IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

IQWiG Reports - Commission No. S05-02

# Screening for visual impairment in children younger than 6 years[1]

# Executive Summary

[1] Translation of the executive summary of the final report "Früherkennungsuntersuchung von Sehstörungen bei Kindern bis zur Vollendung des 6. Lebensjahres" (Version 1.0; Status: 01.04.2008). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

# Publishing details

**Publisher:**
Institute for Quality and Efficiency in Health Care

**Topic:**
Screening for visual impairment in children younger than 6 years

**Contracting agency:**
Federal Joint Committee

**Commission awarded on:**
15.03.2005

**Internal Commission No.:**
S05-02

**Publisher's address:**

Institute for Quality and Efficiency in Health Care
Dillenburger Str. 27
51105 Cologne
Germany

Tel: ++49 (0)221/35685-0

Fax: ++49 (0)221/35685-1

E-mail: berichte@iqwig.de

Homepage: www.iqwig.de

# Executive summary

## Research question

The main aim of this review was the benefit assessment (i.e. the assessment of patient-relevant outcomes) of screening for visual impairment (universal vision screening) in children up to the age of 6. By diagnosing and treating amblyopia or amblyogenic risk factors as early as possible, paediatric developmental delay and its potentially lifelong consequences should be prevented, or at least ameliorated.

## Methods

The report investigated the research question in a descending hierarchical approach: the greatest evidential value was to be provided by studies investigating the whole screening chain, thus providing the best answer to the question about the benefit of universal vision screening. These studies are presented in the *screening section* of the report. If no clear evidence was available from these studies, then evidence of the effectiveness of screening might also be valid if sufficient evidence of the benefit of earlier vs. later treatment was available, and if visual impairment in the relevant age group could be diagnosed appropriately. With this aim in mind, the *treatment section* investigates the benefit of earlier initiation of treatment as a necessary precondition for screening. The *diagnostics section* deals exclusively with the diagnostic accuracy of the relevant screening tests.

Studies were assessed that included children up to the age of 6 from the total population (preschool children). Studies in children with risk factors (e.g. diabetes, dyslexia, deafness, or congenital disorders) were excluded, independent of whether such factors are associated with visual disorders or not. Nor were studies considered in children with organic eye diseases (e.g. congenital glaucoma, cataract, retinoblastoma, premature retinopathy, and other congenital defects of the eye or optic tract).

The screening section includes only studies in which universal screening was compared with no screening, or screening strategies of varying intensity were compared. For treatment studies, there were no restrictions concerning the type of treatment.

For the direct benefit assessment of screening programmes, randomised controlled trials (RCTs) were assessed; as a supplement, non-randomised intervention and cohort studies were also considered. A separate benefit assessment of earlier treatment was conducted by means of *direct comparisons* (within a study) on the basis of RCTs and non-randomised intervention studies, as well as by *indirect comparisons* (between different studies), which were exclusively based on RCTs. All study types were eligible in the separate assessment of diagnostic procedures.

The study endpoints used were those that allowed an assessment of patient-relevant outcomes. The outcomes investigated included: health-related quality of life (e.g. emotional deficits, psychosocial deficits such as social isolation, development of self-concept); vision; cognitive and educational disadvantages (e.g. school failure, lack of educational options); adverse effects of screening/diagnosis due to false-positive or false-negative test results (e.g. parental anxiety, over-treatment) or “labelling”; and adverse effects of treatment (e.g. psychological effects of earlier or later intervention).

The systematic literature search was conducted in 9 electronic databases (including MEDLINE, EMBASE, and COCHRANE CENTRAL), and covered the period up to December 2007. In addition, reference lists of primary and relevant secondary publications were screened (e.g. systematic reviews, HTA reports, evidence-based guidelines), as well as comments on the list of questions of the Federal Joint Committee. Moreover, requests for data were made to the manufacturers of the relevant medicinal products.

The literature screening was performed by at least 2 reviewers independently of each another. The prespecified methodological approach (report plan) and IQWiG's preliminary benefit assessment (preliminary report) were published on the IQWiG website, and interested persons and parties were invited to submit comments. Insofar as changes were made on the basis of unclear aspects addressed in the comments, this was noted in the report. Relevant unclear aspects were discussed in a scientific debate. The final report was subsequently prepared.

**Results**

A comprehensive systematic search in bibliographic databases and other sources identified a total of 36 studies, which, with reservations, allowed robust conclusions on the benefit of universal vision screening in preschool children. These studies included 5 screening studies, 7 treatment studies, and 27 diagnostic studies (in addition, 3 screening studies were also included in the diagnostics section of the report).

A total of 1 RCT, 1 non-randomised controlled study, and 3 cohort studies were identified for the comparison of screening programmes of varying intensity and, in one case, for screening vs. no screening. Seven controlled studies (including 5 RCTs) were included in the assessment of the effects of earlier vs. later treatment. The assessment of diagnostic test accuracy was based on cross-sectional studies (with 2 exceptions). Most studies were of limited quality: 25 of 39[2] studies were classified as showing "major deficits" ("minor deficits": 13; "no deficits": 1). The results should therefore be interpreted with caution.

The studies included results on the outcome "visual acuity", as well as on the additionally assessed outcomes "strabismus" and "refractive errors". No data were available on other relevant outcomes (e.g. quality of life, mental health, satisfaction, educational and occupational development). In addition, due to the insufficient data basis, no robust conclusions could be made on potentially harmful aspects of screening or on earlier initiation of treatment.

*Screening*

The evidence obtained from the 5 screening studies identified did not provide a consistent picture. Three studies indicated a beneficial effect (with regard to vision); however, this was qualified by the poor study or publication quality.

[2] The 39 studies included 3 studies that were considered both in the screening and in the diagnostics section, and, depending on the section, had to fulfil different requirements regarding study quality.

*Treatment*

The results of the 7 treatment studies (comprising 5 direct comparisons and 1 indirect comparison between 2 studies) were also not homogeneous. With regard to the primary outcome "visual acuity", 2 studies and 1 indirect comparison between 2 studies indicated an advantage of earlier treatment; the effect detected was questionable in 1 study due to a substantial bias potential, evidently caused by different study populations. The initially impressive effect from the indirect comparison disappeared if one considered the (more interesting and actually more meaningful) subgroup of children who did not receive prior treatment. The third study found a small but significant effect. In contrast to the common justification for the conduct of screening, the results from the indirect comparison (2 RCTs) indicated that treatment of amblyopia may also be successful after the age of 6 (until adolescence) and may achieve comparable results to those in younger children. A further study showed that delaying amblyopia treatment by one year (in children aged 4 at the time of diagnosis) evidently had no demonstrable disadvantage in affected children.

*Diagnostics*

In the diagnostic studies, the particular problem existed that comparable reference standards were hardly applied, and that an estimation of the accuracy of relevant diagnostic procedures on the basis of several studies was therefore not possible. Furthermore, it was relevant that a screening test intended to fulfil 2 requirements, namely the identification of the manifest disease and its risk factors. However, for each risk factor different test procedures with different reference standards were applied. In addition, recognized gold standards were only available for a few study outcomes.

The main aspect of the prognostic value of a diagnosis made in early childhood was represented in 3 of 27 studies on diagnostic accuracy. However, in all cases methodological limitations existed. Singular tests validated against a reference test combination that covered both manifest amblyopia as well as its risk factors were also of interest. Even without a specific singular test or test combination demonstrating a clear advantage on the basis of test characteristics, the reference standards described in the studies varied so widely regarding their defined reference populations that an estimation of the test accuracy of singular tests or test combinations was impossible. This heterogeneity of the reference tests used was the reason that the populations defined in this way were not identified in the treatment studies. It cannot therefore be estimated with which diagnostic accuracy and precision children could be identified for whom a possible advantage through earlier initiation of treatment was shown in treatment studies. For 1 treatment study, agreement could be assumed (with limitations); this study found a moderate or no treatment advantage for the target population identified in such a way.

Neither evidence nor clear indications of a benefit or harm through screening could ultimately be inferred from the studies; however, nor could the lack of a benefit or harm.

*Conclusions*

No robust conclusions can be directly inferred from the studies identified, so that neither evidence nor indications of a benefit of preschool vision screening are available. This is not

only due to the small number, poor quality, and inconsistent results of studies, but also to the lack of studies on potentially harmful aspects of vision screening.

However, the lack of effects noted in comparisons between vision screening programmes of *varying intensity* do not in principle exclude the existence of a benefit, as the studies did not have the discriminatory power to detect smaller differences. A comparable situation exists in the German health care setting: against the background of the legally specified paediatric screening tests (§ 26 SGB[3] V), where 8 of 9 examinations include the visual system, a vision screening programme would have to show a(n) (additional) benefit compared with the current health care setting. As there is also no evidence base for paediatric screening tests that fulfils the formulated requirements, in this context the term *additional benefit* is to be regarded relatively in the sense of a comparison with the (established) current setting.

From the combination of the results of treatment and diagnostic studies, the necessary preconditions for a screening programme could at least be inferred indirectly. For this, it would first have to be demonstrated that earlier treatment of visual impairment (in preschool age) is superior to treatment in school age (or later). Secondly, it would have to be shown that children treated earlier could be diagnosed with sufficient reliability, so that any harm (which cannot be excluded and can be caused solely by false diagnoses) did not outweigh the potential benefit. No evidence or clear indications were found for either of these 2 aspects. In fact, the findings indicate that later treatment of amblyopia in school age could possibly result in comparable outcomes.

No reliable conclusions on the reliability of diagnosis can be inferred from studies on the diagnostic accuracy of the tests applied; in particular, this refers to amblyopia or amblyogenic visual disorders *in need of treatment*. This is mainly caused by the (cross-sectional) study design, which is unsuitable for this purpose.

Even if the direct and indirect evidence found does not in principle call a possible benefit of a screening programme into question, at this point in time it does not seem justified to infer a rationale for *intensifying* screening procedures already implemented. These intensified procedures would mainly affect children with normal vision (i.e. children not needing treatment), and would be conducted without evidence-based knowledge of the potentially harmful effects in inevitably overtreated children.

**Key words**

Vision screening, amblyopia, visual impairment, strabismus, refraction, systematic review

[3] Sozialgesetzbuch = Social Code Book