



Alberta Heritage Foundation  
for Medical Research

# **A SELECTED INVENTORY OF ABSTRACTS FOR SYSTEMATIC REVIEWS ON OPTOMETRIC SERVICES**

INTERIM REPORT FOR EXPERT ADVISORY PANEL AND THE RESEARCH TEAM  
OCTOBER, 2002

## **ABBREVIATIONS**

DARE	Database of Abstracts of Reviews of Effectiveness
EED	Economic Evaluation Database
HTA	Health technology assessment
NHS	National Health Service
NHS CRD	National Health Service Centre for Reviews and Dissemination
RCT	Randomised controlled trial

## SUMMARY STATEMENTS

These statements are a compilation of the concluding remarks from the selected abstracts (see Table 1) and comments based on the feedback received from the clinical expert(s). Further comments from the clinical expert(s) and the questions posed to the clinical expert(s) for the selection process are presented in Appendix 1. Those statements that are italicised denote disagreement between the clinical expert(s) and the assessors regarding the inclusion of the abstract.

### **Abnormal conditions of the eye and associated structures**

#### **Conclusions <sup>1</sup>:**

Screening and early treatment of diabetic retinopathy can prevent substantial disability. The effectiveness and efficiency of screening could be enhanced by improving the performance of current tests or increasing the use of mydriatic retinal photography, and by increasing uptake, particularly among diabetics at greatest risk.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

#### **Conclusions <sup>2</sup>:**

Efficacy/Effectiveness: There was adequate evidence that screening should be provided for all people with diabetes who are not being treated for retinopathy. The service needs to be organised efficiently at the local level to ensure adequate population coverage. Screening can be provided effectively by accredited optometrists, reimbursed on a per capita basis, or by mobile retinal photography operating in a variety of locations as necessary. The evidence was insufficient to make specific recommendations on the best method of screening which may vary according to local circumstances. Training should be provided for screeners and quality control systems are essential.

Cost Effectiveness: None of the studies included all the costs of screening programs so conclusions could not be drawn on the relative cost-effectiveness of different screening methods.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

#### **Conclusions <sup>3</sup>:**

Efficacy/Effectiveness: There were no adequate treatment options for the correction of impaired colour vision based on current evidence. There was insufficient evidence for the use of colour vision screening as a method of first detection of an adverse health outcome other than impaired colour vision. A change in the colour vision screening test currently in use in New Zealand (Ishihara's pseudo-isochromatic test) on the basis of its

validity was not supported by the current evidence. Ideally, colour vision screening should be performed when it will make a difference to the three potential sequelae of impaired colour vision: educational and occupational difficulties, and increased problems with driving. Four studies evaluated aspects of colour vision screening programs but they were not sufficiently rigorous in design to allow an estimation of the effectiveness of the programs surveyed.

Cost Effectiveness: The cost-effectiveness of colour vision screening could not be estimated due to lack of research in this area.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

#### **Conclusions 4:**

##### Efficacy/Effectiveness:

*Treatment:* There was no clear evidence for the effectiveness of treatments for amblyopia, refractive errors, or squints. No studies comparing treatment with no treatment were found.

*Screening:* Orthoptic screening programs performed better than either health visitor or general practitioner screening in terms of yield and positive predictive value. Only two studies reported numbers of false negative cases. The one prospective study did not support the belief that identifying children with amblyopia in the pre-school period reduces the prevalence of this condition in children aged seven.

Overall, in the absence of sound evidence that amblyopia, refractive errors, and squints in pre-school aged children are disabling, and that the interventions available to correct them do more good than harm, the ethical basis for such interventions is doubtful.

Cost Effectiveness: No studies were identified that were designed to evaluate the costs of screening. Estimates from observational studies and audits, which included cost data, suggested that the cost of orthoptic screening was not great.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

#### **Conclusion 5:**

Efficacy/Effectiveness: The evidence as to the effectiveness of antioxidant vitamin and mineral supplementation in halting the progression of age-related macular degeneration was dominated by one large trial that showed modest benefit in people with moderate to severe signs of the disease. There was no evidence that people with early signs of the disease should take supplementation, however, current studies were underpowered to answer that question. The generalisability of these findings to other populations with a different nutritional status is not known.

Safety: Long-term harm from supplementation cannot be ruled out, particularly in smokers. Of the safety outcomes evaluated, hospitalisation for genitourinary problems was more common in people taking zinc while yellowing of skin was more common in people taking antioxidant micronutrients.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

#### **Conclusion 6:**

The question as to whether people with age-related macular degeneration should take Ginkgo Biloba extract to prevent progression of the disease has not been answered by research to date.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

#### **Conclusion 7:**

There was no evidence that community-based screening of asymptomatic older people resulted in improvements in vision.

Expert advice: This is within the scope of practice but it was uncertain if this is provided for this indication and this group of patients.

Expert comments: "Subjective measurements of vision (or of any cognitive skill) are notoriously unreliable."

#### **Conclusion 8:**

*Questions about the effectiveness of ivermectin in preventing visual acuity loss have not been answered by the best available evidence.*

Expert advice: This is **not** within the scope of practice.

Expert comments: "Op's don't have oral meds in Alberta".

## **Ocular manifestations of systemic conditions**

#### **Conclusions 9:**

No RCTs were available to assess the various treatments used for idiopathic intracranial hypertension.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

## Other conditions

### Conclusions <sup>10</sup>:

Efficacy/Effectiveness: Acute bacterial conjunctivitis is frequently a self-limiting condition but the use of antibiotics was associated with significantly improved rates of early clinical remission, and early and late microbiological remission.

Safety: No serious outcomes were reported in either the active or placebo arms of the three RCTs, indicating that important sight-threatening complications are an infrequent occurrence.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

### Conclusion <sup>11</sup>:

There was some evidence that antibiotics reduce active trachoma but results were not consistent and cannot be pooled. For the comparisons of oral or topical antibiotic against placebo/no treatment, the data were consistent with there being no effect of antibiotics but were suggestive of a lowering of the point prevalence of relative risk of both active disease and laboratory evidence of infection at three and 12 months after treatment. For the comparison between oral and topical antibiotics, the results suggested that oral treatment was neither more nor less effective than topical treatment.

Expert advice: This is within scope of practice but is **not** provided for this indication and this group of patients.

Expert comments: "Is of interest to those of us who go to third world countries."

### Conclusions <sup>12</sup>:

The results indicated that medical prophylaxis for aphakic and pseudo-phakic cystoid macular edema following cataract surgery, and medical treatment for chronic cystoid macular edema, was beneficial. However, a well-designed RCT using clinical chronic macular edema and vision outcomes is needed to confirm this result because most of the RCTs performed to date have problems relating to quality.

Expert advice: This is within the scope of practice and is provided for this indication and this group of patients.

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## INTRODUCTION

This exercise was undertaken at the request of Alberta Health and Wellness to inform the Expert Advisory Panel and the Research Team on the effectiveness of optometric services based on a select set of systematic reviews. For a detailed outline of the methodology used to conduct this project please see Appendix 2. Explanations of terms are provided in Appendix 3.

Thirty-five abstracts of systematic reviews were found (after removal of duplicates) and 12 abstracts met the inclusion criteria (see Appendix 2). These form the basis of the evidence summarised in Table 1. Of the 35 abstracts, 23 were excluded and the reasons for their exclusion are listed in Table 2 (see Appendix 4).

Clinical input was sought to determine the clinical relevance of the evidence provided in the systematic reviews. All 35 abstracts were reviewed by a clinical expert(s) who addressed three questions as listed in Appendix 1. Eight abstracts were excluded or not deemed to be within the scope of optometric practice while 27 abstracts were included, based on the information provided in the abstracts. The results from this screening process were compared to the screening approach used by the HTA assessors (which is outlined in Appendix 2).

Within this report the discrepancies resulting from the two independent screening processes are noted using italics. For example, when the clinical experts' selection varied from the HTA assessors' selection, the entire concluding statement in the 'Summary Statements' section was italicised (according to the clinical expert this abstract should be excluded as it was not within the scope of practice) and in Table 1 the entire extraction from that abstract was italicised. Table 2 lists in italics those excluded abstracts for which the clinical expert noted that they should be included as the intervention was within the scope of practice. Since these abstracts were not included in Table 1, the entire abstract is provided for reference in Appendix 4 following Table 2.

## ROLES OF EYE CARE PROFESSIONALS IN ALBERTA

An optometrist in Alberta, as described by The Alberta College of Optometrists<sup>13</sup>, is licensed to examine, assess, measure and diagnose disorders and diseases of the eye and its associated structures as well as diagnose systemic conditions that have ocular manifestations. They are also permitted to provide and prescribe treatment, management and correction including vision therapy, prescription medications for the eye, the dispensing and fitting of corrective lenses, and referral to a medical specialist for further treatment such as eye surgery. An ophthalmologist in Alberta is a medical doctor who has completed up to six years as an Ophthalmology resident physician in an accredited university hospital and specialises in secondary and tertiary treatment of eye disease and disorders, which may include surgery. Opticians in Alberta are

licensed to design, supply, prepare, adjust and dispense optical appliances, including corrective glasses, as prescribed by an optometrist or ophthalmologist. However, additional training is required before they can fit and dispense contact lenses.

The discrepancies that resulted from the two independent screening processes used for this report highlighted some important issues with respect to the limitations of the review process as it was applied to the assessment of the effectiveness of optometric services. It was clear from the literature and the comments from the clinical expert that there is often a considerable overlap in the role of opticians, optometrists, ophthalmologists and general practitioners in the management of patients with eye conditions. Variations in licensing and accreditation regulations for optometrists and opticians across different countries can also make generalisability of the literature problematic. This is an important issue because a major part of optometric practice is comprised of using diagnostic testing procedures to identify ocular deficiencies and defects. Generally, the success of a diagnostic test is inextricably linked to the expertise, training and skill level of the operator, and this is certainly true for optometry<sup>2</sup>. The included studies represented a very heterogeneous international sample and many did not clearly state who provided the optometric intervention under assessment. Therefore, the results summarised in this inventory of systematic reviews may potentially either over-estimate or under-estimate the effectiveness of certain optometric services and may not be applicable to the optometric health service environment within Alberta.

## **LIMITATIONS OF USING ABSTRACTS FROM SYSTEMATIC REVIEWS AS EVIDENCE ON EFFECTIVENESS OF OPTOMETRIC SERVICES**

This work is not a HTA. It is an inventory of selected abstracts of systematic reviews on the topic of optometric services. Systematic reviews may not synthesise and analyse cost-effectiveness studies.

This approach does not reflect 'best practice' for providing evidence on effectiveness through an HTA process. Information was extracted (in a tabulated format) from abstracts of systematic reviews focused on determining the evidence on the effectiveness of optometric services. Because of the time constraint, the full text articles were not analysed for this exercise.

This approach introduces a selection bias because it is limited to systematic reviews that had abstracts available. It includes only systematic reviews published by Cochrane review groups (Cochrane systematic reviews are considered the 'gold standard') and systematic reviews (produced by other organisations) which are contained in the NHS CRD databases (HTA and DARE).

Evidence on the effectiveness of some interventions used by optometrists may be missed if these interventions were not evaluated in the selected systematic reviews. In

addition, the search strategy used to locate the systematic reviews was not comprehensive as the strategy did not include terms for specific services.

The subjects, services/interventions, comparators and outcomes evaluated in the selected systematic reviews may not be of clinical relevance to Alberta. Particularly, since the Cochrane Collaboration's mandate is not to inform policy but to facilitate evidence-based medicine internationally.

This approach also does not allow for a critical appraisal of the quality of the selected systematic reviews (to assess the reliability and validity of the conclusions). It is important to emphasise here that ten methodologists affiliated with the Cochrane Collaboration independently examined the quality of the Cochrane reviews published in 1998<sup>14</sup> and found that some review conclusions did not match the data presented. They concluded that:

- "Cochrane reviews are, on average, more systematic and less biased than systematic reviews published in paper journals".
- "Errors and biases also occur in Cochrane reviews".
- "Too often, reviewers' conclusions over-rated the benefits of new interventions"
- "Readers of Cochrane reviews should remain cautious, especially regarding conclusions that favour new interventions".

Summary statements resulting from this approach are limited to the conclusions as declared in the abstracts. These statements are directly lifted from the abstract with no additional analysis by the HTA assessors. The conclusions of the abstracts are usually very general and do not reflect the precise, detailed results of the review, or address the specific questions or objectives of the review.

Information provided in the abstracts is inconsistent and insufficient (there are length restrictions on abstracts; for example Cochrane abstracts are limited to 400 words) in a number of ways:

- Information of interest (type of provider and setting, safety, cost effectiveness, etc.) is generally not available in the abstract.
- Information on subjects' characteristics is often not provided in the abstract. Important information on subjects' age, gender, and level of disease severity as well as total number of study participants is often not reported.
- Description of the services/interventions may be insufficient.

#### **Other issues:**

Optometry practice in Alberta may differ from that in other countries in the following ways:

- Definition and scope of practice for optometry in Alberta may differ from that in other countries.

- Services/interventions which are or can be provided by optometrists in Alberta may be provided by other health professionals in other countries.
- Methods/regimens/protocols/equipment used to provide optometric services/treatments/interventions in Alberta may differ from those used in other countries.
- Training and experience of optometrists providing optometric services/treatments/interventions in Alberta may differ from the training and experience of optometrists/other health professionals providing optometric services/treatments/interventions in other countries.

## SUMMARY TABLE 1

Summary Table 1 summarises the information provided in abstracts of the selected systematic reviews looking at effectiveness of optometric services.

### Grouping of Indications for Optometric Services

The grouping of indications/conditions for optometric services was based on the information provided by the Alberta Association of Optometrists in the document submitted to the Expert Advisory Panel and information synthesised from the following sources:

- <http://www.optometrists.ab.ca/guide/provider.htm>
- <http://www.opto.ca>
- [http://www.opto.ca/caosection/docs/Role\\_document\\_final.pdf](http://www.opto.ca/caosection/docs/Role_document_final.pdf)

The following are indications that potentially can be treated by optometric services:

- 1) **Abnormal conditions of the eye and associated structures** - myopia, astigmatism, cataracts, glaucoma, posterior uveitis, macular degeneration, non-arteritic anterior ischemic optic neuropathy, retinal detachment.
- 2) **Ocular manifestations of systemic conditions** - diabetic retinopathy, hypertension, idiopathic intra-cranial hypertension.
- 3) **Other conditions** – eye injury, post-surgical management.

### Summary Table Explanation of Terms

#### Comparisons (Subheading)

The treatment comparisons examined by the systematic review are listed under this subheading. These are tabulated in such a way as to identify the intervention under investigation (in this case optometric services) and the control treatment that it was compared to (which may be no treatment, watchful waiting, a non-optometric treatment, or a different type of treatment modality within optometry). Since multiple

treatment comparisons are often made within a single systematic review, only the comparisons relevant to optometric services were tabulated. In addition, any comparisons between treatments in the systematic review that included individual studies that did not meet the inclusion criteria (for example, a study in which the provider of the treatment was not an optometrist) were not tabulated, unless the results for the included and excluded studies could be separated from the aggregate data for that particular comparison.

If the study comparisons cannot be derived from the results/conclusions section of the systematic review abstract, this information will be sought from other sections of the abstract. However, since the latter will only reflect the intentions of the review authors rather than what they were actually able to achieve, it is important that this distinction is made clear. Therefore, when information on study comparisons has been extracted from a section of the abstract other than the results/conclusions it will be accompanied by a comment in parentheses stating which section of the abstract the information came from.

### **Outcomes Measured (Subheading)**

This comprises a listing of the primary and secondary outcomes used in the systematic review to measure the treatment effect. It is not a list of the actual results of these outcomes (this information is summarised in the Relevant Results/Conclusions column of the table).

If the outcome measures cannot be derived from the results/conclusions section of the systematic review abstract, this information will be sought from other sections of the abstract. However, since the latter will only reflect the intentions of the review authors rather than what they were actually able to achieve, it is important that this distinction is made clear. Therefore, when information on outcome measures has been extracted from a section of the abstract other than the results/conclusions it will be accompanied by a comment in parentheses stating which section of the abstract the information came from.

### **Relevant Results/Conclusions (Column Heading)**

This section of the table contains a selected summary of the results and conclusions of the systematic review with respect to optometric treatment only. For example, if the review assessed both an optometric treatment versus medication comparison and a medication versus no medication comparison, in which no optometric treatment was involved, only the results/conclusions for the comparison involving optometry were tabulated.

In instances when only the abstract of the systematic review was available, the relevant summary statements regarding optometric treatment were extracted directly from the results/conclusion section of the abstract. However, when the full-text of the systematic review was available, a summary synthesised by the HTA assessor from the

results, discussion and conclusion sections of the review was tabulated to ensure that points not adequately covered in the limited conclusion statement of the review abstract were addressed.

### **Cochrane Review Publication Date**

The uniform requirement for citing a Cochrane review is to list the publication date as that of the Cochrane Library issue that was used to retrieve the study, rather than the actual date the study was published in the Library. However, this can be misleading since a Cochrane review published in 1999 would be cited as being published in 2002 if that was the issue of the Cochrane library that it was retrieved from. Therefore, in order to give an indication of how up-to-date the information contained in the Cochrane review is, the date cited for the Cochrane Reviews listed in Summary Table 1 corresponds to the date of the most recent substantive update that was made to it, rather than the date of the Cochrane Library issue from which it was retrieved (which, in this case was Issue 3, 2002).

## Summary Table 1

Indication: Abnormal conditions of the eye and associated structures

Systematic Review	Study Population	Intervention/Comparison	Provider/Setting/Cost	Relevant Results/Conclusions
<p><sup>1</sup> - 1998</p> <p><b>Objective:</b> To quantify case-detection and blindness prevention attainable through screening for diabetic retinopathy in a district population. To develop a simple model to estimate the probable yield from a screening program and its impact on the incidence of blindness in a diabetic population.</p> <p><b>Studies Reviewed:</b> Five studies on diabetes prevalence, two on prevalence of treatable retinopathy, one on mortality and retinopathy incidence in diabetes, 11 on test validity and six RCTs of treatment effectiveness</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> Not stated</p> <p><b>Condition:</b> Diabetic retinopathy</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not applicable</p>	<p><b>Comparisons:</b></p> <p><i>Interventions:</i> screening for diabetic retinopathy; diagnostic tests included mydriatic and non-mydriatic cameras and tests performed by ophthalmologists, general practitioners and opticians; treatment was laser coagulation.</p> <p><b>Outcomes Measured:</b> Prevalence and incidence of treatable retinopathy, incidence of blindness, validity of screening tests, effectiveness of treatment</p>	<p><b>Provider:</b> Not stated</p> <p><b>Setting:</b> Not stated</p> <p><b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> Screening and early treatment of diabetic retinopathy can prevent substantial disability. The effectiveness and efficiency of screening could be enhanced by improving the performance of current tests or increasing the use of mydriatic retinal photography, and by increasing uptake, particularly among diabetics at greatest risk.</p> <p><b>Safety:</b> Not stated</p>
<p><sup>2</sup> - 1999</p> <p><b>Objective:</b> To assess the effectiveness of different screening methods for diabetic retinopathy.</p> <p><b>Studies Reviewed:</b> 20 studies</p> <p><b>Note:</b> Eight of the studies described a treatment provided by a provider other than an optometrist. Therefore, any comparisons between treatments in the review that included these studies were excluded because the results for the different providers could not be separated from the aggregate data.</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> Not stated</p> <p><b>Condition:</b> Diabetic retinopathy</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b></p> <p><i>Interventions:</i> retinal photography, ophthalmoscopy, combined ophthalmoscopy and retinal photography</p> <p><i>Comparators:</i> ophthalmoscopy conducted by a different provider, five field stereoscopic fundus photography, photos assessed by a different provider, slit lamp bio-microscopy, seven field stereo photography</p> <p><b>Outcomes Measured:</b> Side effects, discomfort, sensitivity, technical failure, specificity, negative predictive value</p>	<p><b>Provider:</b> Ophthalmologist, trained grader, retinal specialist, general practitioner, optometrist, physician</p> <p><b>Setting:</b> Not stated</p> <p><b>Cost:</b> None of the studies included all the costs of screening programs so conclusions could not be drawn on the relative cost-effectiveness of different screening methods.</p>	<p><b>Efficacy/Effectiveness:</b> There was adequate evidence that screening should be provided for all people with diabetes who are not being treated for retinopathy. The service needs to be organised efficiently at the local level to ensure adequate population coverage. Screening can be provided effectively by accredited optometrists, reimbursed on a per capita basis, or by mobile retinal photography operating in a variety of locations as necessary. The evidence was insufficient to make specific recommendations on the best method of screening which may vary according to local circumstances. Training should be provided for screeners and quality control systems are essential.</p> <p><b>Safety:</b> Not stated</p>

**Indication: Abnormal conditions of the eye and associated structures (cont'd)**

Systematic Review	Study Population	Intervention/Comparison	Provider/Setting/Cost	Relevant Results/Conclusions
<p><sup>3</sup> - 1998  <b>Objective:</b> To provide an evidence-based review evaluating colour vision screening through the use of recognised criteria.  <b>Studies Reviewed:</b> 27 studies</p>	<p><b>Included Patients:</b>  <b>Total number:</b> Not stated  <b>Condition:</b> Colour vision defects  <b>Age:</b> Range 4-74 years  <b>Excluded Patients:</b> Not applicable</p>	<p><b>Comparisons:</b>  <i>Sensitivity and Specificity of Screening Tests:</i>            Colour screening test versus anomaloscopy  <i>Treatment:</i>            Long wave length pass filters (no comparator specified)  <b>Outcomes Measured:</b>            Sensitivity, specificity, reproducibility, acceptability, positive predictive value, negative predictive value</p>	<p><b>Provider:</b> Not stated  <b>Setting:</b> Not stated  <b>Cost:</b> The cost-effectiveness of colour vision screening could not be estimated due to lack of research in this area.</p>	<p><b>Efficacy/Effectiveness:</b> There were no adequate treatment options for the correction of impaired colour vision based on current evidence. There was insufficient evidence for the use of colour vision screening as a method of first detection of an adverse health outcome other than impaired colour vision. A change in the colour vision screening test currently in use in New Zealand (Ishihara's pseudo-isochromatic test) on the basis of its validity was not supported by the current evidence. Ideally, colour vision screening should be performed when it will make a difference to the three potential sequelae of impaired colour vision: educational and occupational difficulties, and increased problems with driving. Four studies evaluated aspects of colour vision screening programs but they were not sufficiently rigorous in design to allow an estimation of the effectiveness of the programs surveyed.  <b>Safety:</b> Not stated</p>

**Indication: Abnormal conditions of the eye and associated structures (cont'd)**

Systematic Review	Study Population	Intervention/Comparison	Provider/Setting/Cost	Relevant Results/Conclusions
<p><sup>4</sup>- 1997</p> <p><b>Objective:</b> To examine the effectiveness of pre-school vision screening, to provide evidence on which decisions about the future provision of this service can be made, and to indicate areas where further research is needed.</p> <p><b>Studies Reviewed:</b>  <i>Treatment:</i> Five RCTs and six prospective non-randomised controlled trials, most of which were methodologically flawed.  <i>Screening:</i>                      One prospective controlled trial and 16 retrospective observational studies or audits</p>	<p><b>Included Patients:</b>  <b>Total number:</b>                      Not stated  <b>Condition:</b> Amblyopia, refractive errors, and squints  <b>Age:</b> Range 3-7 years for treatment and 3-4 years for screening  <b>Excluded Patients:</b>                      Children with both severe disabilities and visual defects.</p>	<p><b>Comparisons:</b>  <i>Treatment Interventions:</i>                      CAM vision stimulator, conventional orthoptic treatment, levodopa or carbidopa, prism adaptation, occlusion, surgery or placebo  <i>Screening Interventions:</i>                      Orthoptic screening programs versus health visitor or general practitioner screening  <b>Outcomes Measured:</b>  <i>Treatment:</i> visual outcomes, visual complications associated with surgery, spectacle use, disability, patient perceived outcomes, side-effects  <i>Screening:</i> uptake rates, referral rates, diagnostic yield, positive and negative predictive value, sensitivity, specificity, costs, visual outcomes, patient perceived health outcomes</p>	<p><b>Provider:</b> Not stated  <b>Setting:</b> Not stated  <b>Cost:</b> No studies were identified that were designed to evaluate the costs of screening. Estimates from observational studies and audits which included cost data suggested that the cost of orthoptic screening is not great.</p>	<p><b>Efficacy/Effectiveness:</b>  <i>Treatment:</i>                      There was no clear evidence for the effectiveness of treatments for amblyopia, refractive errors, or squints. No studies comparing treatment with no treatment were found.  <i>Screening:</i>                      Orthoptic screening programs performed better than either health visitor or general practitioner screening in terms of yield and positive predictive value. Only two studies reported numbers of false negative cases. The one prospective study did not support the belief that identifying children with amblyopia in the pre-school period reduces the prevalence of this condition in children aged seven.                      Overall, in the absence of sound evidence that amblyopia, refractive errors, and squints in pre-school aged children are disabling, and that the interventions available to correct them do more good than harm, the ethical basis for such interventions is doubtful.  <b>Safety:</b> Not stated</p>

**Indication: Abnormal conditions of the eye and associated structures (cont'd)**

Systematic Review	Study Population	Intervention/Comparison	Provider/Setting/Cost	Relevant Results/Conclusions
<p><sup>5</sup> - 2002</p> <p><b>Objective:</b> To assess the effects of antioxidant vitamin and/or mineral supplementation on the progression of age-related macular degeneration.</p> <p><b>Studies Reviewed:</b> Seven RCTs. The majority of people (88%) were randomised in one trial. The other six trials were small and results were inconsistent.</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> N = 4,119</p> <p><b>Condition:</b> Age-related macular degeneration</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b> Antioxidant vitamin and/or mineral supplement (alone or in combination) versus control (not specified) (as described in "Selection criteria")</p> <p><b>Outcomes Measured:</b> Not stated</p>	<p><b>Provider:</b> Not stated</p> <p><b>Setting:</b> Not stated</p> <p><b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> The evidence as to the effectiveness of antioxidant vitamin and mineral supplementation in halting the progression of age-related macular degeneration was dominated by one large trial that showed modest benefit in people with moderate to severe signs of the disease. There was no evidence that people with early signs of the disease should take supplementation, however, current studies are underpowered to answer this question adequately. The generalisability of these findings to other populations with a different nutritional status is not known.</p> <p><b>Safety:</b> Long-term harm from supplementation cannot be ruled out, particularly in smokers. Of the safety outcomes evaluated, hospitalisation for genitourinary problems was more common in people taking zinc while yellowing of skin was more common in people taking antioxidant micronutrients.</p>
<p><sup>6</sup> - 1999</p> <p><b>Objective:</b> To determine the effect of Ginkgo Biloba extract on the progression of age-related macular degeneration.</p> <p><b>Studies Reviewed:</b> One RCT (small sample size, no blinding)</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> N = 20</p> <p><b>Condition:</b> Age-related macular degeneration</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b> Ginkgo Biloba extract versus control (not specified)</p> <p><b>Outcomes Measured:</b> Not stated</p>	<p><b>Provider:</b> Not stated</p> <p><b>Setting:</b> Not stated</p> <p><b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> The question as to whether people with age-related macular degeneration should take Ginkgo Biloba extract to prevent progression of the disease has not been answered by research to date.</p> <p><b>Safety:</b> Adverse effects have not been addressed.</p>

**Indication: Abnormal conditions of the eye and associated structures (cont'd)**

Systematic Review	Study Population	Intervention/Comparison	Provider/Setting/Cost	Relevant Results/Conclusions
<p><sup>7</sup> - 1998</p> <p><b>Objective:</b> To assess the effects on vision of mass screening of older people for visual impairment.</p> <p><b>Studies Reviewed:</b> Five RCTs</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> N = 3,494</p> <p><b>Condition:</b> Visual impairment</p> <p><b>Age:</b> ≥ 65 years</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b> Visual or multi-component screening for vision impairment versus control (vision component not included in the multi-component screening)</p> <p><b>Outcomes Measured:</b> Proportion of people reporting visual problems (self-reported measures of visual impairment)</p>	<p><b>Provider:</b> Not stated</p> <p><b>Setting:</b> Community setting</p> <p><b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> There was no evidence that community-based screening of asymptomatic older people results in improvements in vision.</p> <p><b>Safety:</b> Not available</p>
<p><sup>8</sup> - 2000</p> <p><b>Objective:</b> To assess the effectiveness of ivermectin in preventing visual acuity and visual field loss in onchocercal eye disease (secondary aim was to assess effects of ivermectin on lesions affecting the eye in onchocerciasis).</p> <p><b>Studies Reviewed:</b> Five RCTs (with ≥ 1 year follow up). Trials varied in design and setting.</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> N = 3,810</p> <p><b>Condition:</b> Blindness due to onchocercal eye disease (ocular onchocerciasis)</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b> Ivermectin versus placebo</p> <p><b>Outcomes Measured:</b> Visual acuity loss</p>	<p><b>Provider:</b> Not stated</p> <p><b>Setting:</b> Not stated</p> <p><b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> Questions about the effectiveness of ivermectin in preventing visual acuity loss have not been answered by the best available evidence.</p> <p><b>Safety:</b> Not available</p>
<p><sup>9</sup> - 2002</p> <p><b>Objective:</b> To assess the evidence from controlled trials looking at the various treatments used for idiopathic intracranial hypertension with a view to producing an evidence-based treatment strategy.</p> <p><b>Studies Reviewed:</b> No RCTs were found that met the inclusion criteria.</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> Not applicable</p> <p><b>Condition:</b> Idiopathic intracranial hypertension</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b> Dietary modification, medication, repeated lumbar puncture, or any other form of treatment versus placebo (as described in 'Selection Criteria')</p> <p><b>Outcomes Measured:</b> <i>Primary:</i> reduction in vision, reduction in measured cerebrospinal fluid pressure, resolution of papilloedema and/or oculomotor disorders, improvement of headache, relapse rate <i>Secondary:</i> cost, quality of life</p>	<p><b>Provider:</b> Not applicable</p> <p><b>Setting:</b> Not applicable</p> <p><b>Cost:</b> Not applicable</p>	<p><b>Efficacy/Effectiveness:</b> No studies available</p> <p><b>Safety:</b> No studies available</p>

**Indication: Other conditions**

Systematic Review	Study Population	Intervention/Comparison	Provider/Setting/Cost	Relevant Results/Conclusions
<p><sup>10</sup> - 1999</p> <p><b>Objective:</b> The aim of this review is to assess the benefit and harm of antibiotic therapy in the management of acute bacterial conjunctivitis.</p> <p><b>Studies Reviewed:</b> Three RCTs</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> N = 527 randomised</p> <p><b>Condition:</b> Acute bacterial conjunctivitis</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b> Antibiotic treatment versus placebo</p> <p><b>Outcomes Measured:</b> Clinical remission, microbiological remission, adverse events</p>	<p><b>Provider:</b> Not stated</p> <p><b>Setting:</b> Not stated</p> <p><b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> Acute bacterial conjunctivitis is frequently a self-limiting condition but the use of antibiotics is associated with significantly improved rates of early clinical remission, and early and late microbiological remission.</p> <p><b>Safety:</b> No serious outcomes were reported in either the active or placebo arms of the three RCTs, indicating that important sight-threatening complications are an infrequent occurrence.</p>
<p><sup>11</sup> - 2001</p> <p><b>Objective:</b> To assess the evidence supporting the antibiotic arm of the SAFE strategy by assessing the effects of antibiotics on both active trachoma (primary objective) and on Chlamydia trachomatis infection of the conjunctiva (secondary objective).</p> <p><b>Studies Reviewed:</b> 15 RCTs. For both outcomes, results of chi-square tests suggested significant statistical heterogeneity among trials. There was also marked clinical heterogeneity.</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b> N = 8,678</p> <p><b>Condition:</b> Active trachoma</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b> Not stated</p>	<p><b>Comparisons:</b></p> <ol style="list-style-type: none"> <li>1) oral or topical antibiotic versus placebo or no treatment</li> <li>2) oral antibiotics versus topical antibiotics</li> </ol> <p><b>Outcomes Measured:</b> Active trachoma and laboratory evidence of infection</p>	<p><b>Provider:</b> Not stated</p> <p><b>Setting:</b> Not stated</p> <p><b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> There was some evidence that antibiotics reduce active trachoma but results are not consistent and cannot be pooled. For the comparisons of oral or topical antibiotic versus placebo/no treatment, the data were consistent with there being no effect of antibiotics but are suggestive of a lowering of the point prevalence of relative risk of both active disease and laboratory evidence of infection at 3 and 12 months after treatment. For the comparison between oral and topical antibiotics, the results suggested that oral treatment is neither more nor less effective than topical treatment.</p> <p><b>Safety:</b> Not available</p>

**Indication: Other conditions (cont'd)**

Systematic Review	Study Population	Intervention/Comparison	Provider/Setting/Cost	Relevant Results/Conclusions
<p><sup>12</sup> - 1998</p> <p><b>Objective:</b> To determine the effectiveness of prophylactic medical intervention in reducing the incidence of cystoid macular edema (CME), and the effectiveness of medical treatment for chronic CME after cataract surgery.</p> <p><b>Studies Reviewed:</b>  <i>Treatment of Surgically Induced CME:</i>                      16 RCTs, 13 non-randomised controlled trials and 7 case series studies.  <i>Treatment of Chronic CME:</i>                      24 studies, four of which were RCTs.                      Only RCT results were used to obtain a pooled estimate of treatment effect.                      A number of the RCTs had problems in their design, execution, and reporting.</p>	<p><b>Included Patients:</b></p> <p><b>Total number:</b>  <i>Treatment of Surgically Induced CME:</i>                      n = 2,898 eyes  <i>Treatment of Chronic CME:</i>                      n = 187 eyes</p> <p><b>Condition:</b> Chronic cystoid macular edema</p> <p><b>Age:</b> Not stated</p> <p><b>Excluded Patients:</b>                      Patients with macular edema other than aphakic or pseudo-phakic CME following cataract extraction; patients with CME after other surgical procedures.</p>	<p><b>Comparisons:</b>  <i>Surgically Induced CME:</i> cyclo-oxygenase inhibitors or corticosteroids versus comparator (not specified)  <i>Chronic CME:</i> cyclo-oxygenase inhibitors or non-steroidal anti-inflammatory drugs versus comparator (not specified)</p> <p><b>Outcomes Measured:</b>  <i>Surgically Induced CME:</i>                      occurrence of angiographically diagnosed CME, visual acuity  <i>Chronic CME:</i> visual acuity, improvement in fluorescein angiography</p>	<p><b>Provider:</b> Not stated  <b>Setting:</b> Not stated  <b>Cost:</b> Not stated</p>	<p><b>Efficacy/Effectiveness:</b> The results indicated that medical prophylaxis for aphakic and pseudo-phakic cystoid macular edema following cataract surgery, and medical treatment for chronic cystoid macular edema, was beneficial. However, a well-designed RCT using clinical chronic macular edema and vision outcomes is needed to confirm this result because most of the RCTs performed to date have problems relating to quality.</p> <p><b>Safety:</b> Not stated</p>

## APPENDIX 1: CLINICAL EXPERT(S) EVALUATION QUESTIONS AND COMMENTS

### Question for expert(s):

Is the service/intervention evaluated in this abstract from a systematic review within the scope of practice for optometric services in Alberta?

YES                      NO                      UNCERTAIN

If YES, is the service/intervention provided in Alberta

- for the indication described in this review?

YES                      NO                      UNCERTAIN

- for the group of patients described in this review?

YES                      NO                      UNCERTAIN

### Comments from expert(s):

“The abstracts were interesting to optometrists in Alberta but, as you suspected, not all were within our scope. For interest, trachoma is extremely rare in Alberta (usually among recent immigrants) but many Alberta optometrists work in third world places. Some of the articles addressed surgical techniques – we are not surgeons but advise on patients – perhaps more than the surgeons themselves.

Anyway, I answered to the best of my ability. It was surprising that several of the abstracts refuted large, well-respected studies in North America – in fact, these abstracts seemed to ignore them. Interesting.

I trust my answers were straight forward.”

## APPENDIX 2: APPROACH USED FOR PROVIDING EVIDENCE ON THE EFFECTIVENESS OF OPTOMETRIC SERVICES

The intent of this section is to ensure that the process used for this approach is open and transparent.

### Literature search strategy

- **Main databases searched:** The Cochrane Library (Cochrane Database of Systematic Reviews), and the CRD databases (DARE and HTA).
- **Additional databases searched:** CMA Infobase, U.S. National Guideline Clearinghouse, the CRD Database (NHS EED).
- **Limits:** publication date: from 1997 to present, and only English language abstracts included.

### Literature search results

Well-designed and conducted systematic reviews or meta-analyses provide high level evidence on the effectiveness of health technologies. (Please see Appendix 3 for definitions). Therefore, this search was limited to systematic reviews.

The literature search details (\* is a wildcard):

- **Cochrane Database of Systematic Reviews**

Search terms: vision NEAR (communit\* OR population\* OR program\*) OR optometr\* OR eye\* NEXT exam\* OR eye\* NEXT health\* OR eye\* NEXT assess\* OR eye\* NEXT care OR vision NEXT care OR vision NEXT exam\* OR vision NEXT health\* OR vision NEXT assess\* OR refractive NEXT correct\*

Retrieved 19 citations.

- **NHS CRD Databases (DARE, HTA and NHS EED)**

Search terms: (vision AND (communit\* OR population OR program)) OR optometr\* OR (eye exam) OR (eye health) OR (eye assess\*) OR (eye care)/ All fields OR (vision exam) OR (vision health) OR (vision assess\*) OR (vision test) OR (vision care) or (refractive correct\*)

Retrieved 21 references from DARE and 9 references from the HTA database.

Results from the following databases were not abstracted in this inventory. However, summaries are provided in this information package as additional information.

- **CMA Infobase** (as of October 15, 2002)

Search terms: eye care OR eye test OR eye assess OR vision test OR vision care OR vision exam OR vision assess\* OR optometr\*; retrieved two references.

## U.S. National Guideline Clearinghouse (NGC) (as of October 15, 2002)

Search terms: "eye assess\*" OR "vision test\*" OR "vision care" OR "vision exam\*" OR "vision assess\*" OR optometr\*; retrieved 36 references.

- The search of the **NHS EED** database retrieved 16 citations.

NOTE: There were some duplicates among the citations retrieved from the different databases. We tried as much as possible to identify and eliminate the duplicates and to report on only the unique publications.

### Search strategy issues:

1. Individual, specific service/treatments/interventions, such as orthoptics, glaucoma treatments, etc. may have been missed due to the broad search terms used. Within the short time line allowed for this project it was not possible to identify and search for all terms relevant to the many optometric interventions. The search terms used capture references in the databases that mention "optometric", "optometrist", or "optometrists". If such terms are not included in the individual record this search strategy will not retrieve them. Consequently, some references that could be relevant to optometric services may have been missed.
2. Due to the short time frame for this project a more comprehensive literature search was not performed. Such a search would typically involve searches of the main biomedical literature databases such as PubMed (MEDLINE), EMBASE, CINAHL, and others. Normally, searches would also attempt to identify "grey literature", for example, through Internet searches for publications from government, relevant associations, and research agencies.
3. To be consistent throughout the searches for the Expert Advisory Panel projects, searches were restricted to sources that would provide the best quality evidence – in the form of systematic reviews.

### Selection of material

Since less than 100 Cochrane systematic reviews were identified, systematic reviews produced by other organisations were also included. Information provided in Summary Table 1 was extracted from the abstracts of systematic reviews located through the literature search of the Cochrane Database of Systematic Reviews and of the NHS CRD databases (HTA and DARE).

Reasons for choosing abstracts from systematic reviews indexed in the Cochrane Database of Systematic Reviews and the NHS CRD databases include:

- **The Cochrane Collaboration** is an international organisation that aims to help people make well-informed decisions about health care by preparing, maintaining and ensuring the accessibility to systematic reviews of the effects of health care interventions (<http://www.cochrane.org>).

- Preparation and maintenance of Cochrane reviews is the responsibility of international collaborative review groups. At the beginning of 2001, the existing review groups covered all of the important areas of health care. The members of these groups - researchers, health care professionals, consumers, and others - share an interest in generating reliable, up-to-date evidence relevant to the prevention, treatment and rehabilitation of particular health problems or groups of problems.
- The Cochrane reviewers undertake thorough reviews and regularly update them as new evidence is published.
- As they carry out their review, Cochrane reviewers employ a series of methods to assemble, appraise, and sometimes synthesize data from the trials (usually they select only RCTs, considered as the “gold standard” for primary research) that are relevant to their question. In doing so, they draw on the work of Cochrane Methods Groups, which are created to organize and disseminate the work of methodologists who have come together to improve the validity and precision of systematic reviews.
- The **NHS CRD** was established to provide the NHS in United Kingdom (UK) with information on the effectiveness of treatments and the delivery and organisation of health care. Within the NHS R&D programme, CRD is a sibling organisation of the UK Cochrane Centre.
  - CRD offers rigorous and systematic reviews on selected topics, a dissemination service and an information service, and helps to promote research based practice in the NHS.
  - CRD also maintains databases of abstracts of good quality reviews of health research, abstracts of economic evaluations of health, and health technology assessments (DARE, EED and HTA databases).
- No specialized optometric literature database was located.

## **Screen process for abstracts**

Nineteen Cochrane systematic reviews, 21 references from the DARE database and nine references from the HTA databases were found. After the removal of duplicates, the remaining 35 abstracts were retrieved for further review. All abstracts were screened by two researchers according to the following set of inclusion and exclusion criteria:

### A. Inclusion Criteria for Systematic Reviews on Optometric Services:

- Systematic reviews of primary research studies that evaluated the efficacy/effectiveness and safety of optometry services provided by optometrists;
- Services provided for the examination, diagnosis, treatment, management, and prevention of diseases and disorders of the visual system, the eye and associated structures;

- Services that fall into the categories of optometric services currently covered in Alberta as listed in the documents submitted to the Expert Advisory Panel;
- Services that fall within the professional scope of practice for optometrists defined by the Alberta Association of Optometrists ([http://www.opto.ca/caosection/docs/Role\\_document\\_final.pdf](http://www.opto.ca/caosection/docs/Role_document_final.pdf)).

If the optometric service(s) was not the main intervention under assessment but was one of the comparators, the full text of the systematic review was retrieved so that all the relevant information regarding optometric service(s) as the comparator was tabulated.

#### B. Exclusion Criteria for Abstracts of Systematic Reviews on Optometric Services:

- a systematic review of other systematic reviews;
- all services were provided by health care providers (practitioners) other than optometrists;
- if the review's author(s) did not report a method for assessing validity (checklist or set of criteria on which the validity or quality of the included studies was assessed);
- services involved in the treatment of systemic diseases other than local manifestations of those diseases;
- services provided to treat disorders/conditions located in areas other than the eye and its associated structures;
- they involved surgical eye procedures.

For those systematic reviews in which the abstracts did not mention the provider, full text articles were retrieved. The subsequent screening (inclusion for/exclusion of the abstract from abstract extraction) process was based on additional information provided in the full text:

- If in the full text none of the studies reviewed identified the provider(s), the systematic review is included for abstract abstraction;
- If in the full text only some of the studies reviewed identified the provider(s) and some studies did not identify the provider, the systematic review will be included for abstract abstraction;
- If in the full text all of the studies reviewed identified the provider(s) as health care practitioner(s) other than optometrist(s), the systematic review will be excluded from abstract abstraction.

Also, for abstracts for which there was uncertainty on whether to include or exclude, full text articles were retrieved. The subsequent inclusion/exclusion process was based on the full text of the systematic reviews. In instances where the full text could not be retrieved or was written in a language other than English, such that it was not possible

to gain the extra information required from the review within the timeline, the systematic review was included for abstract abstraction.

Another screen of all abstracts was conducted independently by a contracted clinical expert(s) to determine clinical relevance (please see Appendix 1).

Abstracts excluded during the screen process are listed in Appendix 4 (Table 2) together with reasons for their exclusion.

### **Extraction of relevant information**

Extractions of relevant information from the selected abstracts were conducted by two researchers according to a standardised format (please see Summary Table 1).

## APPENDIX 3: DEFINITION OF TERMS<sup>1</sup>

### **Case-control study (synonyms: case referent study, retrospective study)**

A study that starts with identification of people with the disease or outcome of interest (cases) and a suitable control group without the disease or outcome. The relationship of an attribute (intervention, exposure or risk factor) to the outcome of interest is examined by comparing the frequency or level of the attribute in the cases and controls. For example, to determine whether thalidomide caused birth defects a group of children with birth defects (cases) could be compared to a group of children without birth defects (controls). The groups would then be compared with respect to the proportion exposed to thalidomide through their mothers taking the tablets. Case-control studies are sometimes described as being retrospective as they are always performed looking back in time.

### **Cohort study (synonyms: follow-up, incidence, longitudinal, prospective study)**

An observational study in which a defined group of people (the cohort) is followed over time. The outcomes of people in subsets of this cohort are compared to examine, for example, people who were exposed or not exposed (or exposed at different levels) to a particular intervention or other factor of interest. A cohort can be assembled in the present and followed into the future (this would be a prospective study or a "concurrent cohort study"), or the cohort could be identified from past records and followed from the time of those records to the present (this would be a retrospective study or a "historical cohort study"). Because random allocation is not used, matching or statistical adjustment at the analysis stage must be used to minimise the influence of factors other than the intervention or factor of interest.

### **Control**

1. In clinical trials comparing two or more interventions, a control is a person in the comparison group that receives a placebo, no intervention, usual care or another form of care.
2. In case-control studies a control is a person in the comparison group without the disease or outcome of interest.
3. In statistics control means to adjust for or take into account extraneous influences or observations.
4. Control can also mean programs aimed at reducing or eliminating the disease when applied to communicable (infectious) diseases.

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<sup>1</sup> Clarke M, Oxman AD, editors. Glossary. Cochrane Reviewers Handbook 4.1.1 [updated December 2000]. In: The Cochran Library, Issue 1, 2001. Oxford: Update Software. Updated quarterly.

**Controlled clinical trial**

Refers to a study that compares one or more intervention groups to one or more comparison (control) groups. Whilst not all controlled studies are randomised, all randomised trials are controlled.

**Cost-effectiveness analysis**

An economic analysis that converts effects into health terms and describes the costs for some additional health gain (e.g. cost per additional stroke prevented).

**Double-blind (synonym: double-masked)**

Neither the participants in a trial nor the investigators (outcome assessors) are aware of which intervention the participants are given. The purpose of blinding the participants (recipients and providers of care) is to prevent performance bias. The purpose of blinding the investigators (outcome assessors, who might also be the care providers) is to protect against detection bias.

**Economic analysis (synonym: economic evaluation)**

Comparison of the relationship between costs and outcomes of alternative health care interventions. See also cost-effectiveness analysis.

**Effectiveness**

The extent to which a specific intervention, when used under ordinary circumstances, does what it is intended to do. Clinical trials that assess effectiveness are sometimes called management trials.

**Efficacy**

The extent to which an intervention produces a beneficial result under ideal conditions. Clinical trials that assess efficacy are sometimes called explanatory trials and are restricted to participants who fully co-operate.

**Meta-analysis (see systematic review)**

The use of statistical techniques in a systematic review to integrate the results of included studies.

**Observational study (synonym: non-experimental study)**

A study in which nature is allowed to take its course. Changes or differences in one characteristic (e.g. whether or not people received the intervention of interest) are studied in relation to changes or differences in other(s) (e.g. whether or not they died), without action by the investigator. There is a greater risk of selection bias than in experimental studies (RCTs).

**Placebo**

An inactive substance or procedure administered to a patient, usually to compare its effects with those of a real drug or other intervention, but sometimes for the

psychological benefit to the patient through a belief that s/he is receiving treatment. Placebos are used in clinical trials to blind people to their treatment allocation. Placebos should be indistinguishable from the active intervention to ensure adequate blinding.

### **Placebo effect**

A favourable response to an intervention, regardless of whether it is the real thing or a placebo, attributable to the expectation of an effect, i.e. the power of suggestion. The effects of many healthcare interventions are attributable to a combination of both placebo and "active" (non-placebo) effects.

### **Prospective study**

In evaluations of the effects of healthcare interventions, a study in which people are divided into groups that are exposed or not exposed to the intervention(s) of interest before the outcomes have occurred. RCTs are always prospective studies and case control studies never are. Concurrent cohort studies are prospective studies, whereas historical cohort studies are not (see cohort study), although in epidemiology a prospective study is sometimes used as a synonym for cohort study. See retrospective study.

### **Quasi-random allocation**

A method of allocating participants to different forms of care that is not truly random; for example, allocation by date of birth, day of the week, medical record number, month of the year, or the order in which participants are included in the study (e.g. alternation).

### **Randomisation**

Method used to generate a random allocation sequence, such as using tables of random numbers or computer-generated random sequences. The method of randomisation should be distinguished from concealment of allocation because of the risk of selection bias despite the use of randomisation, if there is not adequate allocation concealment. For instance, a list of random numbers may be used to randomise participants, but if the list is open to the individuals responsible for recruiting and allocating participants, those individuals can influence the allocation process, either knowingly or unknowingly.

### **Randomised controlled trial (Synonym: randomised clinical trial)**

An experiment in which investigators randomly allocate eligible people into intervention groups to receive or not to receive one or more interventions that are being compared. The results are assessed by comparing outcomes in the treatment and control groups.

**Retrospective study**

A study in which the outcomes have occurred to the participants before the study commenced. Case-control studies are always retrospective, cohort studies sometimes are, RCTs never are. See prospective study.

**Systematic review**

A systematic review has a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review.

**Validity (synonym: internal validity)**

Validity is the degree to which a result (of a measurement or study) is likely to be true and free of bias (systematic errors). Validity has several other meanings, usually accompanied by a qualifying word or phrase; for example, in the context of measurement, expressions such as "construct validity", "content validity" and "criterion validity" are used. The expression "internal validity" is sometimes used to distinguish validity (the extent to which the observed effects are true for the people in a study) from external validity or generalisability (the extent to which the effects observed in a study truly reflect what can be expected in a target population beyond the people included in the study).

## APPENDIX 4: TABLE 2 EXCLUDED ABSTRACTS

Abstract	Reasons for exclusion
<p>Andersen CC, Phelps DL <sup>15</sup> Peripheral retinal ablation for threshold retinopathy of prematurity in preterm infants In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</p>	<p>In-hospital procedure on pre-term infants.</p>
<p>Gillespie LD, Gillespie WJ, Robertson MD, Lamb SE, Cumming RG, Rowe BH <sup>16</sup> Interventions for preventing falls in elderly people In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</p>	<p>Interventions focus on muscle strengthening, balance retraining, etc. No visual care.</p>
<p>Kwan I, Mapstone J, Roberts I <sup>17</sup> Interventions for increasing pedestrian and cyclist visibility for the prevention of death and injuries In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</p>	<p>Assessing aids to improve visibility; not an eye service.</p>
<p>Long V, Chen S <sup>18</sup> Surgical interventions for bilateral congenital cataract In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</p>	<p>Comparison of surgical procedures – lensectomy and lens aspiration.</p>
<p>Phelps DL, Watts JL <sup>19</sup> Early light reduction for preventing retinopathy of prematurity in very low birth weight infants In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</p>	<p>Treatment provided to premature infants within the first 7 days following birth.</p>
<p>Snellingen T, Evans JR, Ravilla T, Foster A <sup>20</sup> Surgical interventions for age-related cataract In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</p>	<p>Comparisons of surgical procedures.</p>
<p>Sultana A, Reilly J, Fenton M <sup>21</sup> Thioridazine for schizophrenia In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software. <b>(subsequent exclusion process based on full text article)</b></p>	<p>Evaluation of the effects (visual changes) of thioridazine for people with schizophrenia. No mention of optometrists conducting any visual tests.</p>

DISCREPANCIES: EXPERT REVIEWER AND ASSESSORS	
Abstract	Reasons for exclusion
<p><i>Anonymous</i><sup>22</sup>  <i>Pre-school hearing, speech, language and vision screening</i>            University of York            NHS Centre for Reviews and Dissemination.  <i>Effective Health Care</i>, 1998; 4(2), 1-12.  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>This is a summary of the review by Snowdon</i><sup>4</sup>.</p>
<p><i>Burls A, Clark W, Gold L, Simpson S</i><sup>23</sup>  <i>Sildenafil: an oral drug for the treatment of male erectile dysfunction</i>            1998, 1-94 Birmingham: University of Birmingham, Department of Public Health and Epidemiology.            (West Midlands Development and Evaluation Committee Report)</p>	<p><i>Assessing the effectiveness of Viagra to placebo for erectile dysfunction.</i></p>
<p><i>Byles JE</i><sup>24</sup>  <i>A thorough going over: evidence for health assessments for older persons.</i>  <i>Australian and New Zealand Journal of Public Health</i>, 2000; 24(2), 117-123.  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>Visual assessments not conducted by an optometrist.</i></p>
<p><i>Dickersin K, Manheimer E. Dickersin K, Manheimer E</i><sup>25</sup>  <i>Surgery for nonarteritic anterior ischemic optic neuropathy (Cochrane Review)</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software</i>  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>The comparator group received 'careful follow-up' that consisted of an ophthalmologic exam at all follow-up visits.</i></p>
<p><i>Facey K, Cummins E, Macpherson K, Morris A, Reay L, Slattery J</i><sup>26</sup>  <i>Organisation of services for diabetic retinopathy screening</i>            Glasgow: Health Technology Board for Scotland (HTBS), 2002. (Health Technology Assessment Report 1) ISBN: 1903961122  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>This review does not meet the definition of a systematic review as it did not mention the use of a formal method for assessing validity.</i></p>

Abstract	Reasons for exclusion
<p>Griffin S, Kinmonth AL<sup>27</sup>  <i>Systems for routine surveillance for people with diabetes mellitus</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</i>  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>No actual optometrist involvement mentioned.</i></p>
<p>Grilli R, Ramsay C, Minozzi S<sup>28</sup>  <i>Mass media interventions: effects on health services utilization</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</i></p>	<p><i>Assessing the effects of mass media.</i></p>
<p>Knight M, Duley L, Henderson-Smart DJ, King JF<sup>29</sup>  <i>Antiplatelet agents for preventing and treating pre-eclampsia</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</i></p>	<p><i>Anti-platelet agents for treating pregnant women to prevent pre-eclampsia. Not a service or intervention provided by an optometrist.</i></p>
<p>Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J<sup>30</sup>  <i>Interventions for providers to promote a patient-centred approach in clinical consultations</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</i></p>	<p><i>Interventions for health providers, not interventions provided by health providers.</i></p>
<p>Leyland M, Zinicola E<sup>31</sup>  <i>Multifocal versus monofocal intraocular lenses after cataract extraction</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.</i></p>	<p><i>Surgical intervention, comparison of intra-ocular lenses.</i></p>
<p>Lipscomb HJ<sup>32</sup>  <i>Effectiveness of interventions to prevent work-related eye injuries.</i>  <i>American Journal of Preventive Medicine, 2000; 18(4 Supplement S),27-32.</i></p>	<p><i>This review does not meet the definition of a systematic review as it did not use a formal method for assessing validity.</i></p>
<p>Renders CM, Valk GD, Griffin S, Wagner EH, Eijh JThM van, Assendelft WJJ<sup>33</sup>  <i>Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software</i>  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>Not an optometry service; no optometrists mentioned as participating in the programs.</i></p>

Abstract	Reasons for exclusion
<p>Sanderson D, Wright D, Acton C, Duree D <sup>34</sup>  <i>Cost analysis of child health surveillance</i>  <i>Health Technology Assessment Vol.5: No.36, 2001.</i>  <i>ISBN: 13665278</i></p>	<p><i>This is not a systematic review, it presented results from a postal questionnaire.</i></p>
<p>Stickler GB <sup>35</sup>  <i>Are yearly physical examinations in adolescents necessary.</i>  <i>Journal of the American Board of Family Practice, 2000; 13(3), 172-177.</i></p>	<p><i>This review does not meet the definition of a systematic review as it did not use a formal method for assessing validity.</i></p>
<p>Trindade E, Menon D, Topfer L A, Coloma C <sup>36</sup>  <i>Adverse effects associated with selective serotonin reuptake inhibitors and tricyclic antidepressants: a meta-analysis</i>  <i>Canadian Medical Association Journal, 1998; 159(10), 1245-1252.</i>  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>Evaluation of the adverse effects associated with anti-depressants. No mention of optometrists conducting any visual tests.</i></p>
<p>Wormald R, Evans J, Smeeth L, Henshaw K <sup>37</sup>  <i>Photodynamic therapy for neovascular age-related macular degeneration</i>  <i>In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software</i>  <b>(subsequent exclusion process based on full text article)</b></p>	<p><i>Photodynamic therapy was compared to a surgical procedure.</i></p>

# Abstracts Excluded by Assessors but Considered to be in Scope by Clinical Experts

## Pre-school hearing, speech, language and vision screening

University of York

NHS Centre for Reviews and Dissemination. *Effective Health Care*, 1998; 4(2), 1-12.

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This review has been produced as an Effective Health Care Bulletin by the NHS Centre for Reviews and Dissemination. Effective Health Care Bulletins are based on a systematic review and synthesis of research on the clinical effectiveness, cost-effectiveness and acceptability of health service interventions. This is carried out by a research team using established methodological guidelines, with advice from expert consultants for each topic. The bulletins are subject to extensive and rigorous peer review.

**Authors' conclusions:** Child health screening focuses on the early detection of childhood disorders in order to reduce disability. This includes screening for hearing, speech and language and vision problems in pre-school children.

Screening for permanent childhood hearing impairment is usually carried out by health visitors using the infant distraction test (HVDT) at 6-9 months. This test fails to detect a significant number of hearing problems sufficiently early.

There is good evidence that universal neonatal hearing screening is more effective and cost-effective than HVDT at detecting significant congenital hearing loss.

A significant number of pre-school children show signs of speech and language delay at some point. Delay which would not spontaneously improve can be effectively treated. However, it is not yet clear how to identify children who will fail to progress without treatment.

Pre-school vision screening for refractive errors and non-obvious squints may not be beneficial because these minor conditions, by themselves, do not appear to be problematic and because the advantages of treating them have not been demonstrated. Major defects are identified without screening.

The direct research evidence that amblyopia in young children is disabling and can be effectively treated is weak. However, there is strong clinical opinion that identifying and treating amblyopia at an early age produces benefits. Better research is required to provide a clearer picture of the likely benefits, harms and costs of pre-school vision screening.

NHS organisations may wish to review their hearing screening in the light of this evidence but further change is not recommended in advance of the advice from the National Screening Committee and/or further research.

## **Sildenafil: an oral drug for the treatment of male erectile dysfunction**

**Burls A, Clark W, Gold L, Simpson S**

**1998, 1-94 Birmingham: University of Birmingham, Department of Public Health and Epidemiology. (West Midlands Development and Evaluation Committee Report; 12)**

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This record is a structured abstract written by CRD reviewers. The original has met a set of quality criteria. Since September 1996 abstracts have been sent to authors for comment. Additional factual information is incorporated into the record. Noted as (A:.....).

**Authors' objectives:** To examine the effectiveness, safety and cost-effectiveness of sildenafil for the treatment of male erectile dysfunction.

**Type of intervention:** Treatment.

**Specific interventions included in the review:** Sildenafil (Viagra) compared to placebo. The authors planned to compare sildenafil to other current treatments for erectile dysfunction, but no evidence was found.

**Participants included in the review:** The review did not specify inclusion criteria for participants, but all included studies recruited men aged 18 years and over with erectile dysfunction of at least 6 months duration, in a heterosexual relationship for at least 6 months: aetiology included diabetes and spinal cord injury. Men with the following disorders were excluded: anatomical deformities; other sexual disorders; elevated prolactin (3xULN) or low free testosterone (20% below LLN); major uncontrolled psychiatric disorders; history of alcohol or drug abuse; history of major haematological, renal or hepatic disorder; stroke or MI within 6 months; cardiac failure, unstable angina, ECG ischaemia or life threatening arrhythmia within 6 months; BP outside the range 90/50 to 170/100 mmHg; active peptic ulcer disease of bleeding disorder; clinically significant baseline laboratory abnormality; need for anticoagulants, nitrates, androgen or trazodone; need for aspirin or NSAIDs and history of peptic ulcer disease; unwillingness to cease using other therapy for erectile dysfunction; other experimental drug use within 3 months; history of retinitis pigmentosa.

**Outcomes assessed in the review:** The review did not specify which outcomes included studies should measure. Phase II trials measured penile rigidity (using a Rigiscan) during visual or vibratory sexual stimulation. Phase III and some Phase II trials measured outcomes using the International Index of Erectile Function (IIEF): a self-administered questionnaire consisting of 15 questions around 5 domains of male sexual function: erectile function, orgasmic function, sexual desire, intercourse satisfaction, overall satisfaction.

**Study designs of evaluations included in the review:** Randomised controlled trials (RCTs). Both Phase II and Phase III studies were included.

**What sources were searched to identify primary studies?:** MEDLINE (1966 - June 1998), EMBASE (1988 - June 1998), Cochrane Library 1998 Issue 3, PsycLIT (1996 - 1987 (sic)), National Research Register Interim version June 1998 and Pharmline were all searched for articles containing the free-text terms "sildenafil" or "Viagra". The main Internet search engines were used using the terms "sildenafil" or "Viagra". The FDA centre for Drug Evaluation and Research, Joint Clinical Review for NDA-20-895 Viagra (Sildenafil), the BMJ, Lancet, JAMA, NEJM, BJGP, Drug, Inpharma and SCRIIP were all hand-searched. Experts in the field and the manufacturers (Pfizer Ltd) were contacted. Reference lists of all relevant studies identified were scanned. The Science Citation Index was searched using all relevant studies identified.

There were no language restrictions.

**Criteria on which the validity (or quality) of studies was assessed:** The authors do not report a method for assessing validity. However, in the results section the following aspects are considered: blinding, control group, sample size, loss to follow up.

**How were decisions on the relevance of primary studies made?:** The authors do not state how many of the reviewers performed the selection.

**How were judgements of validity (or quality) made?:** Validity assessment was undertaken independently by two reviewers.

**How were the data extracted from primary studies?:** Two reviewers extracted data from all trials independently into pre-defined tables. Discrepancies were resolved by discussion. Data were extracted on: source of information; cause of erectile dysfunction; number of patients; patient characteristics; treatments; duration; outcomes; p values; date of study.

**Number of studies included in the review:** Twenty one RCTs (n=4199). Seven were Phase III trials and 14 were Phase II trials.

**How were the studies combined?:** A narrative synthesis, with some pooling where mean scores (for response to questions) and mean proportions are presented. The methods used to combine data are not presented in the report.

**How were differences between studies investigated?:** No formal investigation of heterogeneity was carried out.

### **Results of the review**

Penile rigidity (Phase II trials only, n=7): In all studies an increased duration of rigidity >60% was seen with increasing doses of sildenafil.

Primary endpoints: Frequency of penetration: 9/9 RCTs showed statistically significant improvements with all doses of sildenafil compared to placebo. Increasing improvement was apparent with increasing dose over the range 25-100mg.

Maintenance of erection after penetration: 9/9 RCTs showed a statistically significant improvement with all doses of sildenafil compared to placebo. Increasing improvement was apparent with increasing dose over the range 25-100mg.

Secondary endpoints: General efficacy question: 21/21 RCTs reported an improvement in erections with sildenafil treatment (65-82% improved) compared to placebo (18-26% improved). A dose-response relationship was seen over the dose range 25-100mg.

Successful intercourse: Proportion of attempts at intercourse that were successful with sildenafil treatment increased compared to placebo treatment (6/9 RCTs list a positive outcome). One RCT found no increase in rates of attempted intercourse with sildenafil, despite increased success rates.

Erections hard enough for intercourse: In 6/6 RCTs a significant improvement in the number of grade 3 and 4 erections was seen with sildenafil treatment. A dose-response relationship was apparent.

Partner's questionnaire: Generally increasing partner satisfaction was seen with increasing sildenafil dose (10-100mg).

Quality of life: Statistically significant but small quality of life treatment effects were seen in 4 RCTs.

Adverse effects: Adverse events reported in >2% (range 2% - 10%) of patient treated (2RCTs) include headache, flushing, dyspepsia, nasal congestion, urinary tract infection, abnormal vision, diarrhoea, dizziness, rash, respiratory tract infection. No cases of priapism were reported in any of the sildenafil studies.

Cardiovascular: 18 RCTs give an overall incidence of cardiovascular events (other than flushing) of 3.0% with sildenafil and 3.5% with placebo. A comparable incidence rate was seen with sildenafil and placebo for serious cardiovascular events. No clinically significant changes in blood pressure, heart rate or ECG were seen with sildenafil treatment. Sildenafil had no direct effect on platelet aggregation.

Death: 8/4500 patients treated with sildenafil in clinical trial died whilst taking the study drug or within 30 days of treatment. Six deaths were related to cardiovascular causes; in all cases it was plausible that the event was not related to the study drug.

Diabetics: In general, smaller improvements were seen in diabetics than in those without diabetes.

Spinal cord injury: sildenafil appears to show comparable efficacy in patients with erectile dysfunction solely attributable to spinal cord injury (but with intact spinal cord-mediated reflexes) to patients with erectile dysfunction of broad spectrum aetiology.

Radical prostatectomy: 4% of participants had erectile dysfunction as a result of radical prostatectomy. A subgroup analysis of the patients appeared to show lower efficacy with sildenafil, with 40-50% achieving improved erections.

Age: Age did not affect response to sildenafil.

**Was any cost information reported?:** A cost-utility analysis concluded that there is a great deal of uncertainty surrounding the assumptions used to calculate the cost/QALY of treating erectile dysfunction with sildenafil. The best estimate was approximately 7000/QALY. Sensitivity analysis around the assumptions produced a range of cost/QALYs within the 3000-20,000/QALY "strongly supported" decision band used by the Development and Evaluation Committee.

**Authors' conclusions:** All trials showed a statistically significant improvement in erectile function in patients using sildenafil compared to placebo. About 75-80% of men show a clinically significant improvement in erectile or sexual function on sildenafil compared to around 25% on placebo. The number needed to treat (NNT) was about 2. Many of the patients in the studies had some baseline erectile function and it is probable that in clinical practice, where the erectile function tends to be more impaired, the NNT may be higher. The drug has a relatively safe side-effect profile. The major contraindication is concurrent use of nitrates.

**CRD commentary:** The research question and inclusion criteria for the review were clear, however inclusion criteria for the primary studies were quite restrictive and possibly resulted in the population studied having more baseline erectile function than would be seen in clinical practice, which would limit the generalisability of the review findings. The authors state that validity assessment was undertaken but few details of this are presented in the report. The literature search was comprehensive and it is unlikely that any studies were missed. Some details of the review process are given but it is not stated how many reviewers screened studies for relevance. As all included phase III trials used the same outcome measures data could have been pooled using standard methods for meta-analysis and presented as forest plot and as relative risks and weighted mean differences with 95% CIs: this was not done and there is no description in the methods section of how the review authors synthesised data.

The authors' conclusions do seem to follow from the results.

**What are the implications of the review?L:** The authors state that if sildenafil were available for prescription in primary care the drug costs to an average Health Authority with a total population of 500,000 are estimated to be between 750,000 and 1,250,000 per annum, depending on the percentage of men who present for treatment.

## A thorough going over: evidence for health assessments for older persons.

Byles J E.

Australian and New Zealand Journal of Public Health, 2000; 24(2),117-123.

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This record is a structured abstract written by CRD reviewers. The original has met a set of quality criteria. Since September 1996 abstracts have been sent to authors for comment. Additional factual information is incorporated into the record. Noted as (A:.....).

**Authors' objectives:** To evaluate the effect of health assessments in maintaining health and quality of life for older people, and to identify those factors associated with more successful health assessment programmes.

**Type of intervention:** Prevention.

**Specific interventions included in the review:** Health assessments were eligible. These were performed by volunteers, nurses, geriatricians, social workers, physicians and their assistants, interviewers, office staff, multi-disciplinary teams, health visitors, or were self-administered. The most common components assessed were: height and/or weight; blood-pressure; vision and/or hearing; teeth and/or oral status; balance and/or gait; medications; activities of daily living; functional status; medical problems; nutrition; alcohol; smoking; exercise; depression; cognition; social support; service use; and home environment.

**Participants included in the review:** People aged at least 65 years, who were living independently in the community, were eligible.

**Outcomes assessed in the review:** Inclusion criteria were not defined in terms of outcomes. A variety of health outcomes were assessed across the studies; these included perceived health, functional status, hospital admission and mortality rates. Follow-up periods ranged from 3 months to 3.2 years.

**Study designs of evaluations included in the review:** Randomised controlled trials (RCTs) and meta-analyses were eligible.

**What sources were searched to identify primary studies?:** MEDLINE, CINAHL and the Cochrane Library were searched from 1970 to 1999 using the exploded terms 'aged' or 'aged 80, and over' in combination with the terms 'geriatric assessment', 'health services for the aged' or 'preventive health services'. Manual searches were conducted of the Australian Journal on Aging, Gerontology, Gerontologist, Journal of the American Gerontology Society, Medical Journal of Australia, and bibliographies of identified studies. Experts in the field were contacted for information on further studies, and abstracts of reports relating to health assessments or prevention for older people were reviewed.

**Criteria on which the validity (or quality) of studies was assessed:** The validity of full reports was assessed using criteria developed by the Centre for Clinical Epidemiology and Biostatistics (see Other Publications of Related Interest no.1). The criteria assessed were: identification of research question; study and outcome factors; effectiveness of randomisation; follow-up; validity of measures; appropriateness of statistical methods; and external validity.

**How were decisions on the relevance of primary studies made?:** The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

**How were judgements of validity (or quality) made?:** Two reviewers independently applied the validity criteria, and any discrepancies were resolved by discussion.

**How were the data extracted from primary studies?:** Two reviewers independently completed the data extraction forms and then checked them for agreement. Tables were presented reporting the following information: author and year of publication; the number of persons performing the intervention; the number of persons in each treatment arm; problems with confounding; losses to follow-up; length of follow-up; and main findings.

**Number of studies included in the review:** Twenty-one RCTs involving over 13,000 people were included.

**How were the studies combined?:** The studies were combined in a narrative review.

**How were differences between studies investigated?:** Differences between studies were discussed.

**Results of the review:** The studies varied considerably in methodological quality, assessment content and outcome variables. The results were inconsistent, although the majority of higher-quality studies reported improvements in health. The ten studies reporting positive outcomes were applied to all people who had reached the required age and were not targeted at high-risk groups.

The methodological problems included limited statistical power, unequal groups at baseline, confounding, and losses to follow-up that were greater than 10% of the participants in most studies.

**Was any cost information reported?:** The costs of the assessments and follow-up, relative to the cost-savings from reduced health care use, were assessed in 14 studies. Results were inconsistent: 6 studies reported lower net costs, 3 studies reported neutral costs, and 5 studies reported increased costs from the intervention.

**Authors' conclusions:** Health assessments have been associated with improved health outcomes for older people. An evidence base has yet to be derived for specific components to be included in the assessments.

**CRD commentary:** The aims were stated, and the inclusion criteria were defined in terms of study design, participants and intervention. Several relevant databases were searched, details of the search strategy were given, and attempts were made to locate unpublished material, though the methods used to select studies were not described. The included studies were restricted to RCTs and a formal validity assessment was undertaken, although the results were not reported in full. The methods used to assess validity and extract data were described. Given the heterogeneity among studies, a narrative review was appropriate. Attention in the review was drawn to better quality studies.

The evidence presented supports the author's conclusion.

#### **What are the implications of the review?**

**Practice:** The author states that the acceptability, adoption and effectiveness of new Medicare items, to cover health assessments for people aged at least 75 years in Australia, needs careful monitoring.

**Research:** The author states that attention needs to be given to the development of a brief reliable tool to enable assessment, training in the use of this tool, and appropriate opportunities for follow-up of the identified health needs. The acceptability of the assessment process to older people needs to be evaluated, and careful public communication of the role of assessments is required.

**Surgery for nonarteritic anterior ischemic optic neuropathy**  
**Dickersin K, Manheimer E. Dickersin K, Manheimer E**  
**Surgery for nonarteritic anterior ischemic optic neuropathy (Cochrane Review)**  
**In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software**

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This is a regularly updated Cochrane review. Please contact the author of the review using the contact details provided if you have comments or criticisms. The complete review is available in The Cochrane Library. For information on The Cochrane Library, contact Update Software Ltd, Summertown Pavilion, Middle Way, Summertown, Oxford OX2 7LG, England. Tel: +44 1865 513902, Fax: +44 1865 516918, Email: info@update.co.uk

**Authors' objectives**

**Background:** Nonarteritic ischemic optic neuropathy is characterized by sudden and painless loss of vision in one eye, accompanied by pallid swelling of the optic disc. Although various medical interventions, such as corticosteroids and phenytoin sodium, have been used to treat nonarteritic ischemic optic neuropathy, no therapy has been proven effective.

**Objectives:** The objective of this review is to assess the safety and efficacy of surgical treatment compared with other treatment or usual care in people with nonarteritic ischemic optic neuropathy.

**Search strategy:** We searched the Cochrane the Cochrane Controlled Trials Register - CENTRAL/CCTR (which includes the Cochrane Eyes and Vision Group specialised register) and MEDLINE.

**Selection criteria:** We included randomized trials comparing surgery to no surgery in people with nonarteritic ischemic optic neuropathy.

**Data collection and analysis:** We obtained full copies of all potentially relevant articles. Only one article described a randomized trial of surgery and it was eligible for inclusion. No formal assessment of quality was done. One reviewer extracted data. No synthesis was required, as there was only one trial.

**Main results:** The one trial identified randomized 258 patients. The only published report with outcomes data for that trial presents preliminary results from 244 participants who had achieved six months of follow-up at the time of the report. Participants assigned to surgery did no better than participants assigned to careful follow-up regarding improved visual acuity of three or more lines of vision at six months: 32.6% of the surgery group improved compared with 42.7% of the careful follow-up group. The adjusted odds ratio (OR), adjusted for baseline visual acuity and diabetes, comparing the two groups for three or more lines improvement was 0.74 (95% confidence interval (CI) 0.39 to 1.38) (surgery group improvement was worse than careful follow-up). In addition, participants receiving surgery had a significantly greater risk of losing three or more lines of vision at six months: 23.9% in the surgery group worsened compared with 12.4% in the careful follow-up group. The six-month adjusted OR comparing the two groups for loss of three or more lines of vision was 1.96 (95% CI 0.87 to 4.41). Spontaneous improvement of three or more lines of vision was observed in 42.7% of participants in the careful follow-up group.

**Reviewer's conclusions:** Results from the Ischemic Optic Neuropathy Decompression Trial indicate that optic nerve decompression surgery for nonarteritic ischemic optic neuropathy is not effective.

**Organisation of services for diabetic retinopathy screening**  
**Facey K, Cummins E, Macpherson K, Morris A, Reay L, Slattery J**  
**Glasgow: Health Technology Board for Scotland (HTBS), 2002. (Health Technology Assessment**  
**Report 1) ISBN: 1903961122**

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This is a publication undertaken by a member of INAHTA. For further information please contact the agency using the contact details in Correspondence Address field.

**Authors' objectives:** The aim of this report is to determine the most effective and efficient approach to achieving, implementing and sustaining a quality assured, comprehensive national screening programme for diabetic retinopathy that takes account of patient requirements.

**Type of intervention:** Screening

**Study Design:** Systematic review

**Sources searched:** The following electronic databases were searched: MEDLINE, HealthStar, CINAHL, Cochrane Library, EMBASE, PsycInfo, Science Citation Index, Social Science Citation Index, HEED, NHS EED, HMIC, SIGLE, DARE, HTA Database, National Research Register, BIOSIS, EconLit.

**Methodology:**

For clinical effectiveness, guidelines produced by the National Institute for Clinical Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN) and the UK National Screening Committee (UK NSC) were used as the starting point for assessment. Additional relevant studies were identified and added to the overall analysis.

The patient issues component used published scientific literature, educational materials from patient groups, patient surveys, discussions at the HTBS patient workshops and focus group work undertaken by HTBS in Scotland.

For the economic evaluation, information was obtained from existing UK diabetic retinopathy screening programmes and a comprehensive systematic literature review was carried out.

**Was any cost information reported?:** Adopting a three-stage process for the national screening programme is estimated to cost NHS Scotland approximately 3.7 million GBP in the first year and 1.9 million GBP per annum thereafter. The screening programme will result in more people with diabetes requiring some form of treatment to improve their sight. The additional annual treatment costs could be around 65,000 GBP.

The modelling shows that moving to systematic screening from an opportunistic programme is cost-effective for all people with diabetes.

**Authors' conclusions:** The HTBS proposed model for diabetic retinopathy screening:

1. A quality assured national diabetic retinopathy screening programme is proposed that is sufficiently flexible to accommodate the needs of patients living in all communities (urban, rural and island) in Scotland.

2. Following evaluation and analysis of data and evidence available up to February 2002 on clinical effectiveness, organisational issues, patient issues and economics, HTBS proposes that the national systematic screening programme for diabetic retinopathy in Scotland uses the following three-stage process:

- 1) Macular single-field digital retinal photography, without mydriasis, for each eye.
- 2) If there is a technical failure, macular single-field digital retinal photography, with mydriasis, for each eye.
- 3) If there is a technical failure with mydriatic digital photography, biomicroscopy with a slit lamp.

Visual acuity, with refractive correction if required, should be recorded for each eye.

HTBS believes this sequential and pragmatic model optimises clinical effectiveness, cost-effectiveness and patient preferences. Evidence suggests that in approximately 80% of people, images suitable for grading and detection of referable (sight-threatening) retinopathy will be obtained through undilated pupils, so mydriasis will not be needed in the majority of patients. However, no patient will be denied mydriasis when it is necessary and patients known to require mydriasis should start at the second stage. This sequential, potentially three-stage, process is felt to be both efficient and failsafe.

3. The screening/grading will be performed by appropriately trained, accredited and competent professionals.

4. A national survey indicates that a large number of local schemes exist in Scotland but none meets the required specifications of a national scheme. It is important that the introduction of the national screening programme for diabetic retinopathy does not disadvantage these existing schemes but allows for their enhancement to meet the approved quality assured specifications.

5. Screening must be accessible to all patients, whether they receive community-based and/or hospital-based diabetic care. HTBS has made no restrictive recommendations on the organisation of the programme in any area, or precluded any professional groups from participating in the screening programme. The local implementation must allow easy access for patients and may include services in diabetes centres, primary healthcare facilities, mobile vans or community optometrists.

6. Several important research questions have been identified in this Health Technology Assessment. One of the key questions relates to the performance of the sequential three-stage screening model. This will be addressed in the first year of the roll out of the programme, taking account of data arising from this programme and that available elsewhere, particularly in the rest of the UK. This will allow modifications to be made to improve the efficiency of the Scottish screening programme.

7. HTBS recommends that the national programme for diabetic retinopathy screening is achieved by building upon established local systems: evolution rather than revolution, with best practice and learnings shared across Scotland. This will be achieved with the help of the Scottish Diabetes Group who will be taking forward implementation of this programme in 2002.

## Systems for routine surveillance for people with diabetes mellitus

Griffin S, Kinmonth AL

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This review should be cited as: Griffin S, Kinmonth AL. Systems for routine surveillance for people with diabetes mellitus (Cochrane Review). In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 19 November 1997. Cochrane reviews are regularly checked and updated if necessary.

**Background:** There is wide variation in the extent of general practice involvement in diabetes care.

**Objectives:** To assess the effects of involving primary care professionals in the routine review and surveillance for complications of people with established diabetes mellitus compared with secondary care specialist follow up.

**Search strategy:** We searched the Cochrane Diabetes Group specialised register, The Cochrane Library, MEDLINE (January 1966 to December 1996), EMBASE (to December 1996), Cinahl (to December 1996), National Research Register (to December 1996), PsycLIT (to December 1996), HealthSTAR (to December 1996), CRIB (to December 1996), Dissertation Abstracts (to December 1996), and reference lists of articles.

**Selection criteria:** Randomised trials in which people with diabetes were allocated to a system of review and surveillance for complications by primary care professionals. Outcomes included mortality, metabolic control, cardiovascular risk factors, quality of life, functional status, satisfaction, hospital admissions, costs, completeness of screening, and development of complications.

**Data collection and analysis:** The reviewer assessed trial quality and extracted data. Analysis was on an intention to treat basis. General practice care was categorised into routine or prompted care and a stratified analysis undertaken.

**Main results:** Five trials involving 1058 people were included. Results were heterogeneous between trials. In those schemes featuring more intensive support through a prompting system for general practitioners and patients, there was no difference in mortality between hospital and general practice care (odds ratio 1.06, 95% confidence interval 0.53 to 2.11), HbA1 tended to be lower (a weighted difference in means of -0.27%, 95% confidence interval -0.59 to 0.03) and losses to follow up were significantly lower (odds ratio 0.37, 95% confidence interval 0.22 to 0.61) in primary care. However, schemes with less well-developed support for family doctors were associated with adverse outcomes for patients. Quality of life, cardiovascular risk factors, functional status and the development of complications were infrequently assessed.

**Reviewers' conclusions:** Unstructured care in the community is associated with poorer follow up, greater mortality and worse glycaemic control than hospital care. Computerised central recall, with prompting for patients and their family doctors, can achieve standards of care as good or better than hospital outpatient care, at least in the short term. The evidence supports provision of regular prompted recall and review of people with diabetes by willing general practitioners and demonstrates that this can be achieved, if suitable organisation is in place.

## Mass media interventions: effects on health services utilisation

Grilli R, Ramsay C, Minozzi S

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This review should be cited as: Grilli R, Ramsay C, Minozzi S. Mass media interventions: effects on health services utilisation (Cochrane Review). In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 16 November 2001. Cochrane reviews are regularly checked and updated if necessary.

**Background:** The mass media frequently cover health related topics, are the leading source of information about important health issues, and are targeted by those who aim to influence the behaviour of health professionals and patients.

**Objectives:** To assess the effects of mass media on the utilisation of health services.

**Search strategy:** We searched the Cochrane Effective Practice and Organisation of Care Group specialised register (1996 to 1999), MEDLINE, EMBASE, Eric, PsycLit (to 1999), and reference lists of articles. We hand searched the journals Communication Research (February 1987 to August 1996), European Journal of Communication (1986 to 1994), Journal of Communication (winter 1986 to summer 1996), Communication Theory (February 1991 to August 1996), Critical Studies in Mass Communication (March 1984 to March 1995) and Journalism Quarterly (1986 to summer 1996).

**Selection criteria:** Randomised trials, controlled clinical trials, controlled before-and-after studies and interrupted time series analyses of mass media interventions. The participants were health care professionals, patients and the general public. Data collection and analysis: Two reviewers independently extracted data and assessed study quality.

**Main results:** Twenty studies were included. All used interrupted time series designs. Fifteen evaluated the impact of formal mass media campaigns, and five of media coverage of health-related issues. The overall methodological quality was variable. Six studies did not perform any statistical analysis, and nine used inappropriate statistical tests (ie not taking into account the effect of time trend). All of the studies apart from one concluded that mass media was effective. These positive findings were confirmed by our re-analysis in seven studies. The direction of effect was consistent across studies towards the expected change.

**Reviewers' conclusions:** Despite the limited information about key aspects of mass media interventions and the poor quality of the available primary research there is evidence that these channels of communication may have an important role in influencing the use of health care interventions. Although the findings of this review may be affected by publication bias, those engaged in promoting better uptake of research information in clinical practice should consider mass media as one of the tools that may encourage the use of effective services and discourage those of unproven effectiveness.

## Antiplatelet agents for preventing and treating pre-eclampsia

Knight M, Duley L, Henderson-Smart DJ, King JF

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This review should be cited as: Knight M, Duley L, Henderson-Smart DJ, King JF. Antiplatelet agents for preventing and treating pre-eclampsia (Cochrane Review). In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 21 February 2000. Cochrane reviews are regularly checked and updated if necessary.

**Background:** Pre-eclampsia is associated with deficient intravascular production of prostacyclin, a vasodilator, and excessive production of thromboxane, a platelet-derived vasoconstrictor and stimulant of platelet aggregation. These observations led to the hypotheses that antiplatelet agents, and low dose aspirin in particular, might prevent or delay the development of pre-eclampsia.

**Objectives:** To assess the effectiveness and safety of antiplatelet agents when given to women at risk of developing pre-eclampsia, and to those with established pre-eclampsia.

**Search strategy:** This review drew on the search strategy developed for the Pregnancy and Childbirth Group as a whole. The Cochrane Controlled Trials Register was also searched, The Cochrane Library 1999 Issue 1, Embase was searched from 1994-1999 and hand searches were performed of the congress proceedings of the International and European Societies for the Study of Hypertension in Pregnancy.

**Selection criteria:** All randomised trials comparing antiplatelet agents with either placebo or no antiplatelet agent during pregnancy. Quasi random study designs were excluded. Participants were pregnant women considered to be at risk of developing pre-eclampsia, and those with pre-eclampsia before delivery. Women treated postpartum were excluded. Interventions were any comparisons of an antiplatelet agent (such as low dose aspirin or dipyridamole) with either placebo or no antiplatelet agent.

**Data collection and analysis:** Assessment of trials for inclusion in the review and extraction of data was performed independently and unblinded by two reviewers. Data were entered into the Review Manager software and double checked.

**Main results:** Forty two trials involving over 32,000 women were included in this review, with 30,563 women in the prevention trials. There is a 15% reduction in the risk of pre-eclampsia associated with the use of antiplatelet agents [32 trials with 29,331 women; relative risk (RR) 0.85, 95% confidence interval (0.78, 0.92); Number needed to treat (NNT) 89, (59, 167)]. This reduction is regardless of risk status at trial entry or whether a placebo was used, and irrespective of the dose of aspirin or gestation at randomisation.

Twenty three trials (28,268 women) reported preterm delivery. There is a small (8%) reduction in the risk of delivery before 37 completed weeks [RR 0.92, (0.88, 0.97); NNT 72 (44, 200)]. Baby deaths were reported in 30 trials (30,093 women). Overall there is a 14% reduction in baby deaths in the antiplatelet group [RR 0.86, (0.75, 0.98); NNT 250 (125, >10000)]. Small for gestational age babies were reported in 25 trials (20,349 women), with no overall difference between the groups, RR 0.92, (0.84, 1.01).

There were no significant differences between treatment and control groups in any other measures of outcome.

Five trials compared antiplatelet agents with placebo or no antiplatelet agent for the treatment of pre-eclampsia. There are insufficient data for any firm conclusions about the possible effects of effects of these agents when used for treatment of pre-eclampsia.

**Reviewers' conclusions:** Antiplatelet agents, in this review largely low dose aspirin, have small-moderate benefits when used for prevention of pre-eclampsia. Further information is required to assess which women are most likely to benefit, when treatment should be started, and at what dose.

## Interventions for providers to promote a patient-centred approach in clinical consultations

Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J

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This review should be cited as: Lewin SA, Skea ZC, Entwistle V, Zwarenstein M, Dick J. Interventions for providers to promote a patient-centred approach in clinical consultations (Cochrane Review). In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 02 August 2001. Cochrane reviews are regularly checked and updated if necessary.

**Background:** Communication problems in health care may arise as a result of health care providers focusing on diseases and their management, rather than people, their lives and their health problems. Patient-centred approaches to care are increasingly advocated by consumers and clinicians and incorporated into training for health care providers. The effects of interventions that aim to promote patient-centred care need to be evaluated.

**Objectives:** To assess the effects of interventions for health care providers that aim to promote patient-centred approaches in clinical consultations.

**Search strategy:** We searched Medline (1966 - Dec 1999); Health Star (1975 - Dec 1999); PsycLit (1987- Dec 1999); Cinahl (1982 - Dec 1999); Embase (1985-Dec 1999) and the bibliographies of studies assessed for inclusion.

**Selection criteria:** Randomised controlled trials, controlled clinical trials, controlled before and after studies, and interrupted time series studies of interventions for health care providers that promote patient-centred care in clinical consultations. Patient-centred care was defined as a philosophy of care that encourages: (a) shared control of the consultation, decisions about interventions or management of the health problems with the patient, and/or (b) a focus in the consultation on the patient as a whole person who has individual preferences situated within social contexts (in contrast to a focus in the consultation on a body part or disease). The participants were health care providers, including those in training.

**Data collection and analysis:** Two reviewers independently extracted data onto a standard form and assessed study quality for each study. We extracted all outcomes other than health care providers' knowledge, attitudes and intentions.

**Main results:** 17 studies met the inclusion criteria. These studies display considerable heterogeneity in terms of the interventions themselves, the health problems or health concerns on which the interventions focused, the comparisons made and the outcomes assessed. All included studies used training for health care providers as an element of the intervention. Ten studies evaluated training for providers only, while the remaining studies utilised multi-faceted interventions where training for providers was one of several components. The health care providers were mainly primary care physicians (general practitioners or family doctors) practising in community or hospital outpatient settings. In two studies, the providers also included nurses.

There is fairly strong evidence to suggest that some interventions to promote patient-centred care in clinical consultations may lead to significant increases in the patient centredness of consultation processes. 12 of the 14 studies that assessed consultation processes showed improvements in some of these outcomes. There is also some evidence that training health care providers in patient-centred approaches may impact positively on patient satisfaction with care. Of the eleven studies that assessed patient satisfaction, six demonstrated significant differences in favour of the intervention group on one or more measures. Few studies examined health care behaviour or health status outcomes.

**Reviewers' conclusions:** Interventions to promote patient-centred care within clinical consultations may significantly increase the patient centredness of care. However, there is limited and mixed evidence on the effects of such interventions on patient health care behaviours or health status; or on whether these

interventions might be applicable to providers other than physicians. Further research is needed in these areas.

## Multifocal versus monofocal intraocular lenses after cataract extraction

Leyland M, Zinicola E

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This review should be cited as: Leyland M, Zinicola E. Multifocal versus monofocal intraocular lenses after cataract extraction (Cochrane Review). In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 30 May 2001. Cochrane reviews are regularly checked and updated if necessary.

**Background:** Good unaided distance visual acuity is now a realistic expectation following cataract surgery and intraocular lens implantation. Near vision however still requires additional refractive power, usually in the form of reading glasses. Multiple optic (multifocal) intraocular lenses are available that are claimed to allow good vision at a range of distances. It is unclear whether this benefit outweighs the optical compromises inherent in multifocal intraocular lenses.

**Objectives:** The objective of this review is to assess the effects of multifocal intraocular lenses, including effects on visual acuity, subjective visual satisfaction, spectacle dependence, glare and contrast sensitivity, compared to standard monofocal lenses.

**Search strategy:** We searched the Cochrane Controlled Trials Register - CENTRAL (which includes the Cochrane Eyes and Vision Group specialised register), MEDLINE and EMBASE. The reference lists of relevant articles were searched. Investigators of included studies and manufacturers of multifocal intraocular lenses were contacted for information about additional published and unpublished studies.

**Selection criteria:** All randomised controlled trials comparing a multifocal intraocular lens of any type with a monofocal intraocular lens as control were included. Both unilateral and bilateral implantation trials were included.

**Data collection and analysis:** Data were collected and trial quality assessed. Where possible, statistical summary measures were calculated, otherwise data were tabulated.

**Main results:** One ongoing and six completed trials were identified. There was significant variability between the trials in the outcomes reported. Unaided distance acuity was similar in multifocal and monofocal intraocular lenses (Peto odds ratio 1.27 (95% Confidence Interval (CI) 0.76 to 2.11)), with a small increase in the proportion of multifocal intraocular lens participants achieving less than 6/6 best corrected visual acuity Peto odds ratio 1.64 (95% CI 1.10 to 2.42)). Unaided near vision tended to improve with the multifocal intraocular lenses. This resulted in decreased spectacle dependence with use of the multifocal intraocular lenses (Peto odds ratio 0.16 (95% CI 0.11 to 0.23)). Adverse effects included reduced contrast sensitivity and the subjective experience of haloes around lights.

**Reviewers' conclusions:** Multifocal intraocular lenses are effective at improving near vision relative to monofocal intraocular lenses. Whether that improvement outweighs the adverse effects of multifocal intraocular lenses will vary between patients, with motivation to achieve spectacle independence likely to be the deciding factor.

**Effectiveness of interventions to prevent work-related eye injuries.**  
**Lipscomb HJ**  
**American Journal of Preventive Medicine, 2000; 18(4 Supplement S),27-32.**

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This record is a structured abstract written by CRD reviewers. The original has met a set of quality criteria. Since September 1996 abstracts have been sent to authors for comment. Additional factual information is incorporated into the record. Noted as (A:....).

**Authors' objectives:** To describe the effectiveness of interventions designed to prevent work-related eye injuries in the construction, manufacturing and agricultural industries.

**Type of intervention:** Prevention.

**Specific interventions included in the review:** Any intervention that sought to prevent eye injuries or decrease the severity of injury sustained by the workers. Two types of intervention were of interest.

1. Different types of eye protection and/or environmental controls in the workplace.
2. Behavioural interventions that focused on increasing the use of protection among at-risk workers.

Studies that dealt with the prevention of injuries from exposure to lasers, radiation, or microwaves were not included.

**Participants included in the review:** The participants of interest were workers employed in the manufacturing, construction or agricultural industries. The participants in the included studies were: shipfitters and shipyard workers; workers involved in operations involving grinding; and workers involved in diverse manufacturing settings, such as chemical plants, aerospace products, light engineering, and electronic components.

**Outcomes assessed in the review:** Eye injury rates were considered to be the primary outcome. The secondary outcomes included the increased use of eye protection, the costs for eye injury care, and environmental changes in the workplace.

**Study designs of evaluations included in the review:** All types of study designs were included in the review. These were controlled trials, observational studies, pre-test post-test evaluations, and comparisons to other populations. Only English language articles were considered for inclusion.

**What sources were searched to identify primary studies?:** Relevant studies from peer-reviewed journals, technical and government reports, and unpublished reports were retrieved using a systematic approach to literature searching. The databases searched were: MEDLINE from 1966 to 1999, EMBASE from 1974 to 1999, NIOSHTIC, from 1973 to 1999, and Dissertation abstracts from 1861 to 1999.

In addition, other relevant information sources were identified by checking references and consulting with experts in the field.

**Criteria on which the validity (or quality) of studies was assessed:** The author does not report a formal method for assessing validity. However, the methodological description and quality of the studies was discussed.

**How were decisions on the relevance of primary studies made?:** Abstracts were initially reviewed independently by two investigators for relevance. The potentially relevant articles were then obtained and independently screened. The author made the final decision on which articles were included.

**How were judgements of validity (or quality) made?:** The author does not state how the papers were assessed for validity, or how many of the reviewers performed the validity assessment.

**How were the data extracted from primary studies?:** The author does not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. The categories of data extracted from each study were: author, date, study population, sample size, intervention, study design, outcome measures, follow-up time period, findings and comments.

**Number of studies included in the review:** Seven studies met the inclusion criteria: 1 controlled study, 5 before-and-after studies, and 1 case-control study. Not all of the studies reported details on the number of participants.

**How were the studies combined?** A narrative synthesis was undertaken, with studies grouped by the type of intervention. Publication bias was not assessed.

**How were differences between studies investigated?:** Heterogeneity was not assessed.

**Results of the review:** Two studies involved multifaceted programmes with variable components, such as vision screening, education, provision of glasses at no charge, and policy changes requiring the use of eye protection. One of the studies, in which an official policy change was announced after the first wave of interventions, reported a 100% use of eye protection 8 weeks into the programme, compared with 10% at the initiation. This effect began to wane by the fifteenth week. This programme subsequently reported a 92% reduction in injuries and a 98% reduction in lost work time due to eye injuries. The other study reported a 75% reduction in injuries requiring medical care, and a 230% reduction in disabling eye injuries 4 years after the programme was initiated.

Two other studies involving primary policy changes both reported positive effects: one showed a greater than 50% reduction in eye injuries 5 months after the programme, whilst the other showed a 68% reduction in the number of injuries in the year after the programme. The varied magnitude of these effects could have been influenced by baseline rates or by changes in population sizes that were not reported consistently.

Two studies involved primarily behavioural interventions. One study reported a greater reduction in eye injury rates amongst those whose supervisors positively reinforced the use of eye protection: a decrease of 7.48 per 100 workers was reported among the experimental group, compared with 1.16 per 100 workers among controls. In addition, the experimental group had higher injury rates before the intervention than the control group. However, this study did not have adequate power to detect significant differences.

In the other study, short-term use of safety glasses increased from 84.7% during the baseline evaluation period, to 93% after signing a 'promise card' after worker training to garner the commitment to the use of eye protection. However, the behaviour was not maintained at a 1- and 2-month follow-up. The relatively high use of eye protection at baseline could have influenced these results.

In the case-control study, individuals with eye injuries were less likely to report the use of proper grinding goggles in preventing injuries from grinding operations (crude odds ratio 0.38), compared with other types of eye protection (face shields, standard spectacles with some side shielding, custom fit and a standard fit). A widespread use of incorrect protectors due to a misunderstanding of proper use was also reported.

**Was any cost information reported?:** No.

**Authors' conclusions:** There was some evidence that policy changes were effective in changing behaviours and reducing eye injuries in manufacturing settings, either in conjunction with a broader programme focusing on eye safety or by policy alone. However, there was limited scientific literature about the effectiveness of interventions in preventing eye injuries.

**CRD commentary:** The review question was stated clearly and was well supported by the study inclusion criteria. The literature search was comprehensive and identified unpublished reports. However, the author did not report whether foreign language papers were identified. The decision on whether or not to include retrieved articles was undertaken by only one reviewer.

There was no formal validity assessment of primary studies. The narrative synthesis of the results was appropriate, but heterogeneity was not assessed. Some details on the review process were provided, such as how decisions were made on the relevance of primary studies, whereas other details were missing, such as how the data were extracted from the primary studies.

The author's conclusions appear to follow on from the findings.

**What are the implications of the review?**

**Practice:** The authors state that there is evidence that policy changes may be effective in changing behaviours and reducing eye injuries in manufacturing settings, either in conjunction with a broader programme focusing on eye safety, or by policy alone. This review also indicates that workers might benefit from training that is specific to their tasks and exposures. This type of training should be directed by an appropriate hazard assessment, which should describe under what circumstances protection is needed, the appropriate type of protection required, and how and when to use the protection.

**Research:** The authors state that there is a need for systematic evaluation of interventions designed to prevent eye injuries, and how they may change the overall safety culture. Carefully designed controlled trials would allow a more clear understanding of the effects of different interventions in different work environments.

## Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings

Renders CM, Valk GD, Griffin S, Wagner EH, Eijh JThM van, Assendelft WJJ

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This review should be cited as: Renders CM, Valk GD, Griffin S, Wagner EH, Eijk JThM van, Assendelft WJJ. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings (Cochrane Review). In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 29 June 2000. Cochrane reviews are regularly checked and updated if necessary.

**Background:** Diabetes is a common chronic disease that is increasingly managed in primary care. Different systems have been proposed to manage diabetes care.

**Objectives:** To assess the effects of different interventions, targeted at health professionals or the structure in which they deliver care, on the management of patients with diabetes in primary care, outpatient and community settings.

**Search strategy:** We searched the Cochrane Effective Practice and Organisation of Care Group specialised register, the Cochrane Controlled Trials Register (Issue 4 1999), MEDLINE (1966-1999), EMBASE (1980-1999), Cinahl (1982-1999), and reference lists of articles.

**Selection criteria:** Randomised trials (RCTs), controlled clinical trials (CCTs), controlled before and after studies (CBAs) and interrupted time series (ITS) analyses of professional, financial and organisational strategies aimed at improving care for people with Type 1 or Type 2 diabetes. The participants were health care professionals, including physicians, nurses and pharmacists. The outcomes included objectively measured health professional performance or patient outcomes, and self-report measures with known validity and reliability.

**Data collection and analysis:** Two reviewers independently extracted data and assessed study quality.

**Main results:** Forty-one studies were included involving more than 200 practices and 48,000 patients. Twenty-seven studies were RCTs, 12 were CBAs, and two were ITS. The studies were heterogeneous in terms of interventions, participants, settings and outcomes. The methodological quality of the studies was often poor. In all studies the intervention strategy was multifaceted. In 12 studies the interventions were targeted at health professionals, in nine they were targeted at the organisation of care, and 20 studies targeted both. In 15 studies patient education was added to the professional and organisational interventions. A combination of professional interventions improved process outcomes. The effect on patient outcomes remained less clear as these were rarely assessed. Arrangements for follow-up (organisational intervention) also showed a favourable effect on process outcomes. Multiple interventions in which patient education was added or in which the role of the nurse was enhanced also reported favourable effects on patients' health outcomes.

**Reviewers' conclusions:** Multifaceted professional interventions can enhance the performance of health professionals in managing patients with diabetes. Organisational interventions that improve regular prompted recall and review of patients (central computerised tracking systems or nurses who regularly contact the patient) can also improve diabetes management. The addition of patient-oriented interventions can lead to improved patient health outcomes. Nurses can play an important role in patient-oriented interventions, through patient education or facilitating adherence to treatment.

**Cost analysis of child health surveillance**  
**Sanderson D, Wright D, Acton C, Duree D**  
**Health Technology Assessment Vol.5: No.36, 2001. ISBN: 13665278**

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This is a publication undertaken by a member of INAHTA. For further information please contact the agency using the contact details in the Correspondence Address field.

**Authors' objectives:** This report aims to provide: - estimates of the costs of individual components of the child health surveillance (CHS) programme - a register of the costs of each element of the CHS programme in a form that can be updated.

It was not part of the purpose of this work to evaluate the cost-effectiveness of CHS, because of the absence of information on the relative effectiveness of components of the programme.

**Type of intervention:** Health promotion

**Study Design:** Cost analysis

**Methodology:** The focus of the study was on costs to the NHS and parents, including the cost of first referrals arising from a routine CHS check. The working hypothesis was that costs are likely to be determined primarily by three variables: the range of tests offered at each visit, the location of the visit and the type of staff involved.

The first stage of the research was designed to identify the range of service models found in practice. A postal questionnaire was sent to relevant Trusts in England and Wales, requesting information on local CHS policy and delivery. Replies were received covering 88 Health Authorities: 81.5% of the possible total. The questionnaire demonstrated a high degree of homogeneity in policy, with most Authorities conforming closely to the recommendations contained in Health for all children. The main differences between Authorities appeared in the organisation of routine eyesight tests, and in the hearing distraction test (HDT).

A sample of 11 Health Authorities was selected. The sample was designed to be representative of differences in geography (north/south), rurality (rural/urban) and local policy on eyesight tests and the HDT. Two areas reporting the highest proportion of children from ethnic backgrounds were also included. The sampling unit was the main Community Trust providing CHS services within each Health Authority. The consultant community paediatrician at the Trust was asked to select two Trust-run clinics and three GP practices for the fieldwork, giving a sample of 55 subsites.

A member of the research team visited each sub-site as an observer. During the visit the researcher collected information on the time spent on each of the components of routine CHS checks and on the type of staff involved. Parents were also asked about the time and other costs involved in attending the clinic. Staff at each subsite completed activity timesheets prospectively over a 3-month period following the initial visit and recorded referrals arising from routine CHS activity.

The aim of the research was to provide information on the costs of individual components of the CHS programme in order to inform policy, and the focus of the study was on identifying the opportunity costs of variable inputs. The research demonstrated that the scale of CHS activity is such that no likely changes in the organisation or content of the programme would be expected to have a significant impact on fixed costs (such as the costs of land, premises or equipment). Costs are estimated on the basis of time inputs valued at midpoint salary scales plus on-costs. Costs associated with gaining qualifications and overhead costs are excluded from the analysis, although the identified costs can be increased by appropriate percentages to reflect these additional costs.

**Authors' conclusions:** Despite common policies (e.g. for a Health Authority), CHS checks (and their components) vary widely in their actual delivery.

Because components are often undertaken simultaneously, it is difficult to identify any significant time savings from omitting any of the individual elements (apart from the HDT and vision tests on separate occasions).

Data on the effectiveness of CHS checks in meeting their broad objectives and on the specific components in meeting their objectives are needed to complement the cost data - cheap models of delivery may or may not be cost-effective.

There appears to be great variation in the coverage of relevant health education topics.

Because of the wide diversity observed in practice, a register of the costed time inputs, which could be updated as salaries change, has not been prepared.

## **Are yearly physical examinations in adolescents necessary.**

**Stickler G B.**

**Journal of the American Board of Family Practice, 2000; 13(3), 172-177.**

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This record is a structured abstract written by CRD reviewers. The original has met a set of quality criteria. Since September 1996 abstracts have been sent to authors for comment. Additional factual information is incorporated into the record. Noted as (A:....).

**Authors' objectives:** To assess the effectiveness of yearly physical examinations in adolescents.

**Type of intervention:** Screening.

**Specific interventions included in the review:** Routine school and pre-athletic examinations by physicians or supervised health professionals were eligible. Examinations were conducted by individual physicians or teams, using an individual or a station approach. Presports examinations were conducted by physicians, nurse practitioners, orthopaedic and medical residents, paediatricians, orthopaediatricians, athletic trainers, sports physicians, and by multiple examiners.

**Participants included in the review:** Studies of male and female adolescents were eligible. Adolescents from various ethnic groups were included in the presports examinations.

**Outcomes assessed in the review:** The inclusion criteria were not defined in terms of outcomes. The principal outcome in the review was the prevalence of serious abnormalities found during the examinations, which required further observation, referral or treatment. The following were also assessed: increased blood-pressure; abnormal heart rates, including murmurs; scoliosis; diminished visual acuity; abnormal genitalia; and exclusions from sport for medical reasons. The definitions of abnormality varied across studies.

**Study designs of evaluations included in the review:** All series of routine school and pre-athletic examinations were eligible.

**What sources were searched to identify primary studies?:** MEDLINE and the Scientific Citation Index appeared to have been searched from their inception to 1995, for articles published in the English language, using the following keywords: 'school medical examinations', 'routine physical examinations in adolescents', 'sports examinations in adolescents' and 'preparticipation physical examinations'. Older literature (back to 1943) were found by reviewing references in more recent studies.

**Criteria on which the validity (or quality) of studies was assessed:** The authors do not report a method for assessing validity.

**How were decisions on the relevance of primary studies made?:** The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

**How were judgements of validity (or quality) made?:** The authors do not state how papers were assessed for validity, or how many of the reviewers performed the validity assessment.

**How were the data extracted from primary studies?:** The authors do not state how data were extracted for the review, or how many of the reviewers performed the data extraction. The tables in the review reported the following information for some studies: author; the number of adolescents and their gender; and the prevalence of specified pathological findings.

**Number of studies included in the review:** Twelve series with 20,047 adolescents were included: 3 routine physical examinations (7,953 adolescents) and 9 presports examinations (12,094 adolescents).

**How were the studies combined?:** Studies were combined in a narrative summary.

**How were differences between studies investigated?:** Differences were discussed in the text of the review, and results were presented separately for the routine physical examinations and presports examinations.

**Results of the review:** Routine school examinations: 3 series with 7,953 adolescents. No serious abnormalities were detected. The percentage of adolescents referred for further testing varied from 3.8 to 4% in the study described as the most detailed evaluation (985 adolescents), but most of the abnormalities were already known. Minor conditions revealed by screening included acne, reduced visual acuity, short stature, obesity and dental caries. Prevalence rates for individual conditions were as follows: increased blood-pressure, 0 to 0.4% in males and 0.2% in females; abnormal heart disease, 0.2% congestive heart disease and 0.7% rheumatic heart disease; abnormal heart murmur, 0.5% in males and 1.0% in females; hernia, 0 to 0.3%; undescended testis, 0 to 0.5%; and serious positive findings, 4% known before examination for one study, 3.8% unknown before examination for another study and not stated for the third study.

Presports examinations: 9 series with 12,094 adolescents.

Two major previously undetected abnormalities, i.e. one mitral valve insufficiency and one unilateral blindness, were found. The percentage of adolescents referred for further testing varied from 1.2 to 13.5%. All the students in the study reporting the highest referral rate were eventually allowed to participate in sports.

Minor orthopaedic problems were found in 1.8 to 16.8% of the students, with higher rates found when orthopaedic residents or physical therapists performed the examinations. The most frequent medical finding was a heart murmur that proved to be unimportant, or some previously known congenital heart defects. The definition of hypertension varied and rates of hypertension (across 4 series) ranged from 0.1 to 1.6%.

**Several factors were thought to limit the usefulness of the review:** Examinations were performed by different physician and paramedical teams; some examinations were conducted by individual physicians whilst others used the team or station approach; the definition of abnormality varied across studies; and most examinations were performed in students interested in participating in sports, and thus may not be representative of the age-group.

**Was any cost information reported?:** Cost analysis was reported in one series, which found that the cost per important finding was US\$4,537. This study also compared examination by physician with the station method, and found the latter to be less expensive.

**Authors' conclusions:** Yearly physical examinations in adolescents are not cost-effective and have practically no value in finding important pathological conditions. This conclusion would not apply to sexually-active teenagers. The value of an examination for health education, or for the detection of mental problems, has never been tested in this population. For entrance to schools or camps for sports participation, questionnaires and screening examinations by allied health providers should be used unless future studies justify yearly examination of adolescents.

**CRD commentary:** The aims were stated, and the inclusion criteria were defined in terms of intervention, participants and study design. By restricting the search to English language articles listed in two databases, other relevant studies may have been omitted. In addition, the lack of attempts to locate unpublished material raises the possibility of publication bias. The methods used to select studies and to extract the data were not described, and validity was not formally assessed. Some relevant data were presented in tables, but no information was provided on the adolescents undergoing routine physical examinations. The author discussed some limitations of the review in the text.

The evidence presented supports the author's conclusions though, as the author states, these results may not be representative of findings among the general adolescent population.

### **What are the implications of the review?**

**Practice:** The author states that healthy adolescents do not need yearly physical examinations and suggest the following screening programme.

1. In early adolescence: one thorough evaluation with recording of immunisation status using a questionnaire; screening for height, weight, vision and blood-pressure; and a physical examination.

2. At entry to high school, start of athletic programme and before college: a new questionnaire, screening tests, and inspection for scoliosis. Special risk groups, such as sexually active adolescents or students with known substance abuse, need to be examined more often. Health education should be part of the medical curriculum. Emotional problems would be more effectively detected by parents, trained teachers, counsellors and school nurses.

**Research:** The author did not state any implications for further research.

## **Adverse effects associated with selective serotonin reuptake inhibitors and tricyclic antidepressants: a meta-analysis**

Trindade E, Menon D, Topfer L A, Coloma C

Canadian Medical Association Journal, 1998; 159(10), 1245-1252.

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This record is a structured abstract written by CRD reviewers. The original has met a set of quality criteria. Since September 1996 abstracts have been sent to authors for comment. Additional factual information is incorporated into the record. Noted as (A:....).

**Authors' objectives:** To examine the adverse reactions associated with the use of selective serotonin reuptake inhibitors (SSRIs) and older tricyclic antidepressants (TCAs).

**Type of intervention:** Treatment.

**Specific interventions included in the review:** Antidepressant treatment with SSRIs (including fluoxetine, fluvoxamine, paroxetine, and sertraline) and TCAs (including secondary, tertiary and quaternary amines) was studied.

**Participants included in the review:** Participants were patients for major depression as defined by DSM-IV criteria.

**Outcomes assessed in the review:** Outcomes were the following adverse reactions for which data from at least 6 trials was available: headache; tremor; urinary disturbances; hypotension; dry mouth; constipation; dizziness; sweating; blurred vision; palpitations; nausea; anorexia; diarrhoea; insomnia; nervousness; fatigue; agitation; and anxiety. Drop-outs due to adverse reactions were also considered.

**Study designs of evaluations included in the review:** Double-blind randomised controlled trials (RCTs) that compared an SSRI with a TCA for major depression were included if they fulfilled the following criteria: study was of 4 to 12 weeks duration; trials had at least 20 patients in each arm; and study reported the number of patients with adverse effects in both the SSRI and TCA arm.

**What sources were searched to identify primary studies?:** The following data bases were searched from January 1980 to May 1996: MEDLINE; EMBASE; PsycINFO; International Pharmaceutical Abstracts; Pascal; Health Planning and Administration (Health); Mental Health Abstracts; and Adis PharmacoEconomics and Outcomes News. Regular searches were made of Current Contents: Clinical Medicine and hand scanning of Journals received by the Canadian Coordinating Office of Health Technology Assessment library throughout the study period. Key words included the following: serotonin uptake inhibitor(s); SSRI(s); antidepressant(s); monoamine oxidase inhibitor(s); antidepressant agents; tricyclic; and the names of the various drugs. References from retrieved articles were scanned and further references obtained from bibliographies provided by other researchers. Additional references were identified from earlier publications on the topic including those by the US Agency for Health Care Policy and Research, clinical practice guidelines, and the UK National Health Service, Centre for Reviews and Dissemination.

**Criteria on which the validity (or quality) of studies was assessed:** The authors do not report a method for assessing validity.

**How were decisions on the relevance of primary studies made?:** The authors do not state how the papers were selected for review, or how many of the authors performed the selection.

**How were judgements of validity (or quality) made?:** The authors do not state how the papers were assessed for validity, or how many of the authors performed the validity assessment.

**How were the data extracted from primary studies?:** Data extracted included the following: sample size by treatment arm; adverse reactions by drug treatment; drop-out rates due to adverse reactions; and methods used to elicit information about adverse effects. The differences in rates of occurrence of specified adverse reactions between treatment arms was calculated for each trial.

**Number of studies included in the review:** 84 double-blind RCTs were included.

**How were the studies combined?:** For each adverse effect a pooled rate difference and 95% confidence interval was obtained by a Bayesian hierarchical meta- analysis.

**How were differences between studies investigated?:** The influence of the method of eliciting information on adverse reactions was tested by grouping the trials according to the method used, then calculating within each group the weighted pooled rate difference between the SSRI and TCA arms for 2 adverse reactions (nausea and dry mouth). Weighting was by variability of each trial.

Pooled rate differences were calculated for each of 4 SSRI and TCAs as a whole. Rates of discontinuation due to adverse reactions were calculated for individual SSRIs or any SSRI and compared with rates for secondary, tertiary, quaternary amines or any TCA. A sub-set meta-analysis compared drop out rates for SSRIs vs TCAs for trials restricted to adult out-patients.

**Results of the review:** Crude rates of occurrence of adverse reactions SSRI vs TCA: constipation (49 trials) 11% vs 22%; dizziness (37 trials) 14% vs 23%; hypotension (8 trials) 9% vs 16%; dry mouth (56 trials) 22% vs 27%; blurred vision (19 trials) 10% vs 14%; sweating (27 trials) 10% vs 14%; urinary disturbance (14 trials) 6% vs 9%; palpitations (11 trials) 4% vs 5%; fatigue (23 trials) 10% vs 11%; tremor (37 trials) 15% vs 15%; anorexia (11 trials) 9% vs 8%; nervousness (14 trials) 14% vs 10%; agitation (11 trials) 12% vs 8%; headache (32 trials) 18% vs 14%; insomnia (32 trials) 12% vs 7%; anxiety (17 trials) 14% vs 7%; diarrhoea (15 trials) 16% vs 4%; nausea (56 trials) 26% vs 11%.

Adverse effects for which there was no statistically significant difference between any one of 4 SSRIs and TCAs: headache, tremor, urinary disturbance, and hypotension.

Adverse effects that occurred statistically significantly more often with TCAs than with at least one of the SSRIs: dry mouth, constipation, dizziness, sweating, blurred vision, and palpitations. Adverse effects that occurred statistically significantly more often with at least one of the SSRIs than with TCAs: nausea, anorexia, diarrhoea, insomnia, nervousness and fatigue.

Adverse effects for which there was no significant rate differences between any individual SSRI and the group of TCAs: agitation and anxiety. Statistically significant difference noted for agitation and anxiety when SSRI data was pooled.

After pooling data for all SSRIs results were as follows: Adverse effects that occurred statistically significantly more often with SSRIs: nausea, anorexia, diarrhoea, insomnia, nervousness, agitation and anxiety. Adverse effects that occurred statistically significantly more often with TCAs: dry mouth, constipation, dizziness, sweating and blurred vision.

**Method of eliciting information about adverse effects:** Details of the method was omitted from some studies. Rate differences were statistically significant for nausea with SSRIs compared with TCAs when information was sought using checklists, questions that indirectly addressed adverse effects, or spontaneous reporting by the patients, but not statistically significant when using Treatment Emergent Symptom Scale. Rate differences were statistically significant using all the above methods for dry mouth but were not statistically different from each other.

Drop-outs due to adverse effects (70 studies): No statistically significant differences in rates for individual SSRIs or any SSRI vs secondary, tertiary and quaternary amines or any of TCAs.

Sub-set analysis restricted to adult outpatients: 2% fewer drop- outs due to SSRIs (statistically significant).

**Was any cost information reported?:** No.

**Authors' conclusions:** SSRIs and TCAs are both associated with adverse effects although the key effects differ between classes. Further explanation of the adverse effects and their relation to discontinuation of medication will require better studies involving prospective collection of quality of life data.

**CRD commentary:** The aims and inclusion criteria are clearly stated. An extensive literature search was conducted. Some investigation was conducted into factors differing among trials. Discussion includes consideration of the following: potential difference between statistically significant and clinically significant rates; insufficient data available to allow comparison of rare event such as suicide; the potential influence of reporting methods on rates reported; unblinding of health professionals due to the profile of adverse reactions reported by patients; no definition of end-points before commencement of individual trials; potential heterogeneity of population; high incidence of symptoms resembling adverse reactions among depressed patient before therapy was started; and lack of reporting of the intensity of symptoms or the impact on patient's quality of life. The paper is based on a larger study of clinical trials of antidepressants (see Other Publications of Related Interest).

No details are given of methods used to select primary studies or extract data and no details are given of the individual trials. Neither validity nor heterogeneity among trials was assessed. Potential bias due to selective reporting of adverse effects cannot be ruled out because the relevant outcomes were not available in a large number of trials.

The conclusions are supported by the evidence presented.

**What are the implications of the review?**

**Clinical:** The authors do not state any clinical implications of the review.

**Research:** The authors consider that more systematic reporting of adverse effects is necessary to increase estimates of rate difference.

## Photodynamic therapy for neovascular age-related macular degeneration

Wormald R, Evans J, Smeeth L, Henshaw K

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This review should be cited as: Wormald R, Evans J, Smeeth L, Henshaw K. Photodynamic therapy for neovascular age-related macular degeneration (Cochrane Review). In: The Cochrane Library, Issue 3, 2002. Oxford: Update Software.

A substantive amendment to this systematic review was last made on 30 May 2001. Cochrane reviews are regularly checked and updated if necessary.

**Background:** In neovascular age-related macular degeneration, new vessels grow under the retina, distorting vision and leading to scarring. This is further exacerbated if the blood vessels leak.

Photodynamic therapy, originally used in cancer treatment, has been investigated as a way to treat the neovascular membranes without affecting the retina.

**Objectives:** The aim of this review is to examine the effects of photodynamic therapy in the treatment of neovascular age-related macular degeneration.

**Search strategy:** We searched for trials in the Cochrane Controlled Trials Register - CENTRAL (which includes the Cochrane Eyes and Vision Group specialised register), MEDLINE and EMBASE. We used the Science Citation Index to search for reports that cited relevant study reports. We contacted experts in the field and we searched the reference lists of relevant studies for further trial reports.

**Selection criteria:** We included randomised trials of photodynamic therapy in people with choroidal neovascularisation due to age-related macular degeneration.

**Data collection and analysis:** Two reviewers extracted the data independently. As only one trial met the inclusion criteria, meta-analysis was not performed.

**Main results:** One published trial was identified which randomised 609 participants. Outcome data were available at 12 and 24 months after the first treatment. Participants in the treatment group received an average of 3.4 treatments in the first year, and 2.2 in the second year. The relative risk of losing three or more lines of visual acuity at 24 months comparing the intervention with the control group was 0.75 (95% confidence interval 0.65 to 0.88). The relative risk of losing six or more lines of visual acuity at 24 months comparing the intervention with the control group was 0.61 (95% confidence interval 0.45 to 0.81). The results at 12 months were similar to those at 24 months. Subgroup analyses suggest that the benefits may be confined to people with no occult choroidal neovascularisation.

**Reviewers' conclusions:** Photodynamic therapy in people with classic choroidal neovascularisation due to age-related macular degeneration is effective in preventing visual loss. This evidence is drawn from a subgroup analysis of 143 participants in one trial. Outcomes and potential adverse effects of this treatment should be monitored closely. There is no evidence that photodynamic therapy is beneficial for people with evidence of occult choroidal neovascularisation. These people should be offered treatment only in the context of a randomised trial.

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