to 2 hours per day prior to cessation.159 To minimize the possibility of recurrent amblyopia, ametropia should continue to be corrected with either eyeglasses or contact lenses until visual maturity is reached, often well into the teenage years. In those cases in which amblyopia does recur, patching or pharmacologic penalization will usually restore the visual acuity to its previous best-corrected level.52

Children who have amblyopia require continued monitoring, because about one-fourth of children successfully treated for amblyopia experience a recurrence within the first year after treatment has been discontinued. (strong recommendation, good evidence)
Outcome of therapy may depend on patient adherence to the treatment plan. Adherence to treatment recommendations is often compromised because the child may not like the patch, eyeglasses, or eyedrops. In one study of 419 children 3 to 7 years old, a slightly higher degree of acceptability was reported for those treated with atropine compared with patching based on a parent questionnaire. Parents/caregivers of pediatric patients who understand the diagnosis and rationale for treatment are more likely to adhere to treatment recommendations. A study that used an educational cartoon story for 4-year-old children beginning occlusion therapy for amblyopia demonstrated improvement in adherence to the treatment plan. It is also important to obtain the commitment of older children to the proposed treatment program. Because improved communication produces better results, written instructions are helpful for the parent/caregiver to understand, remember, and reinforce the plan.

For children with unilateral vision impairment due to amblyopia, the risk of lost vision in the better eye due to disease or injury has been estimated to be approximately 1:1000. Because of this, children who are visually impaired in one eye should wear proper protective eyewear full-time, even if they do not benefit from optical correction. A frame approved by the American National Standards Institute Standard No. Z87.1 with impact-resistant lenses (e.g., polycarbonate) should be worn daily and for low-eye-risk sports. For most ball and contact sports, polycarbonate sports goggles should be worn, and integrated head and face protection should be added for higher risk activities. Functionally monocular individuals should use approved protective eyewear when participating in contact sports or other potentially harmful activities, such as those that involve pellet guns, paintballs, and personal use of fireworks. Special goggles, industrial safety glasses, side shields, and full-face shields should be used in these cases. Functionally monocular patients should be aware of the need to have regular eye examinations throughout their lives.

**PROVIDER AND SETTING**

Certain diagnostic procedures (e.g., acuity measurement or motility testing) may be delegated to appropriately-trained auxiliary personnel under the ophthalmologist’s supervision. The interpretation of results and management of disease, including the supervision of amblyopia therapy, require the training, judgment, and experience of an ophthalmologist. Certified orthoptists may manage amblyopia in conjunction with the ophthalmologist. Consultation with or referral to an ophthalmologist who has expertise and experience in the diagnosis and treatment of amblyopia may be desirable for cases in which the diagnosis or management is in question or when the amblyopia appears unresponsive to treatment.

**COUNSELING AND REFERRAL**

Amblyopia is a long-term problem that requires commitment from the child, parent/caregiver, and ophthalmologist to achieve the best possible outcome. The ophthalmologist should discuss the findings of the evaluation with the patient, when appropriate, as well as with the parent/caregiver. The ophthalmologist should explain the disorder and recruit the family in a collaborative approach to therapy. Parents/caregivers of pediatric patients who understand the diagnosis and rationale for treatment are more likely to adhere to treatment recommendations.

**SOCIOECONOMIC CONSIDERATIONS**

Health care insurance plans should cover amblyopia management, including timely screening, treatment, and monitoring for recurrence because treatment is associated with long-term vision improvement. Management includes maintaining a schedule of vision screening during childhood and adolescence consistent with the Bright Futures initiative of the U.S. Health and Human Services (http://brightfutures.aap.org) and the U.S. Preventive Services Task Force guidelines. Children identified with amblyopia or risk factors should have access to a comprehensive eye examination. Eyeglasses and contact lenses are an integral part of the medical management of amblyopia.
Data about the long-term socioeconomic impact on an individual with amblyopia are limited. Rahi et al reported that 429 of 8861 individuals (4.8%) in a birth cohort in the United Kingdom had residual unilateral amblyopia. They found no association between reduced visual function at age 16 years and having a paying job at age 33 years for either men or women. Furthermore, although there were visual acuity requirements for various jobs, only one person did not meet the visual requirements for his/her current occupation. When compared with a control group, there was no difference in the self-reported assessment of poor health, depression, sports involvement, or work injury.

Despite this report, a doubled risk of bilateral visual impairment in patients with amblyopia has been reported. In older subjects, loss of visual acuity in the fellow eye is usually related to retinal abnormalities such as retinal vein occlusion, age-related macular degeneration, and other macular disorders. Amblyopia treatment improves visual acuity and binocularity and, therefore, decreases the likelihood of severe binocular visual handicap if there is loss of vision in the fellow eye later in life.

| Successful amblyopia treatment may have its greatest impact in later life, when fellow eyes can be injured or affected by diseases of the macula or optic nerve. *insufficient evidence* |
APPENDIX 1. QUALITY OF OPHTHALMIC CARE CORE CRITERIA

Providing quality care
is the physician's foremost ethical obligation, and is
the basis of public trust in physicians.
AMA Board of Trustees, 1986

Quality ophthalmic care is provided in a manner and with the skill that is consistent with the best interests of the patient. The discussion that follows characterizes the core elements of such care.

The ophthalmologist is first and foremost a physician. As such, the ophthalmologist demonstrates compassion and concern for the individual, and utilizes the science and art of medicine to help alleviate patient fear and suffering. The ophthalmologist strives to develop and maintain clinical skills at the highest feasible level, consistent with the needs of patients, through training and continuing education. The ophthalmologist evaluates those skills and medical knowledge in relation to the needs of the patient and responds accordingly. The ophthalmologist also ensures that needy patients receive necessary care directly or through referral to appropriate persons and facilities that will provide such care, and he or she supports activities that promote health and prevent disease and disability.

The ophthalmologist recognizes that disease places patients in a disadvantaged, dependent state. The ophthalmologist respects the dignity and integrity of his or her patients, and does not exploit their vulnerability.

Quality ophthalmic care has the following optimal attributes, among others.

- The essence of quality care is a meaningful partnership relationship between patient and physician. The ophthalmologist strives to communicate effectively with his or her patients, listening carefully to their needs and concerns. In turn, the ophthalmologist educates his or her patients about the nature and prognosis of their condition and about proper and appropriate therapeutic modalities. This is to ensure their meaningful participation (appropriate to their unique physical, intellectual and emotional state) in decisions affecting their management and care, to improve their motivation and compliance with the agreed plan of treatment, and to help alleviate their fears and concerns.

- The ophthalmologist uses his or her best judgment in choosing and timing appropriate diagnostic and therapeutic modalities as well as the frequency of evaluation and follow-up, with due regard to the urgency and nature of the patient's condition and unique needs and desires.

- The ophthalmologist carries out only those procedures for which he or she is adequately trained, experienced and competent, or, when necessary, is assisted by someone who is, depending on the urgency of the problem and availability and accessibility of alternative providers.

- Patients are assured access to, and continuity of, needed and appropriate ophthalmic care, which can be described as follows.
  - The ophthalmologist treats patients with due regard to timeliness, appropriateness, and his or her own ability to provide such care.
  - The operating ophthalmologist makes adequate provision for appropriate pre- and postoperative patient care.
  - When the ophthalmologist is unavailable for his or her patient, he or she provides appropriate alternate ophthalmic care, with adequate mechanisms for informing patients of the existence of such care and procedures for obtaining it.
  - The ophthalmologist refers patients to other ophthalmologists and eye care providers based on the timeliness and appropriateness of such referral, the patient's needs, the competence and qualifications of the person to whom the referral is made, and access and availability.
  - The ophthalmologist seeks appropriate consultation with due regard to the nature of the ocular or other medical or surgical problem. Consultants are suggested for their skill, competence, and accessibility. They receive as complete and accurate an accounting of the problem as necessary to provide efficient and effective advice or intervention, and in turn respond in an adequate and timely manner.
Amblyopia PPP
Appendix 1. Quality of Ophthalmic Care Core Criteria

- The ophthalmologist maintains complete and accurate medical records.
- On appropriate request, the ophthalmologist provides a full and accurate rendering of the patient's records in his or her possession.
- The ophthalmologist reviews the results of consultations and laboratory tests in a timely and effective manner and takes appropriate actions.
- The ophthalmologist and those who assist in providing care identify themselves and their profession.
- For patients whose conditions fail to respond to treatment and for whom further treatment is unavailable, the ophthalmologist provides proper professional support, counseling, rehabilitative and social services, and referral as appropriate and accessible.
- Prior to therapeutic or invasive diagnostic procedures, the ophthalmologist becomes appropriately conversant with the patient's condition by collecting pertinent historical information and performing relevant preoperative examinations. Additionally, he or she enables the patient to reach a fully informed decision by providing an accurate and truthful explanation of the diagnosis; the nature, purpose, risks, benefits, and probability of success of the proposed treatment and of alternative treatment; and the risks and benefits of no treatment.
- The ophthalmologist adopts new technology (e.g., drugs, devices, surgical techniques) in judicious fashion, appropriate to the cost and potential benefit relative to existing alternatives and to its demonstrated safety and efficacy.
- The ophthalmologist enhances the quality of care he or she provides by periodically reviewing and assessing his or her personal performance in relation to established standards, and by revising or altering his or her practices and techniques appropriately.
- The ophthalmologist improves ophthalmic care by communicating to colleagues, through appropriate professional channels, knowledge gained through clinical research and practice. This includes alerting colleagues of instances of unusual or unexpected rates of complications and problems related to new drugs, devices or procedures.
- The ophthalmologist provides care in suitably staffed and equipped facilities adequate to deal with potential ocular and systemic complications requiring immediate attention.
- The ophthalmologist also provides ophthalmic care in a manner that is cost effective without unacceptably compromising accepted standards of quality.

Reviewed by: Council
Approved by: Board of Trustees
October 12, 1988

2nd Printing: January 1991
3rd Printing: August 2001
4th Printing: July 2005
### APPENDIX 2. INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS (ICD) CODES

Amblyopia, which includes entities with the following ICD-9 and ICD-10 classifications:

<table>
<thead>
<tr>
<th>Condition</th>
<th>ICD-9 CM</th>
<th>ICD-10 CM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amblyopia, unspecified</td>
<td>368.00</td>
<td>H53.00–</td>
</tr>
<tr>
<td>Strabismic amblyopia (suppression)</td>
<td>368.01</td>
<td>H53.03–</td>
</tr>
<tr>
<td>Deprivation amblyopia</td>
<td>368.02</td>
<td>H53.01–</td>
</tr>
<tr>
<td>Refractive amblyopia, including anisometropic and isoametropic amblyopia</td>
<td>368.03</td>
<td>H53.02–</td>
</tr>
</tbody>
</table>

**CM** = Clinical Modification used in the United States; (–) = 1, right eye; 2, left eye; 3, bilateral; 9, eye not specified

#### Additional Information for ICD-10 Codes:
- For bilateral sites, the final character of the codes in the ICD-10 CM indicates laterality. An unspecified side code is also provided if the side is not identified in the medical record. If no bilateral code is provided and the condition is bilateral, assign separate codes for both the left and right side.
- When the diagnosis code specifies laterality, regardless of which digit it is found in (i.e., 4th digit, 5th digit, or 6th digit):
  - Right is always 1
  - Left is always 2
  - Bilateral is always 3
  - Unspecified always follows the conventions under “unspecified” above (i.e., either a 0 or 9 depending on whether it is a 4th, 5th, or 6th digit)
APPENDIX 3. VISUAL ACUITY TESTING CHARTS

The World Health Organization (WHO) and the National Academy of Sciences Committee on Vision have made similar recommendations about optotype choice and arrangement on visual acuity testing charts. Optotypes should be clear, standardized, of similar characteristics, and should not reflect a cultural bias. Each line should contain five optotypes. Spacing between the optotypes should be proportional: the horizontal spacing between individual optotypes should be equal to the size of the optotype and the vertical spacing between lines should be the height of the optotypes in the lower line. Optotype sizes should generally be presented in 0.1 logMAR decrements. This arrangement leads to an inverted pyramid design for wall charts.

Visual acuity testing charts used with children that meet these recommendations include LEA Symbols (Good-Lite Co., Elgin, IL), Sloan letters, Sloan numerals, Tumbling E, and HOTV. The Snellen chart is less desirable because the individual letters are not of equal legibility and the spacing of the letters does not meet WHO/Committee on Vision standards.

Several symbol charts have serious limitations for young children. These include Allen figures, the Lighthouse chart, and the Kindergarten Eye Chart. In these charts, the optotypes are not standardized and are presented in a culturally biased fashion. Although the Tumbling E chart meets WHO/Committee on Vision recommendations, it is less desirable because it requires spatial orientation skills not mastered by all children. Other visual acuity charts are being developed to overcome these limitations, including the Handy Eye Chart and the Compact Reduced logMAR chart.

Table A3-1 lists details of design of visual acuity testing charts that are commonly used.

<table>
<thead>
<tr>
<th>Chart</th>
<th>Meets WHO/NAS Recommendations</th>
<th>Attributes/Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEA Symbols</td>
<td>Yes</td>
<td>- Optotypes of similar legibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Inverted pyramid design with five optotypes per line (at visual acuities better than 20/100), proportional spacing between optotypes, and 0.1 LogMAR decrements in optotype size</td>
</tr>
</tbody>
</table>

Reproduced with permission from Good-Lite Co., Elgin, IL.
<table>
<thead>
<tr>
<th>Chart</th>
<th>Meets WHO/INAS Recommendations</th>
<th>Attributes/Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sloan Letters</td>
<td>Yes</td>
<td>Attributes:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Optotypes of similar legibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Inverted pyramid design with five optotypes per line, proportional spacing between</td>
</tr>
<tr>
<td></td>
<td></td>
<td>optotypes, and 0.1 LogMAR decrements in optotype size</td>
</tr>
<tr>
<td>HOTV</td>
<td>Yes</td>
<td>Attributes:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Optotypes of similar legibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Inverted pyramid design with five optotypes per line, proportional spacing between</td>
</tr>
<tr>
<td></td>
<td></td>
<td>optotypes, and 0.1 LogMAR decrements in optotype size</td>
</tr>
<tr>
<td>Snellen Letters</td>
<td>No</td>
<td>Challenges:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Optotypes are not of similar legibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Variable number of optotypes per line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Nonproportional spacing between optotypes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Nonstandard optotype size decrements</td>
</tr>
<tr>
<td>Chart</td>
<td>Meets WHO*/NAS Recommendations</td>
<td>Attributes/Challenges</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Tumbling E Chart</td>
<td>Yes</td>
<td><strong>Attributes:</strong>&lt;br&gt;&lt;ul&gt;&lt;li&gt;Optotypes of similar legibility&lt;/li&gt;&lt;li&gt;Inverted pyramid design available with five optotypes per line, proportional spacing between optotypes, and 0.1 LogMAR decrements in optotype size&lt;/li&gt;&lt;/ul&gt;&lt;br&gt;&lt;strong&gt;Challenges:**&lt;br&gt;&lt;ul&gt;&lt;li&gt;Requires spatial orientation skills not mastered by all children&lt;/li&gt;&lt;/ul&gt;</td>
</tr>
<tr>
<td>Allen Figures</td>
<td>No</td>
<td><strong>Challenges:</strong>&lt;br&gt;&lt;ul&gt;&lt;li&gt;Optotypes are not of similar legibility&lt;/li&gt;&lt;li&gt;Variable number of optotypes per line&lt;/li&gt;&lt;li&gt;Nonproportional spacing between optotypes&lt;/li&gt;&lt;li&gt;Nonstandard optotype size decrements&lt;/li&gt;&lt;li&gt;Optotypes not easily recognized by all children (e.g., telephone)&lt;/li&gt;&lt;/ul&gt;</td>
</tr>
</tbody>
</table>

Reproduced with permission from Good-Lite Co., Elgin, IL.

Allen HF. A new picture series for preschool vision testing. Am J Ophthalmol 1975;44:40. Copyright 1957. Reprinted with permission from Elsevier. All rights reserved.
<table>
<thead>
<tr>
<th>Chart</th>
<th>Meets WHO*/NAS† Recommendations</th>
<th>Attributes/Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lighthouse Chart</td>
<td>No</td>
<td>Challenges:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Optotypes are not of similar legibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Variable number of optotypes per line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nonproportional spacing between optotypes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nonstandard optotype size decrements</td>
</tr>
<tr>
<td>Kindergarten Eye Chart</td>
<td>No</td>
<td>Challenges:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Optotypes are not of similar legibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Variable number of optotypes per line</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nonproportional spacing between optotypes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nonstandard optotype size decrements</td>
</tr>
</tbody>
</table>

Reproduced with permission.

Reproduced with permission from Wilson Ophthalmic Corp., Mustang, OK.

NAS = National Academy of Sciences; WHO = World Health Organization


‡ Sloan, HOTV, and Tumbling E charts have chart designs that do not meet proportional spacing recommendations between individual optotypes and optotype lines.
**APPENDIX 4. PEDIATRIC EYE DISEASE INVESTIGATOR GROUP CLINICAL TRIALS**

**TABLE A4-1  PEDIATRIC EYE DISEASE INVESTIGATOR GROUP STUDIES WITH PUBLISHED RESULTS**

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Patients (age at enrollment)</th>
<th>Follow-up Period</th>
<th>Result</th>
</tr>
</thead>
</table>
| Randomized trial comparing occlusion vs. pharmacologic therapy for moderate amblyopia<sup>56</sup> (ATS 1) | 419 (3 to <7 years)                | 6 months         | - VA improved in both groups: 3.16 lines in occlusion group; 2.84 lines in atropine group  
- Mean difference = 0.34 lines (95% CI, 0.05 to 0.6)  
- VA ≥20/30 and/or improved by ≥3 lines in 79% of occlusion group and 74% of atropine group |
| Randomized trial comparing occlusion vs. pharmacologic therapy for moderate amblyopia<sup>56</sup> (ATS 1) | 419 (3 to <7 years)                | 2 years          | - VA improved in both groups: 3.7 lines in occlusion group; 3.6 lines in atropine group  
- Mean difference = 0.01 lines (95% CI, -0.02 to 0.04)  
- Atropine or patching for an initial 6-month period produced a similar improvement in amblyopia 2 years after treatment |
| Randomized trial comparing part-time vs. full-time patching for severe amblyopia<sup>124</sup> (ATS 2A) | 175 (3 to <7 years)                | 4 months         | - VA improved in both groups: 4.8 lines in the 6 hours patching group; 4.7 lines in the full-time patching (all hours or all but 1 hour per day) group  
- Mean difference = 0.02 lines (95% CI, -0.04 to 0.07) |
| Randomized trial comparing part-time vs. minimal-time patching for moderate amblyopia<sup>130</sup> (ATS 2B) | 189 (3 to <7 years)                | 4 months         | - VA improvement in both groups was 2.40 lines  
- Mean difference = -0.007 lines (95% CI, -0.050 to 0.036)  
- VA ≥20/32 and/or ≥3 lines in 62% of patients in both groups  
- VA improvement similar for 2 hours of daily patching and 6 hours of daily patching |
| Evaluation of treatment of amblyopia<sup>52</sup> (ATS 3) | 507 (7 to 17 years)                | 6 months         | - For moderate amblyopia in children 7 to <13 years old, 36% achieved 20/25 or better with optical correction/occlusion/atropine use compared with 14% with optical correction alone (P<0.001)  
- For severe amblyopia in children 7 to <13 years old, 23% achieved 20/40 or better with optical correction/patching compared with 5% with optical correction alone (P<0.004)  
- For moderate amblyopia in teenagers 13 to 17 years old, 14% achieved 20/25 or better with optical correction/occlusion compared with 11% with optical correction alone (P=0.52)  
- For severe amblyopia in teenagers 13 to 17 years old, 14% achieved 20/40 or better with optical correction/occlusion compared with 0% with optical correction alone (P=0.13) |
| Randomized trial comparing daily atropine vs. weekend atropine for moderate amblyopia<sup>131</sup> (ATS 4) | 168 (3 to <7 years)                | 4 months         | - VA improvement in both groups was 2.3 lines  
- Mean difference = 0.00 (95% CI, -0.04 to 0.04)  
- 47% of daily group and 53% of the weekend group had either VA ≥20/25 or greater than or equal to that of the nonamblyopic eye |
### TABLE A4-1  PEDIATRIC EYE DISEASE INVESTIGATOR GROUP STUDIES WITH PUBLISHED RESULTS (CONTINUED)

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Patients (age at enrollment)</th>
<th>Follow-up Period</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective noncomparative trial to evaluate 2 hours of daily patching for amblyopia(^{37}) (ATS 5 – eyeglasses-only phase)</td>
<td>84 (3 to &lt;7 years)</td>
<td>Up to 30 weeks</td>
<td>• Amblyopia improved with optical correction by ≥2 lines in 77%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Amblyopia resolved with optical correction in 27% (95% CI, 18% to 36%)</td>
</tr>
<tr>
<td>Randomized trial to evaluate 2 hours of daily patching for amblyopia(^{75}) (ATS 5 – randomization phase)</td>
<td>180 (3 to &lt;7 years)</td>
<td>5 weeks</td>
<td>• After a period of treatment with eyeglasses until vision stopped improving, patients treated with 2 hours of daily patching combined with 1 hour of near visual tasks had an improvement in VA of 1.1 lines compared with 0.5 lines in the control group</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Mean difference (adjusted) = 0.07 lines (95% CI, 0.02 to 0.12, (P=0.006))</td>
</tr>
<tr>
<td>Randomized trial comparing near vs. distance activities while occlusion(^{276}) (ATS 6)</td>
<td>425 (3 to &lt;7 years)</td>
<td>17 weeks</td>
<td>• At 8 weeks, improvement in amblyopic eye VA averaged 2.6 lines in the distance activities group and 2.5 lines in the near activities group (95% CI for difference, -0.3 to 0.3 line)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Groups appeared statistically similar at the 2-week, 5-week, and 17-week visits</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• At 17 weeks, children with severe amblyopia improved a mean of 3.7 lines with 2 hours of daily patching</td>
</tr>
<tr>
<td>Treatment of bilateral refractive amblyopia(^{4}) (ATS 7)</td>
<td>113 (3 to &lt;10 years)</td>
<td>1 year</td>
<td>• Binocular VA improved on average 3.9 lines (95% CI, 3.5 to 4.2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• At 1 year, 74% had binocular VA of 20/25 or better</td>
</tr>
<tr>
<td>Randomized trial comparing atropine vs. atropine plus a plano lens for the fellow eye in children 3 to 6 years old(^{33}) (ATS 8)</td>
<td>180 (3 to &lt;7 years)</td>
<td>18 weeks</td>
<td>• Amblyopic eye VA was 20/25 or better in 29% of the atropine-only group and in 40% of the atropine plus plano lens group (P=0.03)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• More patients in the atropine plus plano lens group had reduced fellow eye acuity at 18 weeks; however, there were no cases of persistent reverse amblyopia</td>
</tr>
<tr>
<td>Randomized trial comparing occlusion vs. atropine for amblyopia(^{38}) (ATS 9)</td>
<td>193 (7 to &lt;13 years)</td>
<td>17 weeks</td>
<td>• Similar improvement in VA in both groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Amblyopic eye VA of 20/25 or better in 17% of atropine group and 24% of the patching group (95% CI, -3% to 17%)</td>
</tr>
<tr>
<td>Randomized trial comparing Bangerter filters vs. occlusion for the treatment of moderate amblyopia in children(^{39}) (ATS 10)</td>
<td>186 (3 to &lt;10 years)</td>
<td>24 weeks</td>
<td>• Similar improvement in VA in both groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Amblyopic eye VA of 20/25 or better in 36% of Bangerter group and 31% of patching group (P=0.86)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Patching was not superior (95% CI difference between groups, -0.06 to 0.83 line)</td>
</tr>
<tr>
<td>Randomized trial to evaluate combined patching and atropine for residual amblyopia(^{42}) (ATS 11)</td>
<td>55 (3 to &lt;10 years)</td>
<td>10 weeks</td>
<td>• Before enrollment, eligible subjects had no improvement with 6 hours daily patching or daily atropine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Intensive treatment group had 6 hours of prescribed daily patching combined with daily atropine; weaning group had 4 weeks of reduced treatment, then stopped</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Amblyopic eye VA improved similarly in both groups, an average of 0.56 lines in the intensive group (95% CI, 0.18 to 0.93) and 0.53 lines in the weaning group (95% CI, -0.04 to 1.10)</td>
</tr>
</tbody>
</table>
### TABLE A4-1  Pediatric Eye Disease Investigator Group Studies with Published Results (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Patients (age at enrollment)</th>
<th>Follow-up Period</th>
<th>Result</th>
</tr>
</thead>
</table>
| Nonrandomized prospective trial of eyeglasses alone for strabismic and strabismic-anisometropic combined amblyopia in children\(^{146}\) (ATS 13) | 146 (3 to <7 years) | 28 weeks | • Mean 2.6 lines improvement (95% CI, 2.3 to 3.0)  
• 75% improved ≥2 lines and 54% improved ≥3 lines  
• Resolution in 32% (95% CI, 24% to 41%)  
• Treatment effect was greater for strabismic amblyopia than for combined-mechanism amblyopia (3.2 vs. 2.3 lines; adjusted \(P=0.003\)) |

**NOTE:** In the ATS, mild to moderate amblyopia is defined as VA in the amblyopic eye of 20/80 or better; severe amblyopia is defined as VA in the amblyopic eye of 20/100 to 20/400.

Further information about the published results of the Amblyopia Treatment Study is available from the Pediatric Eye Disease Investigator Group (http://pedig.jaeb.org/Publications.aspx).

ATS = Amblyopia Treatment Study; CI = confidence interval; RCT = randomized clinical trial; VA = visual acuity

### TABLE A4-2  Randomized Trials of the Amblyopia Treatment Study in Progress

<table>
<thead>
<tr>
<th>Objective</th>
<th>Proposed No. of Patients</th>
<th>Follow-up Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trial comparing increased patching with the same dosage for amblyopia that has stopped improving (ATS 15)</td>
<td>158 (3 to &lt;8 years)</td>
<td>10 weeks</td>
</tr>
<tr>
<td>Randomized trial comparing adding a plano lens to the atropine with the same atropine dosage for amblyopia that has stopped improving (ATS 16)</td>
<td>158 (3 to &lt;8 years)</td>
<td>10 weeks</td>
</tr>
<tr>
<td>Randomized trial comparing levodopa plus patching to placebo with patching (ATS 17)</td>
<td>138 (8 to &lt;13 years)</td>
<td>18 weeks</td>
</tr>
</tbody>
</table>

Further information about ongoing trials of the Amblyopia Treatment Study is available from the Pediatric Eye Disease Investigator Group (http://pedig.jaeb.org/Studies.aspx).

ATS = Amblyopia Treatment Study; RCT = randomized clinical trial
SUGGESTED READING


RELATED ACADEMY MATERIALS

Basic and Clinical Science Course
  Pediatric Ophthalmology and Strabismus (Section 6, 2012–2013)

Focal Points
  Advances in the Management of Amblyopia (2010)

Patient Education Brochure
  Amblyopia (2011)
  Pseudostrabismus (2011)
  Strabismus (2012)

Patient Education Downloadable Handout
  Eye Safety for Children (subscription) (2011-2012)

Patient Education Video
  Amblyopia: Waiting Room for the Ophthalmic Practice, Vol. 2 (also available in Spanish) (2009)

  Comprehensive Adult Medical Eye Evaluation (2010)
  Esotropia and Exotropia (2012)
  Pediatric Eye Evaluations (2012)

To order any of these products, except for the free materials, please contact the Academy’s Customer Service at 866.561.8558 (U.S. only) or 415.561.8540 or www.aao.org/store.
REFERENCES

References


