MANUAL FOR IMPLEMENTATION OR MODIFICATION OF CHILD VISION AND HEARING SCREENING PROGRAMMES

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THE EUSCREEN STUDY

THE EUSCREEN STUDY AIMED TO COMPARE VISION AND HEARING SCREENING PROGRAMMES FOR CHILDREN IN ALL EU STATES BY USING A COST-EFFECTIVENESS MODEL. THE COST-EFFECTIVENESS MODEL PREDICTS THE MOST COST-EFFECTIVE AND AFFORDABLE WAY TO SCREEN CHILDREN IN EACH COUNTRY, GIVEN THE LOCAL CIRCUMSTANCES.

REPRESENTATIVES OF COUNTRIES IN EUROPE WERE ASKED TO PROVIDE DETAILED DATA ON THE FOLLOWING DOMAINS: DEMOGRAPHY, THE GENERAL BACKGROUND OF SCREENING SYSTEMS, EXISTING SCREENING SYSTEMS, COVERAGE/ATTENDANCE, TESTS USED, FOLLOW-UP/DIAGNOSIS, TREATMENT, BENEFITS AND ADVERSE EFFECTS. PAEDIATRIC OPHTHALMOLOGISTS, PAEDIATRIC OTOLARYNGOLOGISTS, AUDIOLOGISTS AND PROFESSIONALS WHO ORGANISE AND PERFORM SCREENING IN EACH COUNTRY WERE INVITED TO PARTICIPATE IN THE STUDY AND REPORT ON THE STATE OF SCREENING IN THEIR COUNTRY. AN EXTENSIVE, DETAILED QUESTIONNAIRE WAS DEVELOPED FOR THAT PURPOSE.

SCREENING PROGRAMMES HAVE BEEN TESTED IN THE COUNTY OF CLUJ IN ROMANIA FOR VISION, AND IN THREE COUNTIES IN ALBANIA FOR HEARING SCREENING. THIS MANUAL FOR IMPLEMENTATION OR MODIFICATION OF CHILD VISION AND HEARING SCREENING PROGRAMMES WAS DEVELOPED BY DETAILED TRACKING, AND FROM IDENTIFIED REQUISITES, FACILITATORS AND BARRIERS.

THE COST-EFFECTIVENESS MODEL AND THIS MANUAL FOR IMPLEMENTATION WILL ASSIST HEALTHCARE PROVIDERS AND POLICY MAKERS WORLDWIDE IN THEIR DECISIONS TO INTRODUCE OR MODIFY VISION AND HEARING SCREENING PROGRAMMES, AND INCREASE EFFECTIVENESS, EFFICIENCY AND EQUITY OF CHILD HEALTHCARE.
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Part I: background
1. INTRODUCTION

*Chapter editor: Huibert Jan Simonsz*

a. The EUSCREEN study

*Mission*

The EUSCREEN study compares the cost-effectiveness of paediatric vision and hearing screening programmes in Europe and has developed a cost-effectiveness model that can be used to assist with introduction, modification or disinvestment of a screening programme in a country, taking local circumstances into account, such as professionals available to screen and existing screening pathways.

A pilot study showed that there are vast differences between paediatric vision and hearing screening programmes and that data on these programmes regarding professionals involved, tests and thresholds used, age of the children screened, funding sources and so forth, are often unavailable.\(^1\)

*Collection of data*

Paediatric ophthalmologists and paediatric otolaryngologists as well as audiologists and professionals who organise and perform screening in countries that participate in the European Union’s Horizon 2020 research and innovation programme, were invited to participate in the study and report on the state of screening in their country. Several other countries also expressed an interest in the study and eventually five additional countries supplied data.\(^2\) An extensive, detailed questionnaire was developed for this purpose. These representatives provided data on their countries’ demography, existing screening programmes, coverage/attendance, tests used, follow-up/diagnosis, treatment, benefits and adverse effects.

*Initial conclusions*

The survey showed that there is substantial variation in hearing and vision screening programmes. The tests used, types of professionals involved in screenings, definitions of target conditions, frequency and location of testing and diagnostic pathways differ significantly between, and even within, countries. Monitoring and quality assurance are not routinely or systematically performed, even in countries with otherwise well-organised screening programmes. These issues make it very difficult to compare the effectiveness and cost-effectiveness of screening programmes. The lack of monitoring perpetuates the large
diversity among screening programmes in Europe. Also, there is little to no communication between countries concerning screening programmes. We have developed an interactive cost-effectiveness model to facilitate the comparison of different hearing and vision screening programmes. The model can calculate the most cost-effective and affordable way to screen children in each country or region, taking local circumstances into account: existing provision of preventive healthcare to children, availability of professionals who could screen, available budget and priority given based on prevailing healthcare of children. It should be noted that accuracy of the cost-effectiveness is highly dependent on the quality of the input data. Alongside the development of the model and informed by its preliminary predictions, a hearing screening programme has been implemented in three counties in Albania and a vision screening programme in Cluj County in Romania. Both are High Middle Income Countries (HMICs) who do not have these forms of screening yet. Information gathered by these implementation studies has been used to validate and calibrate the model and also provide additional qualitative data on challenges and practical issues not covered by the model.

b. Development and purpose of this manual
This manual is a product of the EUSCREEN study and contains a generic strategy for implementation of child hearing and vision screening programmes. This strategy has been developed based on analysis of existing screening programmes, model calculations, expert opinion and experiences with the aforementioned implementation studies.

This manual is a complimentary resource to the EUSCREEN cost-effectiveness model: the model compares different hypothetical screening programmes to calculate the most cost-effective programme for a specific country or region. The manual subsequently serves as a practical strategy guide for implementing said programme. The model and manual are therefore complementary.

c. Outline and target audiences
This manual should serve as a useful companion for stakeholders such as professionals deciding to implement a programme, persons or teams managing screening programmes, as well as healthcare policy makers and governmental healthcare administrators.

The manual consists of five parts. Part I provides background information on hearing and vision screening and, because of its general nature, is likely to be of interest to all readers.
Part II deals with establishing a framework for hearing and vision screening programmes and should be of interest to governments and policy makers. These chapters describe the implementation process on a strategic level, based on scientific evidence and data collected within the EUSCREEN study. This section of the manual provides an overview of things to consider and investigate before using the model.

Parts III and IV are practical guides for factors to consider in the implementation of hearing and vision screening programmes respectively. These parts of the manual will be of most use to management teams. These chapters describe the implementation process on an operational level and provide information on what to consider when implementing a screening programme. The information is based on evidence collected within the EUSCREEN study, such as the observations from the implementation of hearing and vision screening in Albania and Romania respectively.

Part V covers communication and monitoring of child vision and hearing screening programmes. These may be the most important chapters of the manual, as the main conclusion of the EUSCREEN study was that, even most countries where screening programmes are otherwise well-organised, appear not to have systematic monitoring systems: data on these programmes are generally reported to not be easily accessible or completely unavailable.

Note that information in the general parts of the manual - chapters not specifically about either hearing or vision screening - applies to both hearing and vision screening, unless specifically stated otherwise.

For a concise introduction to the general concepts of screening, this document published by the World Health Organization in 2020 is a recommended read for policy-makers and public health professionals. The document describes various aspects to consider before starting, continuing or stopping a programme. It also goes into the operational, monitoring and evaluation aspects.

**d. Definition and history of medical screening**

Medical screening has been defined as “actively seeking to identify a disease or pre-disease condition in individuals who are presumed and presume themselves to be healthy”.³

Medical screening is screening offered to persons within an identified target population, defined for example by age, sex or risk. This is different from diagnosis following a patient’s presentation of symptoms.⁴ The objective of screening, in general, is to identify an
unrecognised disease or condition. In case of paediatric vision and hearing screening, the objective is to identify functional sensory losses as early as possible.

A screening programme can be either universal or targeted. A universal programme offers screening to all in the target population, while a targeted programme only offers screening to those in the target population who are considered to be at greater risk for the condition being screened for. The advantage of targeted screening is that it costs less, but the disadvantage is that a substantial number of persons with the target condition may be missed. Which option is the most cost-effective will mostly depend on the prevalence of the condition among persons not considered to be at greater risk.

Historically, screening became practically possible when the following conditions were met:

- establishment of a theory of screening
- availability of simple, valid and acceptable tests
- effective treatments
- widespread access to healthcare

Although there were earlier initiatives that could, in retrospect, be qualified as screening, large-scale population screening began during the inter-war years to identify latent tuberculosis in children, by means of radiological examination. The term ‘screening’ originates from the fact that the X-ray images were viewed on a screen. With new technology becoming available, the decades following World War II were marked by an extensive proliferation of screening programmes. Radiography for tuberculosis was extended to the whole population and screening programmes were initiated for a variety of afflictions such as syphilis, diabetes, glaucoma, anaemia, obesity, visual defects, hearing loss, hypertension and heart disease. Since the early 1960s, screening of newborns for various diseases has also become common, beginning with Guthrie’s phenylketonuria (PKU) test.

In 1968 the World Health Organization (WHO) published screening criteria (see chapter 2a) and nowadays, screening programmes are widespread in most High Income Countries (HICs). Screening programmes are especially common for different forms of cancer as well as for a wide variety of other diseases.

In the last decades of the past century, screening programmes have also begun to draw criticism, mainly focused on ethical and psychological aspects, the relation between benefits and harms and (cost-)effectiveness.
e. Child vision and hearing screening

The United Nations’ Convention on the Rights of the Child recognises the right of all children to “the highest attainable standard of health” and to an education which supports “the development of the child’s personality, talents and mental and physical abilities to their fullest potential”. The World Health Organisation’s 2021 World Report on Hearing further stresses the important role of hearing screening and early intervention to enable the optimum development of a child with hearing loss and includes a worldwide Call to Action. Both vision and hearing problems may go unnoticed by parents. In addition, early identification and treatment of vision and hearing problems have been shown to lead to better outcomes. Screening for vision and hearing problems in children are therefore considered important.

i. Vision screening

There are several types of vision screening: newborn vision screening (chapter 7) targets severe sight-threatening ocular diseases such as cataract, neonatal ocular infections, corneal opacities and ocular tumours. The common causes of low vision in children, such as refractive error or strabismus or amblyopia develop or change after the neonatal period, and therefore should be screened for later.

Beyond the neonatal period the detection of amblyopia is the primary target condition because it needs to be treated in early childhood to avoid permanently reduced vision. It is also the most common cause of low visual acuity in childhood. Amblyopia is a loss of vision mostly affecting one eye due to lack of adequate visual experience during the critical period of visual development. The reported prevalence of amblyopia varies, depending on study population and the definition of amblyopia used, but overall international prevalence estimates range from 1% to 5%. 15% of children under 12 years of age have been shown to have significant refractive errors to cause a significant reduction in uncorrected vision. These conditions are therefore sufficiently common to justify screening programmes.

If amblyopia is left untreated and later in life vision in the other eye is impaired, having an amblyopic eye may make the difference between a normal life and bilateral visual impairment. The treatment for amblyopia in childhood is simple, low-cost, highly successful with life-long improved vision and will protect many of those treated from future visual disability.

Amblyopia is asymptomatic in young children and rarely noticed by parents, except when caused by large angle strabismus or when bilateral and severe. It is much more easily treated in early childhood (before 7 years of age). Without early screening amblyopia is rarely detected until it is too late to be easily treated. Amblyopia is rarely disabling in childhood, but children with low vision due to uncorrected high refractive errors are likely
Manual for implementation or modification of child vision and hearing screening programmes

to be socially and educationally disadvantaged. The goals of vision screening are therefore to identify and correct poor vision in childhood due to amblyopia and significant refractive errors. Screening for amblyopia by measurement of visual acuity at the age of 4, 5 or 6 years is standard in almost all countries in Europe. Other forms of vision screening in childhood are:

- risk factor screening (which targets risk factors for amblyopia, not low vision itself);
- screening of at-risk groups (children born prematurely, or those with disabilities or special educational needs have a higher prevalence of visual defects so they may be targeted specifically, more frequently or with more specific or in-depth testing);
- screening in later childhood. Screening for visual defects beyond seven years of age is not covered in this manual because amblyopia is difficult to treat by this time.

There are many factors that make decisions of how, when, and how often to screen surprisingly complex, and with very different cost-effectiveness implications. Evidence shows amblyopia treatment is more successful when undertaken before the age of seven years, therefore it is desirable to screen children as early as possible. However, in children younger than four years the rate of reliable visual acuity measurement may be too low for screening to be cost-effective, because a much larger percentage of children will need to be tested again or referred to diagnostic assessment. Visual acuity screening is therefore recommended in children no younger than four years and no older than six years. However, screening may need to be offered to older children who may have relocated from a region without vision screening and have not been screened before they were six years old.

Since the early 2000s, screening for risk factors for amblyopia has been advocated instead of measuring visual acuity to establish the diagnosis of amblyopia. Risk factors for the development of amblyopia are strabismus, which is conspicuous for the parents in most cases, and refractive error, especially when strong glasses are needed to correct them. However, there are many issues which make the apparent advantages of this approach less clear than they may seem. Arguments for and against screening for amblyopia versus screening for risk factors for the development of amblyopia are covered extensively in chapter 8.

**ii. Hearing screening**

Undiagnosed or late-diagnosed hearing loss in children can have severe negative impact on development of effective language and communication. Unrecognized childhood deafness not only affects speech, language and communication development, but also social and
emotional development, mental health and family relationships. The disability implications range from mild to severe, depending on the degree of hearing impairment, but can lead to significant educational underachievement which may result in an economic burden to society. Early identification and intervention can lead to better language skills, lower educational costs, and increased lifetime productivity.

The prevalence at birth of bilateral permanent sensorineural hearing loss with hearing thresholds greater than 40 dB is approximately 0.1-0.2% and that number increases to 0.2%-0.3% by the age of nine. The World Health Organization defines disabling hearing loss as “hearing loss greater than 40 dB in the better hearing ear in adults and a hearing loss greater than 30 dB in the better hearing ear in children”. Permanent hearing loss in newborns may be caused by genetic disorders, infectious diseases, or complications related to birth and the neonatal period.

Intervention for hearing loss varies with the type and degree of hearing loss, but the most common interventions are hearing aids and/or cochlear implants. Both types of treatment are feasible in very young children; yet for successful rehabilitation, children using these devices and their parents require intensive support by audiologists, teachers of the deaf, speech therapists and other healthcare or specialist education providers. Before early identification and intervention became possible, children with severe or profound hearing loss typically attended special (often residential) schools for the deaf. As early diagnosis, technology and appropriate interventions improved and became available for many children with hearing loss, attending mainstream education became more widespread.

With modern technology, objective hearing screening devices allow healthcare providers to feasibly and accurately identify hearing loss in a newborn population. Countries, regions, and hospitals across the world have implemented newborn hearing screening (NHS; see chapter 5) targeted at early detection of sensorineural hearing loss. All newborns may be screened using the same test protocol (type and timing of the hearing test and retest). In certain subpopulations, such as infants treated in a neonatal intensive care unit (NICU), it may be relevant to apply a special protocol. Important considerations in these infants include the much higher prevalence of hearing loss, and the detection of auditory neuropathy spectrum disorder (ANSD).

The prevalence of hearing impairment (HI) in children increases with age. This increase can be caused by delayed onset HI, undetected mild HI that has progressed or acquired HI due to infections, trauma and other causes. Further, children may have relocated from a region without NHS, never having had their hearing screened previously. In fact, around
half of all school-age children with hearing loss may be detected later in childhood. These children can be detected by preschool- and/or school-age hearing screening (chapter 6).

By far the most relevant disease in infancy and childhood with regard to hearing loss, is otitis media. **Otitis media with effusion** (OME) is very common during the first six years of life and may cause a conductive hearing loss of, on average, 25-40 dB. Although OME is usually transient and will resolve within weeks or months, it has a tendency to recur or become chronic. A mild hearing loss may be the only symptom in young children and this may go unnoticed. Treatment depends on the severity of the hearing loss, in one or both ears, and its duration. The point prevalence of OME is highly variable, ranging from 1 to 30%\(^23\). Suppurative otitis media may become chronic and result in a permanent conductive hearing loss. The prevalence of chronic otitis media is likely to vary considerably worldwide, depending on therapeutic options under various healthcare conditions\(^24\)\(^25\). They need, in addition to the audiological assessment, also an otological examination and possibly treatment.
2. GENERAL BACKGROUND ON HEARING AND VISION SCREENING

Chapter editors: Jill Carlton, Allison Mackey

a. Criteria for responsible screening

In 1968, the WHO published the following ten “principles of early disease detection”26:

- The condition sought should be an important health problem
- There should be an accepted treatment for patients with recognized disease
- Facilities for diagnosis and treatment should be available
- There should be a recognizable latent or early symptomatic stage
- There should be a suitable test or examination
- The test should be acceptable to the population
- The natural history of the condition, including development from latent to declared disease, should be adequately understood
- There should be an agreed policy on whom to treat as patients
- The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
- Case-finding should be a continuing process and not a ‘once and for all’ project

It is important to notice that the authors of this report considered the above principles as a preliminary checklist. That is, when these criteria are not met, there is no justification or rationale to start a screening programme. When these criteria are met, further research is warranted to determine whether or not it is appropriate to start a screening programme.

Forty years after the publication of the original principles, the WHO published a "synthesis of emerging screening criteria"27:

- The screening programme should respond to a recognized need
- The objectives of screening should be defined at the outset
- There should be a defined target population
- There should be scientific evidence of screening programme effectiveness
- The programme should integrate education, testing, clinical services and programme management
● There should be quality assurance, with mechanisms to minimize potential risks of screening
● The programme should ensure informed choice, confidentiality and respect for autonomy
● The programme should promote equity and access to screening for the entire target population
● Programme evaluation should be planned from the outset
● The overall benefits of screening should outweigh the harm

In 2020, the WHO published a short guide offering operational advice for designing and managing a screening programme.

b. Effectiveness and cost-effectiveness of vision and hearing screening programmes

i. Vision
Vision screening has been shown to be effective in reducing the prevalence of amblyopia among adults. In Denmark, following the implementation of a national preschool vision screening programme, the prevalence of undetected or unsuccessfully treated amblyopia decreased fourfold: the prevalence dropped from 1.8% in the group that was not screened to 0.4% in the screened group\textsuperscript{28}. An earlier, longitudinal and retrospective study in Sweden found that with screening and subsequent diagnosis and treatment, the prevalence of severe amblyopia (visual acuity ≤0.3) was reduced from 2% to 0.2%\textsuperscript{29}.

Amblyopia fulfils most of the WHO criteria as a target condition for screening, but there are many other childhood visual defects, such as refractive error, strabismus, weak stereovision, and poor convergence. They can be detected in early childhood, and would be monitored or treated if presented to an eyecare professional, but they fulfil fewer of the WHO criteria e.g. later treatment may be just as effective, and there may not be a consensus on who to treat as patients. The evidence in terms of better long-term public health outcomes is less clear for population screening to detect and treat for these often mild and asymptomatic conditions. If screening also targets these conditions (as the EUSCREEN Country Reports suggest is common), costs increase and cost-effectiveness may reduce. It is very important that the target condition for the screening is clearly identified from the outset. Each country must decide whether screening is to detect any visual defect outside normal ranges, even if it may be mild with little proven adverse impact on development or long term outcome, or to detect only severe cases where the evidence is clearer. Countries with different economic or health priorities may make very different decisions.
Research has shown that the cost-effectiveness of screening for amblyopia is dependent on the long-term effects of unilateral vision loss on the quality of life, but that even a small effect would mean that screening would be cost-effective\(^3\). Other research has indicated that unilateral amblyopia indeed negatively affects the quality of life\(^3\). Children with unsuccessful treatment for amblyopia have a seven months longer period of bilateral vision loss at the end of life, compared to children without amblyopia or with successfully treated amblyopia\(^3\). The loss in utility in these seven months is measured in elderly people with bilateral vision loss to be 0.08 (8% loss in quality of life)\(^3\). Using the same time trade-off methods, the effect of unilateral vision loss measured in 40-year olds was 0.037 (3.7% loss in quality of life)\(^3\). However, since this figure for unilateral vision loss is considered high compared to the 0.08 utility loss for bilateral vision loss and since only 37% of the people with unilateral vision loss accepted a death risk according to the standard gamble method also used in the study, we can assume a loss in utility for unilateral vision loss of 0.01.

ii. Hearing

The earlier a child's hearing impairment is discovered, the less affected language and speech development will be. Early intervention, before the first birthday, has been shown to prevent disabilities to a much larger degree than interventions at later ages\(^3\). Early hearing loss detection and intervention dramatically improves outcome measures for infants and young children with hearing loss. Therefore, the Joint Committee on Infant Hearing recommends benchmarks, that hearing loss be identified before the age of one month, with audiological evaluation and intervention before three and six months, respectively\(^3\). The introduction of universal newborn hearing screening (NHS) programmes has been instrumental in reducing the age of identification\(^3\).

Healthcare policy-makers must make decisions on how to allocate resources within the healthcare system. Cost-effectiveness analyses are useful in the decision-making process. A systematic review found 29 studies that evaluated the cost-effectiveness of universal newborn hearing screening and concluded that universal NHS is cost-effective\(^3\). This is particularly true when assuming long-term positive effects of early intervention on speech and language development and education\(^4\). Universal NHS is cost-effective when compared to selective (high-risk) screening; however, cost-effectiveness is affected by programme quality measures such as the rate of false referrals and loss to follow-up to diagnostics and intervention\(^4\).

Because a considerable number of children (an additional 50-90% relative to children identified by newborn screening) will develop hearing loss in the postnatal years, studies have advocated for the universal hearing screening of preschool and school-aged children\(^4\). Only some EU countries have established programmes. Despite the
encouragement from European experts to initiate programmes, there is limited evidence showing the societal benefit and cost-effectiveness of childhood hearing screening in countries or regions with existing newborn hearing screening. There is currently a lack of good quality data available.

It should be noted that the situation may be different in countries or regions where there is no NHS.

c. Benefits versus harms of vision and hearing screening programmes

i. Vision

If left untreated, amblyopia nearly doubles the lifetime risk of bilateral visual impairment. Also, amblyopia, significant refractive errors, and non-obvious strabismus (which would not be detected without screening) can affect health, the ability to play sports, development, and academic, occupational and social functioning. Since vision screening can detect these disorders, there is a broad consensus that paediatric vision screening is beneficial.

Even so, issues such as what age to screen, which test to use and how often to screen, remain subject to debate. In the US, the US Preventive Services Task Force (an independent, volunteer panel of national experts in disease prevention and evidence-based medicine) recommends vision screening at least once (but preferably yearly) in all children aged three to five years to detect amblyopia or its risk factors.

A study in Ontario found that the vast majority of children surveyed (90%) perceived vision screening as a game that they enjoyed. Nevertheless, preschool or school-aged vision screening could have possible adverse effects such as unnecessary referrals, overdiagnosis and unnecessary treatment, as well as an increased risk of being bullied because of glasses or therapeutic eye patches and a lower self-perception of social acceptance because of patches.

Skin irritation because of patching has also been reported, although this affected only a small portion of children. The use of eye drops to blur vision in the better seeing eye (BSE), instead of patching, may cause more frequent minor adverse effects, such as light sensitivity.

Amblyopic children themselves have reported that treatment did not significantly affect their quality of life.
ii. Hearing

The long-term benefits of early detection and intervention have been documented by the literature, showing that intervention for hearing impairment before six months of age leads to long-term positive benefits for speech and language development, improved quality of life and improved educational success\(^5\). Early intervention is made possible due to newborn hearing screening programmes. The long-term benefits of preschool or school-age hearing screening have not yet been clearly established, particularly in areas with newborn hearing screening in place.

No physical long- or short-term harms have been reported in the literature or by expert experience for newborn or preschool/school-age hearing screening. No harms have been reported from the screening devices used. Despite some evidence of mild parental anxiety after newborn hearing screening positives (whether true or false), no long-term emotional distress has been reported due to a false positive result from newborn hearing screening\(^5\).
Part II: planning and decision making
3. CONDITIONS FOR IMPLEMENTING CHILD VISION AND HEARING SCREENING PROGRAMMES

Chapter editors: Allison Mackey, Jill Carlton

a. Appropriateness, acceptability, feasibility and sustainability

Appropriateness
Prior to cost-effectiveness analysis, several country- or region-specific circumstances have to be taken into account to decide whether implementation of hearing or vision screening would be appropriate (suitable or fitting for the given context). Countries or regions may have problems that should reasonably be prioritised over hearing or vision screening, such as high infant mortality or low immunisation coverage. Even in the absence of such problems, it should be assessed what degree of priority would be reasonable to assign to a screening programme relative to other healthcare issues, such as access to clean drinking water, vaccination programmes and basic healthcare. Various indicators can be used to assess this, such as the WHO's Sustainable Development Goals and/or the World Bank's Worldwide Governance Indicators.

Acceptability
Acceptability is the perception among stakeholders that an intervention- in this context a screening programme - is acceptable. The following is a proposed formal definition of the concept: “A multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention.”

If a screening programme is not acceptable to, for example parents, then this could be a barrier to the implementation of the programme. Acceptability can be assessed based on the stakeholder's knowledge of or direct experience with various aspects of the programme: awareness of the target condition and the consequences of this condition, but also of the type of screening to be implemented.

Acceptability is presumed to be dynamic and changing with experience. For more detailed information on stakeholders, see chapter 4a.
Feasibility
This is the extent to which an intervention can be successfully carried out in a particular setting. While related to appropriateness, feasibility is not the same. An intervention can be appropriate in a setting (country, region) but not feasible because of practical constraints (for example lack of infrastructure necessary for the intervention, or lack of professionals able to perform the screening). To assess the feasibility, it is necessary to look at practical concerns like whether it is possible to reach the target population, whether there are financial means to pay for the programme and whether diagnosis and treatment are available for and accessible to those who test positively.

Sustainability
The extent to which an intervention is maintained or institutionalised in a given setting; the integration of an intervention within a setting’s culture through policies and practices. Three stages can be distinguished:

- **passage** (for example the transition from temporary to permanent funding)
- **cycle** or **routine** (repetitive reinforcement of the intervention by including it into organisational and community procedures and behaviours)
- **niche saturation** (the integration of the intervention into all subsystems)


It is advisable to assess long-term sustainability of a screening programme before implementing a new programme. It may be possible, for example, to finance a pilot project through incidental means, but this does not serve a real purpose if it is clear from the outset that there will be no funds to continue the programme once the pilot is concluded. This is a risk that is especially present in developing countries.

Further reading: *Outcomes for Implementation Research: Conceptual Distinctions, Measurement Challenges, and Research Agenda.*
b. Minimum resources needed for a screening programme

A screening programme will, at the very least, need the following resources: staff (screeners, administrative support, management), screening equipment and space and a database.

**Staff**

Trained personnel are needed at all levels of the programme. Programmes led by professional audiologists have been shown to be more effective (ref). When starting a new programme, potential screeners have to be identified: they may be dedicated persons who, with adequate training, could perform screening. Often, those leading the programme will have a medical background, especially valuable if they already have experience with (other types of) screening. Also, there have to be enough personnel in a given setting in relation to the size of the target population and they should be able to fit training and screening into their schedules. More detailed information on selecting screeners can be found in part 3 of the manual, the practical implementation guide.

In addition to screeners, supporting staff will be needed to handle the administrative tasks that are essential to ensure the screening programme operates effectively, such as administering consent forms, documenting screening results and entering results in the programme’s database. Ideally, these tasks would be handled by personnel working for the same organisation employing the screeners. In some cases, (part of) the administrative tasks could be handled by the screeners themselves.

Finally, management staff are needed to coordinate the programme. This entails preparing the budget (including resources for training, communication and monitoring), supervising the screeners, monitoring the programme and reporting on the results. Coordination of the programme requires close collaboration with all stakeholders (see chapter 4).

**Equipment**

Equipment is required to conduct the screening: testing devices for hearing screening and vision charts for vision screening or photoscreening devices. When considering equipment costs, it should be taken into account that equipment has a limited lifespan and will need to be replaced over time. Devices may also require regular cleaning and maintenance, which also incurs costs. Budgeting for maintenance, annual calibration and replacement equipment to minimise downtime, is an important consideration for any screening programme.

In addition to equipment, space will be needed to screen. Screening space will have to meet certain specifications, depending on the type of screening to be performed. More
Database
In order to keep track of the results of the screening programme, a database is necessary. A database should include all relevant information related to the screening pathway: screening results and, importantly, referrals, diagnostic reports and treatment results. Applicable data protection regulations must, however, be strictly adhered to (this is covered in detail in chapter 4e). Appropriate technical and organisational measures also have to be followed to ensure the database is secure and regularly backed up. For more detailed information see chapter 11 on monitoring.

c. Minimum standards for diagnosis and treatment
The screening protocol (the choice and sequence of tests; see parts III and IV of the manual for more detailed information on specific protocols for different types of hearing and vision screening) should clearly detail both the testing procedure(s) and the corresponding pass/referral criteria. The protocol should also detail how to refer children who do not pass screening, and specify measures to maximise follow-up.
It is imperative that all children who are referred, have access to diagnostics and treatment. "Facilities for diagnosis and treatment should be available" is one of the original "principles of early disease detection" defined by the World Health Organization (see also chapter 2).

It should be determined, before implementing a new screening programme, that there are enough professionals capable of providing diagnosis and treatment, and that parents can access them, both logistically and financially. How many professionals will be needed can be estimated based on the number of children to be screened, the assumed prevalence of the target condition and the estimated referral rate.

The fact that many subjects who are tested positively and are referred, never get diagnosed and treated (what is called ‘loss to follow-up’ or LTF) is a common problem in screening programmes. Referral and public information procedures should therefore be given appropriate attention. Demographics should be taken into consideration here, because certain groups are more susceptible to ‘loss to follow-up’ than others (see chapter 4-d-iv).

It should be noted that there is a different point of view that emphasizes the importance of starting screening and working on the availability of diagnosis and treatment along the way. The reason for this is that starting a screening programme at least draws attention to the condition being screened for and helps to create awareness. While this view contradicts
the WHO criteria for screening (see chapter 2), it could be argued that, especially in low-resource settings, this may be the only way to get a screening programme started at all.

d. Implementing a new programme

During the start-up phase of any new programme, the results will most likely deviate from the projected results for a running programme, calculated by the cost-effectiveness model. This is because everyone involved in the programme will need time to learn and adapt, especially the professionals doing the actual screening. It should be expected that during the first few months, screening will take longer and referral rates will be higher than to be expected. Therefore it will be necessary to factor in a higher number of diagnostic assessments than would normally be expected. If the programme is set up well, this should normalise within the first year of the programme or even earlier. Also, if local screeners are not able to quickly build up experience, extra attention should be paid to training and quality assurance.

EXAMPLE

In Cluj County in Romania, during the first month of the newly implemented preschool vision screening programme, the referral rate was 20% and during the first quarter of the first year of implementation it was 15%. By the last quarter of the first year, the rate had reduced to 7%. If we consider the average referral rate throughout the first year of the implementation programme, this was 14%. It is therefore important to monitor newly implemented programmes more regularly in the early months. In the second year of the implementation, the average referral rate was 8%.

When screenings were observed during the first month of the implementation, the average time a screening test took was more than eight minutes. By the second year of the implementation, this had reduced to approximately five minutes.

This also applies to established screening programmes that require substantial changes. For example, when a new screening device is introduced to an existing neonatal hearing screening programme, screeners may need time to adjust to the new equipment.

Communities also need to learn to appreciate the benefits of screening and treatment, and some communities may need to get accustomed to the concept of screening, which could
mean attendance being lower than expected in the early stages of the screening programme.
In preparation of a new screening programme follow-up care providers should also be informed about its objectives and their future role. See chapter 10 for more information on public awareness and communication.

Finally, once a screening programme is established, it is important to regularly evaluate it, and be prepared to implement any changes necessary to ensure it is as efficient and as effective as possible (see also chapter 11). The EUSCREEN cost-effectiveness model can assist in modelling alternative scenarios.
4. GOVERNANCE AND LOCAL CONTEXT OF HEALTHCARE: EDUCATION, GEOGRAPHY, DEMOGRAPHY, CULTURAL AND SOCIOECONOMIC FACTORS

Chapter editor: Eveline Heijnsdijk

a. Governance structures and policy-making

i. Governance structures
Health ministries have the responsibility for the management of the national resources to the health benefit of their population by establishing fair health policies and systems. Local and regional authorities can also have a role in this process, along with other stakeholders. Equitable access to healthcare provision should be a point of attention.

In order for a screening programme to be feasible and sustainable, appropriate legal provisions may have to be in place and the governance structure should ensure quality assurance and evaluation of the screening programme. All necessary organisational, legal, logistical and financial frameworks should be adequately addressed in advance. Interaction with decision-makers and stakeholders can assure the quality at all stages of the screening chain.

Examples of the governance of screening that have been defined for cancer screening, can largely be applied to hearing and vision screening as well.

ii. Decision-makers and stakeholders
Stakeholders are persons or organisations with an interest in a specific policy (in this case, a screening programme). Examples of stakeholders are financial donors, national, regional or local politicians and political parties and public servants (legislators, governors, health and finance ministries, social security agency), labour organisations (unions, medical associations), private for-profit parties, non-profit actors such as nongovernmental organisations (NGOs) and foundations, civil society and users or consumers (in this context, users or consumers would be parents of children to be screened).
Policy-makers and managers can undertake a stakeholder analysis to identify relevant stakeholders and to assess their knowledge, interests, positions, alliances, and importance related to the policy. This allows policy-makers and managers to interact more effectively with key stakeholders and to increase support for a policy. This stakeholder analysis guideline can be used to identify important stakeholders and document whether these stakeholders support, oppose, or are neutral towards the policy; and whether they have the power and willingness to lead an action for or against the policy. Policy-makers and managers can use the results of a stakeholder analysis to develop action plans to increase stakeholder support.

**iii. Interaction with decision-makers and other stakeholders**

To increase support for a screening programme and to work towards consensus for implementation, it is necessary to interact with decision-makers and other stakeholders. The aforementioned stakeholder analysis can be a helpful resource for strategic communication with decision-makers. When engaging in communication with decision-makers and other stakeholders, these advocacy guidelines and conflict negotiation guidelines can also be useful. Advocacy refers to targeted actions, aimed at decision-makers and other stakeholders in support of a specific policy (in this case, a screening programme). These actions are necessary to overcome constraints that can be barriers to the implementation of a screening programme. These constraints can be political, resource-related or organisational in nature. Conflict negotiation is a communication process whereby disagreements are contained and resolved in order for parties with conflicting interests to come to mutually acceptable solutions.

**b. Identifying existing preventive child healthcare structures and possibilities for combining programmes**

Hearing and vision screening will, in most cases, only be cost-effective when combined with existing structures with high attendance (for example greater than 85%) because this reduces overhead costs and the burden on parents (less appointments) and can lead to high ‘built-in’ attendance. For example, newborn screening can be performed in a (maternity) hospital where infants stay for a short time after birth, provided the vast majority of children are born in a (maternity) hospital, which may not be the case in all countries or regions. An alternative is to combine screening with the heel prick test in the first week or vaccination in the first month. Childhood vision screening can possibly be
combined with a vaccination booster around age four or five years or with (health) checks at school, since the majority of children will probably be present at these events or locations.

**EXAMPLE**

IN ONTARIO, CANADA, A VISION SCREENING PROGRAMME WAS SUCCESSFULLY COMBINED WITH AN EXISTING PUBLIC HEALTH DEPARTMENT DENTAL SCREENING PROGRAMME. IT WAS FOUND THAT THIS FACILITATED THE IMPLEMENTATION AND MAXIMISED STAFF RESOURCES, BECAUSE THE NECESSARY INFRASTRUCTURE WAS ALREADY IN PLACE: THE PUBLIC HEALTH DEPARTMENT ALREADY HAD A LIST OF SCHOOLS AND CHILDREN AND ALREADY HAD A SYSTEM FOR INFORMING PARENTS AND SENDING LETTERS ABOUT FOLLOW-UP.  

When combining screening with existing structures, care should be taken that screening is implemented in a way that is similar to an organisation’s existing practices and does not require extensive adaptations. When screening is undertaken at school, for example, care should be taken that school staff do not feel their regular activities are being disrupted or their workload has increased too much.

It should also be considered that combining with existing structures can have adverse effects. Children could be burdened with multiple tests on a single occasion and thus making them less ‘testable’ which could lead to more false positives and unnecessary referrals. This also depends on what specific structure is chosen to combine hearing or vision screening with. For example, combining screening with vaccinations may not be ideal because many children will be anxious then and therefore may not be attentive and not in an optimal state to be screened.

c. **Access to population data and records**

Once the screening programme’s target population has been defined, it is necessary to establish the target population’s size in the country or region and where the target population can best be reached. Most countries have national statistical institutes, which generally have data available online that can be helpful. For example information on how many children are born every year, where they are born, how many are born in (maternity) hospitals, and how many children are enrolled in preschool and school and at what ages.
Parents of children born in (maternity) hospitals and children attending preschool can easily be contacted through the hospital or preschool. Should, however, in a country or region many children be born at home or few children attend preschool, alternative ways of contacting the parents will be necessary. The most obvious way would be to contact the parents through the general practitioner (GP) their children are registered with. Therefore access to records of children registered with GPs (usually kept by national health institutes or health insurances) will be necessary. Certain legal provisions may need to be in place to facilitate this (see also chapter 4a).

d. Identifying local barriers and facilitators

i. Healthcare organisation
When the conditions for implementing a screening programme (see chapter 3) have been met, it can be assumed a country or region has an acceptable level of healthcare. When implementing a screening programme, however, it is also relevant how healthcare is organised. It is especially relevant if there are existing structures that screening can be attached to (see chapter 4b) but it is also important to know if there are disparities in healthcare access.
Screening should be available to the entire target population and so should diagnosis and treatment (see chapter 2a). It is therefore important to know if the costs of diagnosis are covered by the government, if parents will have to (partly) pay for these themselves or if these costs are covered by health insurance. Note that some countries have more than one type of health insurance, for example public and private, with differences in what is and what is not covered. If diagnosis and/or treatment are not covered, a solution should be found to provide them. Similarly, if diagnosis and treatment are covered, but a proportion of the population is without health insurance, a solution should be found to insure them since it would be considered unethical to screen children when they do not have access to diagnosis and treatment.

It is also relevant to identify possible existing mechanisms that could be used for tracking follow-up, reporting and feedback (for example common databases). If existing mechanisms are not available, these will have to be created.

ii. Educational systems
Combining screening with existing structures is advisable (chapter 4b). School can be a suitable location for screening once school is compulsory. Although this ranges between three and eight years, in many countries school is compulsory from age six years. For vision
screening, this may be too late as this is preferably done at ages four or five years (see chapter 1-e-ii). If school starts at six years, vision screening could perhaps better be combined with preschool. However, if preschool is not compulsory, attendance rates may be lower than school attendance rates. In such a case, the cost-effectiveness model can assist in calculating the most optimal scenario: either preschool, with lower attendance but better prospects for treatment, or primary school, with higher attendance but worse prospects for treatment. If preschool attendance is very low an alternative may be needed.

In some countries or regions, preschools and/or primary schools have resident nurses to take care of children’s health. If this is the case, they can be trained to screen. If there are no nurses at preschools and/or schools, another cost-saving option could be to train non-healthcare volunteers or professionals, for example teachers, to screen. This is quite common in some countries, but it should be noted that reports on the quality of screening by lay screeners vary. There are studies that indicate that non-healthcare volunteers can be trained to perform screening at an acceptable level of accuracy. However, studies find substantial differences between various lay screeners when it comes to sensitivity and specificity. These differences could be explained by variations in tests and referral criteria used, ages of children screened, personnel involved and the training provided. Some experts are of the opinion that training, evaluation, support and experience are more important for screeners than specific professional background.

iii. Geography and demography

When implementing a screening programme, geography and demography should be taken into account. Within a country or region, differences between densely and sparsely populated areas are relevant. A screening programme will be more difficult (and therefore more expensive) to implement in a sparsely populated area since it will require more effort to reach the whole population. In addition, there may be relevant differences in demographics between for example urban and rural areas, although these differences may not be the same everywhere. In Eastern Europe, for example, rural areas are generally poorer than urban areas while in Western Europe and the United States so-called inner cities tend to be home to low SES populations. In large cities, there will also be relevant differences in demographics between various areas of the same city.

In areas with an ethnically heterogeneous population, it should also be noted that substantial differences have been found between ethnic groups in the prevalence of both several vision disorders and various forms of hearing impairment. Infrastructure should also be a point of attention. In remote areas, roads may be in a poor state, making these areas hard to reach and some areas may be impossible to reach in winter, for example, because of weather conditions.
EXAMPLE
DURING THE FIRST YEAR OF THE IMPLEMENTATION OF A NEWBORN HEARING SCREENING PROGRAMME IN ALBANIA, 32.4% OF INFANTS WITH A ‘FAIL’ OUTCOME IN THE FIRST SCREEN DID NOT ATTEND THE SECOND SCREEN AND 34.4% OF THE INFANTS WITH A ‘FAIL’ OUTCOME IN THE SECOND SCREEN DID NOT ATTEND THE THIRD SCREEN.

IN ADDITION TO COMMON REASONS FOR LOSS TO FOLLOW-UP (LTF), A COUNTRY-SPECIFIC REASON COULD BE THAT PARENTS COME FROM ALL OVER ALBANIA TO GIVE BIRTH IN MATERNITY HOSPITALS IN TIRANA. WHEN THEY RETURNED HOME WITH THEIR CHILD, IT WAS TOO DIFFICULT FOR THEM TO COME BACK TO TIRANA TO REPEAT THE SCREEN BECAUSE OF THE DISTANCE BETWEEN THEIR HOME AND THE HOSPITAL AND THE TIME AND COST REQUIRED TO COVER THIS DISTANCE.

As with all aspects of implementing a screening programme, the local situation should be thoroughly investigated. All local circumstances should be assessed for their implications for screening, so that the programme can be tailored to take these into account. It is very important to make sure that a programme is adapted to and embedded in the local context. Top-down policy-making that ignores diversities between communities in history, geography and so forth, is unlikely to be successful.

iv. Cultural and socioeconomic factors
Conditions that children are screened for will, by definition, most likely not be detected by parents, as children with the target conditions can often function normally on a day-to-day basis. Parents therefore need to be aware that their children may have hearing or vision problems even though they cannot notice these themselves and that these problems are serious enough to warrant early detection and treatment. Communication to parents is therefore of the utmost importance (see also chapter 7c and chapter 10). Parents’ awareness of the importance of screening, and their attitude towards screening, are highly relevant to the success of a screening programme.

Differences in language and culture can hamper effective communication and be significant barriers to healthcare access. It is therefore advisable to investigate whether a screening population is linguistically and culturally homogeneous and, if not, to be aware of such differences and the implications these may have for a screening programme.

Practical issues aside, minority groups, especially marginalised ones, may be less receptive to preventive healthcare and therefore harder to reach. People belonging to marginalised
groups often distrust institutions and also face other barriers in accessing healthcare\textsuperscript{71}. In low SES communities particularly, people may fear health interventions will incur costs. Even when a medical service is nominally free, in many countries or regions some form of ‘informal payment’ is expected\textsuperscript{72} or alternatively people may assume that they are not eligible without insurance\textsuperscript{73}. Additional measures may therefore need to be incorporated into a screening programme to reach such groups.

**EXAMPLE**

**THERE ARE SEVERAL COMMUNES (GROUPS OF VILLAGES THAT TOGETHER FORM AN ADMINISTRATIVE UNIT) IN CLUJ COUNTY WHERE A LARGE PART – IN SOME CASES EVEN THE MAJORITY – OF THE POPULATION SPEAKS HUNGARIAN AS THEIR FIRST LANGUAGE. IN OTHER AREAS A SUBSTANTIAL PART OF THE POPULATION ARE ROMA, A QUARTER OF WHOM ARE NONREADERS. SOME 34\% OF ROMA IN CLUJ COUNTY ALSO DO NOT SPEAK ROMANIAN AS THEIR MOTHER TONGUE.**

**IN SOME KINDERGARTENS, A ROMANIAN SPEAKING NURSE WAS UNABLE TO COMMUNICATE WITH THE CHILDREN TO BE SCREENED, AND BRINGING IN A TRANSLATOR INTRODUCED ADDITIONAL PROBLEMS. A LEAFLET IN ROMANIAN IS UNLIKELY TO BE OF MUCH USE TO EITHER GROUP AND TRANSLATED INFORMATION WAS NOT AVAILABLE.**

Inequitable access to screening is a common issue in preventive healthcare. A consistent finding across various screening programmes is that participation is lowest among the most socially deprived\textsuperscript{74}. Providing equitable access to a screening programme therefore deserves attention. Low SES is the most important determinant of low health literacy\textsuperscript{75} and low health literacy is a significant determinant of screening uptake\textsuperscript{76}. Groups with low SES often overlap with ethnic minority groups.

It is important, when implementing a screening programme, to identify and address health inequalities. One method of doing this is to perform a health equity audit (HEA) to examine "how health determinants, access to relevant health services, and related outcomes are distributed across the population".

*Further reading: NHS population screening: a health equity audit guide*
Aside from access to screening, it should also be noted that low-income populations experience barriers to follow-up. These barriers are related to costs needed for transportation and treatment but also related to family problems, lack of faith in test results, difficulties with written communication and difficulty in planning ahead\textsuperscript{77}. Additionally, poor compliance with treatment of problems with visual acuity has been associated with social deprivation\textsuperscript{78}. Maternal education level is a predictor of hearing aid use time in children with mild to severe hearing loss\textsuperscript{79}.

It is not uncommon for screening programmes, from California\textsuperscript{80} to Peru\textsuperscript{81}, to include measures to maximise follow-up, by including for example free transport, diagnosis and treatment for children whose parents cannot afford these. It should be kept in mind that such measures will incur additional costs. Possible strategies to increase follow-up and treatment include more health education, more personalised communication and better coordination between the different parts of the care pathway.

Further reading: Challenges of Eye Health Care in Children and Strategies to Improve Treatment Uptake: A Qualitative Study from the Perspective of Eye Professionals in the UK.

e. Legal considerations: patient rights, informed consent and personal data

Patient rights
Patient rights are different across countries and jurisdictions, depending upon cultural and social conventions. At least four different models of the physician-patient relationship are distinguished by the World Health Organization in North America and Europe alone: paternalistic, informative, interpretive and deliberative. Many countries have some form of formal definition of patient rights, in law or otherwise.\textsuperscript{82} In spite of the aforementioned differences, there is a growing international consensus that patients are entitled to:

- privacy
- the confidentiality of their (children's) medical information
- to be informed about relevant risk of medical procedures
- to consent to or to refuse treatment

Further reading: Patient rights.
Informed consent
The last two points together constitute what is known as ‘informed consent’. This is “a process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment”.

Further reading: Informed consent - It's more than a signature on a piece of paper.

For hearing and vision screening in children, generally parents’ informed consent will be required, as children will lack the legal competence to provide informed consent themselves. Children’s assent should be obtained, whenever possible (in case of newborn screening, it is obviously not possible).

Opt-in or opt-out
Consent can be obtained in two ways: opt-in or opt-out. Opt-in consent relies on parents actively consenting to the screening, by either bringing their child to be screened, or signing a consent form for their child. Opt-out consent assumes that all children will be screened unless the parents actively request otherwise. Technically, this is only possible if all parents are fully informed of what the screening process entails and are made aware that their child will be screened, unless they object.
Opt-out consent is associated with higher uptake of screening, especially in regions where there is low awareness or uptake of community public health services. Opt-out policies when accompanied by adequate community awareness and knowledge can normalize the perception of the screening process and increase acceptability. An additional advantage of opt-out consent is that it lessens a programme’s administrative burden. In an opt-in service, the children most at risk of undetected poor vision (low SES or parental education levels) are the ones whose active consent and attendance are most difficult to obtain.
Requiring signed consent forms can be a significant barrier to screening access. Consent forms can be burdensome to keep track of, for screening staff, parents and children. In some contexts, language and literacy may be issues that would require translations or additional forms of communication. Additionally, there is the risk that forms may get lost or are forgotten.

Personal data
When registering personal data, applicable rules have to be followed. In the EU, the regulation commonly known as the GDPR prescribes how personal data has to be handled. Any organisation that processes personal data in the EU must comply with this regulation.
Under the GDPR, processing of data is only allowed if there is a justification for it. For screening programmes, the most obvious justifications are article 6-1-e (processing is necessary for the performance of a task carried out in the public interest) and article 9-2-h (processing is necessary for the purposes of preventive or occupational medicine). The existence of a justification for processing data means that a subject’s active consent to process his or her personal data is not required (but subjects still have to be informed their data are being processed, and made aware of their rights concerning the processing of their data).

Further reading: Data protection, GDPR and screening.

Even with a justification for processing data, there are strict rules that apply to handling personal data. Appropriate technical and organisational measures have to be implemented to protect personal data. Very important is ‘pseudonymisation’: “the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person”.

Further reading: GDPR compliance checklist.

Note that outside the EU, different rules apply and applicable local laws should always be consulted before setting up a data registry. The majority of countries have data privacy laws (132 as of 2019)85, often similar to the GDPR or even based on it, such as Brazil’s Lei Geral de Proteção de Dados. In some jurisdictions, formal approval of a specific body may be required before setting up a data registry is allowed.
Part III: practical implementation: hearing screening
5. NEWBORN HEARING SCREENING

Chapter editors: Gwen Carr, Inger Uhlén

a. Context and introduction
Newborn hearing screening aims to enable identification of hearing loss in the earliest weeks and months of life so that babies, and their families, can receive the intervention and support they need for optimal linguistic, communicative and socio-emotional development. Hearing screening for newborns is the first step in the care pathway which importantly includes diagnosis and intervention. There is now compelling evidence that newborn hearing screening, when followed up by appropriate assessment, audiological management and family-centred support for communication development, can radically improve outcomes and life opportunities for children born with hearing loss.86 87. There is little value or benefit in screening without the other essential parts of the care pathway. Therefore, planning for implementation of a newborn hearing screening programme needs to be undertaken in conjunction with steps to ensure that:

- babies who are referred by the screening test can receive timely audiological assessment and, if necessary, treatment
- babies can be provided with appropriately fitted hearing aids and where possible referred for cochlear implants when meeting audiological criteria
- there is skilled support for families and for the assessment and promotion of speech, language and communication development in young children, following confirmation of hearing loss

Research has also shown that “success is achieved when early identification is paired with early interventions that actively involve families.”88 Therefore all parts of the care pathway should ideally be delivered in a family-centred way, responsive to the needs of individual families. Enabling families to meet other families of deaf and hard of hearing children, and adults with hearing loss, can be an important part of providing this support.

Screening can use one of two approaches:

- opportunistic: meaning that the screening is implemented as part of some existing routine care
- proactive: meaning that the population targeted for screening is actively identified to participate in the programme
In the case of newborn hearing screening, there are a number of natural opportunities to integrate into existing care provision: either around the time of birth or during the days following, alongside other elements of routine medical care.

b. Pre-implementation considerations and preparations

Consideration of the political, cultural, geographic, economic and demographic elements in preparation for implementation are covered in chapter 4 of this manual. In addition, from both strategic and practical perspectives to help design the programme delivery, it is essential to determine:

- whether the proposed programme is local, regional, or national
- whether to implement a targeted programme (screening only babies who are considered higher risk) or a universal programme (screening all babies born in the chosen area). Since targeted screening identifies only about half of the of children with hearing loss at birth, a universal programme is recommended
- how the programme will be funded – both for initial implementation and for sustainability
- whether screening will be offered free to families or at a cost
- the number of live births each year in the chosen implementation area
- what kind of maternity care expectant mothers receive
- where babies are born (% hospital, home, elsewhere)
- how many babies, on average, are well babies and how many typically require time or treatment in special care such as neonatal intensive care units (NICU)
- what proportion of babies are full term births and what proportion are premature
- how long mothers of well babies stay in the hospital after the birth, before being discharged
- whether babies receive other routine medical checks (for example hips, eyes, heart), or other screening tests before being discharged from hospital and how and by whom are these done
- if any hospital-born baby were to go home without being screened, whether parents could easily return to the hospital or another location for screening within the first few weeks, or whether babies could be screened at home
- what typical healthcare mothers and babies receive in the period after birth, after they have left hospital or have given birth at home, and when and where that takes place and by whom
- whether there is a childhood vaccination programme, and if so, what is included and how the programme is organised, to assess the possibility of combining hearing screening with vaccinations
- what requirements exist for consent for medical procedures
- whether IT support is available in potential screening locations
- how the newborn hearing screening programme will be administered and managed and how data will be collected and used
- how the screening process itself will be conducted and how it will be reported on, evaluated and quality assured
- who will do the screening: dedicated hearing screening personnel or other professionals (such as maternity nurses) as part of their routine involvement in newborn care/examinations or other existing screening activity
- how screening personnel will be trained and how their performance can be assessed and standards maintained (both at time of completing training and in an ongoing way)
- what equipment and protocols to use, considering the possibilities and limitations of the settings in which screening is to be implemented
- how current hearing care is provided and whether there are audiologists or other hearing professionals (such as ENT physicians or paediatricians with additional training in audiology) able to undertake diagnostic testing and to fit and manage amplification
- whether the necessary follow-up diagnostic testing facilities exist in terms of appropriate venues and equipment and if so, how these are accessed
- what provision exists or could be developed to provide the necessary skilled and trained support to families for developing their child’s language and communication
- whether and what routes exist for raising awareness of hearing screening and informing parents about the screen before the programme is implemented, taking into consideration:
  - how information about healthcare initiatives are typically shared with the public (see also chapter 10)
  - what contacts with expectant mothers are routinely made during pregnancy
  - what opportunities are there to educate them about the screen and the importance of early identification of hearing loss
  - the attitude of the public / community towards identifying disability in babies and young children, and any barriers that exist
c. Planning a screening programme

i. Organisation

The programme requires:

a) Leadership and governance:
   • to provide strategic direction and oversight (including data, finance and equipment)
   • to ensure the whole screening pathway is safe, functional and sustainable
   • to agree the objectives of the programme, to set quality standards and to monitor
     programme performance against agreed benchmarks or **Key Performance
     Indicators** (KPIs)
   • to agree on the screening protocols to be used
   • to ensure clear communication about the programme at all levels: to policy makers,
     health departments, healthcare providers, the general public and parents
   • to produce clear information for parents pre-screening and throughout the
     screening pathway to the point of discharge for those babies passing the test and
     referral to audiology for those babies who need further assessment
   • to quality assure and audit the programme
   • to ensure effective risk and incident management
   • to ensure effective training and competency assessments for all personnel involved

The setting up of a multi-disciplinary board with representatives from all stakeholders
(audiology, neonatal care, ENT, maternity ward, early intervention programme) can
support coordination and effective clinical governance.

b) Management and administration:
   • to co-ordinate and run the programme at national / regional / local level in
     accordance with agreed policy, procedures and protocols
   • to ensure babies to be screened are identified
   • to ensure that all eligible babies are screened according to protocol and receive a
     recorded screen outcome
   • to ensure effective data capture and handling to support the screening and referral
     processes
   • to oversee screener training and to continuously monitor screener performance
   • to report on the performance of the screening programme, including risks and
     incidents
   • to manage all aspects of screening equipment, to ensure that QA checks are
     undertaken, and that the equipment is serviced and calibrated at required intervals
c) Screening personnel:
- to ensure all babies identified for screening are offered the screening test
- to communicate with parents about the purpose of the screen, and gain their consent
- to carry out the hearing screening and to accurately record clinical and test data
- to sensitively and accurately communicate the screening test results to parents and inform them about next steps
- to ensure the safety of the screening equipment
- to ensure screening follows all agreed protocols and best practice

ii. Operational elements of the programme
Operational steps in delivering the programme include:

- identifying the target population
- inviting the target population
- informing and gaining consent
- administrering the test(s) and recording the results
- communicating the test results and taking appropriate action without delay
- enabling / ensuring fit-for-purpose assessment, diagnosis, treatment and support for those babies referred

a) The target population
In a universal programme, all eligible babies born in the agreed area (national, regional or local) within the first month of life. The test can be done for babies up to three months of age (corrected age for premature babies). In some circumstances, this may be extended to six months of age.

In a targeted programme, only those babies at higher risk for hearing loss, for example babies with an illness or condition that requires admission to special care for 48 hours or longer, findings associated with a syndrome known to include hearing loss or a family history of hearing loss. A full list can be found in this paper\textsuperscript{89}.

For some babies routine screening is not appropriate, and they should be referred directly for audiological assessment. These include babies who have:

- atresia (no obvious ear canal in one or both ears)
- suspected or confirmed meningitis
• confirmed congenital cytomegalovirus
• a ventriculoperitoneal shunt inserted to drain extra cerebrospinal fluid from the brain in cases of hydrocephalus

Babies who have tested positive for Zika virus, or whose mothers have tested positive for Zika virus, may also be referred directly for audiological assessment without screening. In some programmes however they may be included in screening, in which case they should receive automated Auditory Brainstem Response (aABR) testing rather than Otoacoustic Emissions testing (OAE). See section Screening tests and equipment below.

b) The target condition
Permanent (sensorineural) hearing loss of 35dB or 40dB or greater, depending on policy choice.

The programme should define the target condition(s). These may be: permanent (sensorineural) hearing loss of 35 or 40dB, depending on policy choice: unilateral loss; permanent conductive hearing loss; and auditory neuropathy spectrum disorder (ANSD).

c) The programme objective
To enable early identification of babies with the agreed target condition(s) and to ensure the provision of safe and effective assessment and support. The desired health outcome is the optimal development of language and communication skills (whether spoken or signed) for children born with hearing loss.

d) Communication and information
A universal programme needs a high level of coverage in order to be successful, with high uptake from the population. Therefore it is important to ensure a good degree of awareness amongst healthcare providers and in the general public. Wide communication is required and needs to cover:

• what the programme aims to achieve and why (the early detection of hearing loss so that children can develop speech language and communication skills, whether spoken or signed, and have better life chances)
• how, when and where the programme will be implemented
• how the programme will operate and what is involved
• how the programme fits in to existing healthcare

In addition, there should be specific more detailed information aimed at expectant parents. This should be available to them as a leaflet or other appropriate format during the
antenatal period so that they know that the screen will be offered for their newborn baby. It needs to be accessible both in terms of language and readability. The leaflet should be given to them again before the screening process begins. It should cover:

- what newborn hearing screening is, its risks and limitations
- an explanation of hearing loss, and its impact on development if it is undiagnosed
- the benefits of early identification
- an explanation of the screening test(s) and the potential outcomes / results
- what the next steps will be, depending on outcome
- details of further contacts for any questions they may have after the screen

The leaflet should be used alongside the verbal explanation by the screener during the consent process and then given to the parent to keep. Programmes may have a second leaflet for babies referred from the screen to Audiology for further assessment, explaining in accessible language what a ‘refer’ result means and what they may expect at that appointment.

Many existing screening programmes have leaflets which could be used as basic templates. These should be adapted in a culturally appropriate way for different national, regional or local circumstances, in keeping with the specific needs of the programme.

e) Screening tests and equipment

High quality screening requires tests with high sensitivity and high specificity. ‘Sensitivity’ means the screening test’s ability to accurately identify babies who do have the target condition. ‘Specificity’ means the screening test’s ability not to refer babies who do not have the condition.

Major reputable manufacturers of screening equipment ensure their products go through rigorous scientific evaluation to make sure the technical specification is fit-for-purpose and has high specificity and sensitivity. However, a number of other issues can affect specificity and sensitivity, including the skills of individual screeners, the conditions in which screening is undertaken and the age of the infant at the time of the screen. Attendance rates and coverage (ie. the proportion of eligible babies receiving a test and having a recorded result) also affect the sensitivity and specificity of the overall screening programme.

There are two screening methods that may be used:

- Otoacoustic Emissions (OAE): this test measures soundwaves produced in the inner ear. A small soft-tipped probe is placed in the baby’s ear canal and tones or clicks
are played. If the cochlea (the organ of hearing) and middle ear are functioning normally, an otoacoustic emission is detected.

- Automated Auditory Brainstem Response (aABR): this test measures how the hearing nerve and brainstem respond to sound. Three electrodes are placed on the baby’s head and neck/shoulder and clicks or tones are played through soft earphones into the baby’s ears.

In both tests, the responses are automatically analysed by the equipment, which then displays the results as ‘pass’ or ‘refer’ (fail). No specialist interpretation of results is required by the screener. Both screening tests are quick and painless and are done when the baby is asleep or awake and quiet. Depending on the protocol chosen, one or both methods may be used.

OAE and aABR technology can be separate pieces of equipment or combined in one screening device which can perform both tests. A combined OAE / aABR device is typically more expensive than separate OAE-only and aABR-only devices, although pricing will vary according to local circumstances and also the amount of equipment purchased. OAE and most aABR technology requires the use of disposables (such as ear probe tips, electrodes, earmuffs, adhesive sensors, and wipes). These come at extra cost. In addition, the equipment needs regular (annual) calibration to make sure it continues to function optimally. Although annual calibration involves a cost, and means that the machine is unavailable for use during the time taken to calibrate, the process is essential to ensure accurate functioning. Choice of technology should be guided by the needs and circumstances of individual programmes, and individual manufacturers provide detailed information on the relative benefits and performance of different equipment. Further detailed information and guidance can be found in the NCHAM e-book A resource guide for early hearing detection and intervention, chapter 2.

Screening needs to take place in an environment which is quiet. If there is too much noise, or a baby is too unsettled, the test results can be affected. It is possible to test babies at the bedside if the room is not noisy, but otherwise it may be better to have a separate quiet room where the mother can be with her baby for the test. A fully sound treated room is not a necessity.

**f) Test protocols**

‘Screening protocol’ refers to the choice and sequence of tests. There are many factors to take into account when choosing a protocol, such as how long mothers stay in hospital after giving birth, and how easy it is for them to return if re-tests are required, as well as financial considerations.
Most existing screening programmes use a combination two-step protocol of OAEs followed by aABR. Some screening programmes use aABR as the preferred method due to its higher specificity and sensitivity to. aABR has higher sensitivity and specificity than OAE and aABR testing can detect auditory neuropathy spectrum disorder (ANSD). However, aABR testing is more costly and takes longer to perform. OAE is a quick and straightforward test but if babies are screened too soon after birth, they may refer (‘fail’) on the test due to having birth fluid in the ear canal or middle ear. For this reason, although babies can be screened within the first 24 hours of birth, and as early as 6 hours of age, it is advisable to wait as long as possible and to perform screening close to the time of discharge home from hospital. Alternatively, babies can be screened later in the following days in a special clinic or community setting or at home, depending on the design of the programme.

Various protocols or test combinations are possible:

For **well babies** the most common protocol are the two-step OAE+OAE and the three-step OAE + OAE + aABR, at least in countries with high health expenditure (countries with lower health expenditure tend to use OAE-only protocols). If the baby passes on both ears on the first OAE, he or she is discharged from the programme. If not, a second OAE is undertaken. If the result is a pass on both ears, the baby is discharged from the programme. If clear responses are not recorded, then aABR is undertaken. If the baby has clear responses on aABR testing, he/she is discharged from the programme. If not, the baby is referred to audiology for further testing. The length of time between each stage is dependent on local factors. Depending on the length of time mother and baby are in hospital, it is possible to complete screening before they leave to go home. For babies who are discharged from hospital, the second OAE and aABR if needed may be done on one or more return visits or in a community setting. The crucial aim is for screening to be completed in proper time and a result recorded, and for babies not to be ‘lost to follow up’ before screen completion. An OAE + aABR protocol may be appropriate and useful for well babies where families may have difficulty returning for a second OAE if they do not receive a pass result on the first OAE. Where local factors mean that it may be the best protocol to ensure good coverage and screen completion, aABR + aABR is also a possible protocol.

An alternative protocol is commonly used for babies who have spent considerable time (more than between 48 and 120 hours) in special care, such as a **neonatal intensive care unit** (NICU). Because these infants are presumed to be at higher risk for neural hearing loss, they must always be screened with aABR (because OAE identifies cochlear or conductive hearing loss but will miss neural hearing loss, unlike aABR)\(^9\). Optionally, OAE can also be used for special care babies in addition to aABR.
Programmes should select protocols which suit their chosen target conditions and also take into account the circumstances of their operational implementation so as to achieve the objective of the programme. The EUSCREEN cost-effectiveness model can simulate different protocols to provide insight into the consequences of changes in protocol.

g) Communicating results to parents
It is important that communication of the screening test results to parents is both clear and sensitive, taking into account both cultural and individual family circumstances. Screener communication should be consistent with the information in the screening leaflets.

When well babies receive a ‘pass’ result on both ears on the initial screening test, it should be explained that this means that the baby appears to have normal hearing and no further testing is needed. It is important for the screener to explain that some babies can develop hearing loss later and so parents should always be alert to their babies’ responses to sound and seek advice if they feel worried or concerned at any time about their child’s hearing or speech and language development.

If a baby does not receive a pass result on the initial test and further testing is required, the possible reasons for not getting clear results should be explained:

- there could have been too much noise for the test to complete successfully
- the baby may have been too unsettled
- the baby may still have birth fluid in the ear canal
- the baby may have a hearing loss and further testing is required

Screeners need to avoid creating over-anxiety in the parents, but at the same time, ensure that they understand the importance of further testing by not unduly minimising the possibility of hearing loss.

If, following screening, results indicate that a baby requires referral to audiology, screeners should explain that this does not necessarily mean the baby has a hearing loss, but that it is a possibility and that it is very important that the family attends the appointment.

For babies who have been in special care such as a neonatal intensive care unit (NICU), screeners need to be aware that the baby may have other health needs or disabilities which may affect how parents feel about hearing screening. It may not be seen by them as a priority, and the possibility of hearing loss could be seen as unimportant. Alternatively, it may be seen as a major issue, and be significantly upsetting to the family. It is important
that screeners work as a team with the medical staff in special care to properly understand the baby’s and the family’s circumstances. In a screening programme, there should be consistency between screeners when it comes to communication. For this reason, ‘scripts’ have been developed by programmes which screeners can follow, whilst personalising the experience to individual parents. Existing scripts could be used as templates for adaptation for particular programmes’ cultural styles and needs.

iii. Quality Standards, benchmarks and Key Performance Indicators (KPIs)

Internationally, as specified in the 2007 Joint Committee on Infant Hearing’s ‘Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs’, the recommended goals for the pathway are to:

- complete screening within 1 month (4 weeks) from birth *
- undertake audiological assessment within the first 3 months from birth *
- fit amplification and begin early language and communication intervention and family support within 6 months from birth *

* For premature babies, the age would be a corrected age (chronological age minus the number of weeks / months premature).

Mature established programmes are now moving from 1-3-6 month goals to 1-2-3 month goals (screening before 1 month, assessment before 2 months, treatment before 3 months), informed by the evidence that earlier intervention can further improve outcomes91.

Coverage and minimising ‘loss to follow-up’ are key aspects of any programme. For this reason, Key Performance Indicators also need to focus on:

- maximising the proportion of babies receiving a completed screen and receiving a documented screen outcome
- minimising unnecessary referrals to follow up by ensuring effective screening

The Joint Committee on Infant Hearing recommends a benchmark of more than 95% of infants completing screening by one month of age, and a target of less than 4% referrals from screening to audiology. It is important however to recognise that benchmarks should be set at an achievable level, with a commitment to regularly review them as measures of performance, and increase them as programmes develop and mature.
Other quality standards may be set according to the needs of a programme. They may relate to data, or screener training, or other aspects of programme delivery which are felt to be really important.

Data
Good data and good data management are essential to the success of a programme. A data management system (whether electronic or paper-based) should assure:

1. the ability to document the instance and result of screening
2. the ability to track whether or not the infants who are referred follow up to further screen and audiological assessment/evaluation
3. the ability to track results of diagnostic audiological evaluation and age at identification
4. if the child is deaf or hard of hearing, the ability to fit and report age at amplification
5. the ability to record referral to early intervention services and age at commencement of early intervention services
6. the ability to report the proportion and number of children who meet the 1-3-6 (or 1-2-3) goals
7. the completeness of inclusion of the to-be-screened group, e.g. access to the birth registries

Screener training and assessment
High quality training and assessment is essential and should ensure that screeners:

- understand the principles of screening and the difference between screening and diagnostics
- recognise and understand the potential risks and harms, limitations and benefits of screening
- fully understand the workings of the chosen equipment, its use and care
- have extensive hands on experience with the equipment and a period of supervised practice before independently screening babies
- are knowledgeable about the policies and procedures of the hospital or clinic in which they are screening and how the screening programme fits in to routine practice
- are knowledgeable about and confident with the screening protocols
- are knowledgeable about the full screening pathway
• understand and can accurately document results and use the data management system
• can communicate sensitively and clearly with parents
• understand about childhood hearing loss, its impact on development, and the interventions and services which exist to support deaf and hard of hearing children and their families
• are confident and calm dealing with babies and new parents
• understand the importance of working as part of a team with both other members of the screening programme and other professionals

On completion of training screeners should be assessed for competency, in both knowledge and skills. Many established programmes have produced guides to training and competency checklists for screenings. Some typical examples of these can be found here and here. The New Zealand UNHS and Early Intervention programme also produces a National Policy and Quality Standards (2016) document which has a detailed section (Section 2) on screening competency, performance and operation. This can be found here.

Quality assurance
The quality assurance of a programme, regularly monitoring its coverage, uptake, attendance, referrals, and meeting of its benchmarks and Key Performance Indicators are crucial to the success and effectiveness of a programme. Good data capture and use is central to this, as is a skilled and competent workforce. For detailed information on monitoring, see chapter 11.

Data should be used to support the ongoing quality of the screening programme delivery as well as for audit purposes. Regular and documented equipment checks and maintenance, including the consumables, are also key elements of assuring quality.

Programme personnel should have ongoing supervision and mentoring. Training should be refreshed and competency checks undertaken at regular intervals. Competency checks should include both assessment of knowledge and understanding and also observation of practical skills, in all the areas covered in the screeners’ initial training. In addition, the checks should include monitoring of screener performance in terms of their use of the data management system, the numbers of declines of the screen and the numbers of referrals made by individual screeners.

Failsafe procedures (systems which can prevent errors or a plan that comes into action when things do go wrong) should be put in place as a core element of the programme and regularly reviewed. All incidents should be investigated and the learning from them used to address any weaknesses in the programme and to strengthen policies and practice.

The performance of the programme, and all its elements, should be subject to periodical, preferably annual, review with an accompanying report produced.
6. CHILDHOOD HEARING SCREENING AFTER THE NEONATAL PERIOD (PRESCHOOL/SCHOOL SCREENING)

Chapter editors: Inger Uhlén, Andrea Bussé

a. Context and introduction
Childhood hearing screening after the neonatal period aims to detect hearing impairment (HI) that was not identified at birth or has been later acquired. In countries with NHS in place, the prevalence of HI in school age children is about twice as high as compared to newborns, though estimates vary depending on thresholds used. The increase of HI with age is explained by delayed onset HI, progression from a mild HI or auditory neuropathy not detected via NHS or acquired HI from infections, ototoxic medication and trauma. HI may present itself any time after NHS, most often as a delayed speech or other communication disorders. Hearing should always be investigated when there is a delay in speech and language development and in children with recurrent ear infections. HI of mild to moderate degree may however go unnoticed for many years and its consequences on a child's behaviour may be misinterpreted as a behavioural or intellectual disorder.

Unlike NHS, the long-term benefits of childhood hearing screening (CHS) after the neonatal period have not yet been established, particularly in the context of a hearing healthcare plan that includes NHS. In Europe, CHS is not as widespread as NHS. Many existing CHS programmes began in the 1950s to 1970s prior to implementation of NHS. In recent years, a few additional countries have adopted a CHS programme while other CHS programmes have been terminated. There is a gap in the literature in the cost-effectiveness of CHS, with only one recent study performed on CHS in the framework of the United Kingdom National Health Service. This study concluded that CHS does not offer good value for money, based on the number of new cases detected; however, the authors themselves noted limitations to the study.

The role of CHS may be different in regions where NHS has not been implemented. In these regions, children with HI may not have been diagnosed until four or five years of age, when the negative effects on language, learning and social interaction are observed. CHS should
Manual for implementation or modification of child vision and hearing screening programmes

not be an alternative to NHS, because moderate or severe congenital hearing loss diagnosed at four or five years of age can never fully be rehabilitated. It is important to note that CHS pick up children with mild hearing loss much more often than those with greater hearing loss in regions where NHS is in place.

Hearing tests for children
Hearing may be assessed with various methods according to the age and developmental level of the child. These methods are objective, observational and behavioural. Objective methods are typically OAE and ABR used for NHS, where a passive response to sound can be recorded from the child. These methods can be applied also in older children and under anaesthesia. Infants from 3 months to about 2 years of age are extremely difficult to test as they cannot take instructions and have a very short attention span. The test person may only observe the child’s reaction to sound which can be very hard. In the distraction test and visual reinforcement test (VRA), the child is conditioned to turn its head towards the direction of the sound. This method has been used for infant hearing screening at 7-8 months of age, a screening that has been abandoned after implementation of NHS. From 3-4 years of age the child can be trained to actively show when they hear a signal, for example by building blocks or pushing a button. This behavioural test method is most often used for pure tone audiometry (PTA), where tones are presented in headphones, at different frequencies and intensities. This is the preferred method for hearing screening in children from 3 years of age and up97 because of its high sensitivity and reliability98. There is also the so-called whisper test which requires no equipment, but is of limited value for CHS due to its poor reliability and sensitivity99.

b. Pre-implementation considerations and preparations
The implementation of a childhood hearing screening needs good planning and detailed preparation to achieve a sustainable and cost-effective programme. Information is essential, including all stakeholders and others involved in the planning and implementation. See the checklist below for what should be taken into consideration.

- Whether the proposed programme is local, regional or national
- How stakeholders will be informed about the proposed programme; such as child healthcare providers, school healthcare, school officials, ENT-centres/clinics, hearing services
- How parents will be informed and consent gained for their child to be tested
- Who/what authority will be in charge of the programme – for implementation and further provision?
- How the programme will be financed – implementation and for sustainability.
• Will screening be free of charge or offered to families at a cost?
• Where are the children available? In preschool, school, healthcare office or other settings.
• Is there one public school organisation or several providers? Boarding schools.
• How large is the population regarding the target age group?
• Where and at what ages are there established health check-ups?
• Is there a routine check-up where hearing screening can be included?
• What requirement exist for consent for medical procedures
• How will the programme be administered, conducted and reported?
• Is IT-support available?
• How will screening results be collected and used?
• How screening results will be informed to parents and caregivers?
• Who will do the screening and how will they be trained?
• The choice of test equipment and screening protocols.
• What routes exists for raising awareness of hearing screening and informing parents about the screening programme?
• What diagnostic and intervention services are available for children referred from the screening programme?
• How are further diagnostics and intervention financed? Is there equity so that every child in need will receive intervention irrespective of family economy?

c. Planning a CHS programme

i. Target population
The target population defines who is eligible for CHS. Factors that are included in eligibility include jurisdiction, age, and universal vs. selective.

• Jurisdiction: The target population must be defined, and responsible authorities appointed. CHS must be connected to an institution where a majority of children can be reached. CHS can be performed in school or in combination with other healthcare appointments to achieve high attendance (see chapter 4b). Furthermore, the healthcare and education boundaries may need clarification to identify in which regions or school systems a screening programme is implemented, as authorities across these organisations may not coincide. In HIC, with well-established healthcare plans for small children and healthcare for schools, the responsibility for screening programmes is often well defined. In countries where healthcare centres
are few and regular check-ups are not available for all, setting up CHS will become very difficult.

- **Age of child:** CHS may be performed at one or more occasions during childhood. In many countries, CHS is performed at age four and in most cases, screening is part of a general health check-up\(^{100}\). Screening may also be performed at school start, since school is mandatory, and attendance is expected to be high. However, this may be late since school start varies between countries from 4 to 6 years of age.

- In addition, children should be old enough to reliably perform a behavioural test. In most cases, behavioural audiometry using play (play audiometry) can be performed by age three (see section v). Screening too early may cause inconclusive test results with unnecessary referrals as a consequence.

- **Hearing screening should target all children, irrespectively of age, who have not previously been offered screening or when a pass result cannot be confirmed, for example children immigrating from countries without screening programmes.**

- **Universal vs. selective:** most CHS opt for implementing a universal programme, in which all children are eligible for screening. It may be important to identify the established local protocols for surveillance of delayed-onset hearing loss among children who pass NHS, prior to defining the target population for CHS. For example, are children with risk factors for hearing loss monitored after NHS and what are the already established checks for at-risk monitoring? It is important to note that childhood hearing loss also affects children without known risk factors.

- **Children who are difficult to test:** tests designed for typically developing children may not be suitable for children with multiple disabilities or syndromes that affect cognitive and intellectual development. Behavioural and objective test methods may be needed to assess hearing, performed by an experienced audiologist. Furthermore, these children may miss routine health check-ups due to intensive medical care. However, it is of utmost importance that these children have their hearing tested as part of other check-ups. In a child where a delayed or absent speech development may be part of the syndrome (for example Down syndrome), HI may go undetected. Guidelines for follow up should include hearing assessment.

### ii. Target condition

Hearing screening is a health check-up, with the specific aim to target children with HI in need of intervention. Hearing thresholds in healthy children, tested at 0.5 – 4 kHz, are normally below 10 dB HL\(^{101}\). Screening at 20 dB will then give robust responses in most children. Higher frequencies (6-8 kHz) show more deviations. Middle ear effusion (OME) may cause a conductive HI of 25-45 dB. CHS programmes may be designed to target children with mild or moderate HI. Prior to a decision, an analysis of the local intervention
practice may be warranted to assess the availability and equity of care across different types and degrees of HI. See Appendix 2 for hearing test protocol.

- Screening is typically performed at a fixed level of 20 or 25 dB, over selected frequencies from 250 to 4000 Hz (6000 Hz), depending on the age of the child and test location. Screening at 20-25 dB is recommended in children from 6 years of age, while 25-30 dB is accepted for younger children. Testing in a sound-treated room also allows lower screening levels.

- Referral criteria need to be defined, as the number of frequencies with a pass at the target screening level in one or both ears. Referral criteria will define whether the protocol will target mild, unilateral or moderate hearing impairment. Screening at 20-25 dB in both ears will target all HI, including mild and unilateral.

- Targeting mild HI (<40 dB) may also include children with temporary HI due to OME. A retest after a couple of weeks may be necessary when the fluid in the middle ear has resolved and the hearing is normal. If not, the child should be referred to a diagnostic centre or ENT physician (see section Referral routines below).

- All children who do not pass CHS, have an inconclusive test result or are not able to perform the test must be referred for further investigation.

iii. Screening location

The three most common locations for CHS are at preschool, at school or at a child healthcare centre. The EUSCREEN survey revealed that in approximately half of the countries that have CHS programs, screening is performed in school and in the other half in a healthcare centre.

A careful look at the infrastructure around school and healthcare check-ups should be performed. At early ages CHS may be combined with regular health controls and vaccination programmes, while for school age children testing may be better performed in school. For the test to be effective and to ensure accurate referrals, it is important that children are well prepared by the screener so that they understand the nature of the test and feel confident about how to respond. All hearing tests require a quiet environment, a specific test device and a trained staff who can support the child to perform the test and evaluate the result. Please refer to chapter 4 for more information regarding general concepts and potential effects regarding selecting location (school versus child healthcare centre). In addition, the financing authority may also affect the decision on location. Within the selected location, the test environment needs to be established. All test methods require a quiet room for screening, preferably a sound-treated test room, since background noise can significantly affect the results. The test environment is ideally quiet without distractions, so that the child can engage with the tester to perform the test. A small child also needs to find the test playful. The hearing test needs the child’s full involvement, or the results may be inconclusive.
• In a healthcare centre, hearing screening should be incorporated into the general healthcare programme.
• Hearing screening can be incorporated into an already-established check-up in order to ensure high levels of attendance. However, too many tests at the same appointment may exhaust the child. In this situation, requiring a separate appointment for hearing screening. Thus, hearing screening should be offered according to the needs of the population.
• In a school setting, hearing screening will be performed on certain age groups or all children in the school. In this situation, the day and time of screening can be selected. Screening should be coordinated with the teachers in the schools to ensure that as many children are in attendance as possible.
• Ensuring that parents have given appropriate consent.

iv. Screening personnel
Implementation of screening in child healthcare centres would imply that child healthcare workers (physicians, nurses, or nursing assistants) would need training and adequate ongoing practice. Healthcare workers should be performing screening regularly, several times per month to maintain proficiency. In contrast, in a school setting, one screener may perform all screening for the children in the school. This may be a school nurse, or a travelling nurse or audiologist.
Training to become a screener should include theoretical and practical parts. Basic knowledge about hearing, hearing impairment and intervention is essential. Basic knowledge is also required about the anatomy of the ear and ear canal, including common deviations such as clogging cerumen, discharge and atresia. Audiometry requires understanding sound levels in dB, hearing thresholds, the test device (audiometer) and the test procedure.
Testing children requires interest in and ability to communicate with a child and the accompanying caregiver. Practical training with an experienced screener for a period of days, is necessary to assure adequate ability to perform the test. Examination and repeated re-examination of theoretical and practical skills is necessary to assess good quality screening. A certificate for screening personnel may also enhance the status of hearing screening. If appropriate retraining should be done.
Regular follow up with feedback to screening personnel about the outcome of the screening program is important to confirm the importance of their work performance. The screener’s self-esteem, accuracy and reliability are key factors to maintain high quality.
v. Screening methods

A child of 4-6 years of age is in most cases able to respond to a signal by pushing a button or in some other way. Hearing thresholds may be assessed at four or more frequencies in one ear at a time, providing information of hearing in both ears. Pure tone audiometry is the most prevalent and recommended method for childhood hearing screening. Other test methods in use are also described below. Tympanometry and otoscopy are methods for examining the ear as part of a diagnostic investigation, and should only be used by a medically trained screener.

- **Pure tone audiometry** (PTA) is the recommended method for CHS. PTA requires calibrated equipment, trained personnel, and a behavioural response from the child. Hearing thresholds may be assessed, meaning the lowest sound stimuli that gives a response from the child. For screening purposes a fixed level that will be accepted as a pass is recommended. Screening level of 25 dB, or 20 dB for older children, is most commonly used since it refers to normal hearing. A child that does not meet these criteria will be referred for further diagnostics (for screening test protocol see Appendix 2).
  - Advantages: can detect both unilateral and bilateral HI, can detect mild HI if desired, highly reliable.
  - Disadvantages: does not distinguish between sensorineural or conductive hearing impairment, may be difficult for children with intellectual or cognitive disability.

- **Play audiometry**: Pure tone audiometry adapted for children 3-4 years of age, where a play component (for example to put an object in a box or put rings on a stick) replaces pushing a button when hearing a tone. Pure tones may also be replaced by warble tones that will easier catch the child’s attention. The number of frequencies tested may also be reduced. The child will need to do some activity to show that they can hear the tones. Some children will be able to respond by simply putting up their hand. Other children may need a game to stay engaged. The activity should be very simple, easy and not take too much time, for example placing an object in a bucket or sliding a ring onto a peg each time a tone is heard.

- **Whisper test** is a method that refers to the child’s ability to repeat words or numbers produced with a low voice in a quiet environment. Typically, both ears are tested separately, by turning the ear being tested towards the test person/screener and blocking the other ear with the hand or a headphone.
  - Advantages: No expensive device is needed.
  - Disadvantages: Significant issues are shown with regards to the reliability of the whisper test, which is also not ear specific. Results vary with the voice of the screener, sound environment and the child’s ability to clearly repeat
target words/numbers. This also requires normal hearing in the screening personnel. The whisper test is not a recommended screening method.

- **Speech in noise or digits in noise test** may be an alternative for testing via smartphones or laptops where stimulus levels cannot be calibrated. Hearing is assessed via an automatic adaptive procedure with a signal-to-noise ratio as outcome where the result will indicate need for further investigation.
  - Advantages: Testing possible at remote places. No expensive test device needed.
  - Disadvantages: Lack of evidence, especially in children. Headphones with specific requirements needed and a trained screener in place to support the child. Does not work in small children due to the level of language and cognitive development.

- **Otoacoustic emissions (OAE)**, transient or distortion products, have recently been investigated as a possible tool for screening children this age. It is a sensitive method to detect mild and unilateral HI. In diagnostic evaluation it is a useful complement to PTA in children difficult to test. None of the countries surveyed perform otoacoustic emissions during childhood hearing screening.
  - Advantages: does not depend on behavioural responses of the child, can detect unilateral and bilateral HI, highly reliable.
  - Disadvantages: sensitive to fluid in the middle ear, difficult to achieve results in the low frequencies, sensitive to restlessness and noise, insertion of ear tips in the ear canal may require a medically trained screener.

- **Tympanometry** is a test that reveals the status of the middle ear and may be used in addition to above test methods to further explain the test result. In a CHS programme it may be used to diagnose or exclude OME and then either plan a rescreen or direct referral. Tympanometry may thus reduce the referral rate. However, it requires special expertise on the part of the screener, complicates the referral routine, and may lead to delay of necessary diagnostics and treatment of chronic middle ear pathology.

- **Otoscopy** with a handheld device may be used for inspection of the ear canal to ensure free passage to the eardrum. Otoscopy may, similar to tympanometry, explain a refer result due to a wax plug or infection. For diagnosis and treatment, a medical professional is required.

- **Hearing test via smartphones** and other ways of remote testing for screening purposes may be administered in certain areas. These tests are based on a signal-to-noise ratio that will indicate a need for further hearing investigation. For screening purposes these methods also require a set standard of equipment and a screening staff in place. The possibilities with this method have to be further investigated.
d. Equipment
Screening must be conducted in a reasonably quiet environment, with as few distractions as possible. Ambient noise (from ventilation, stairs, hall traffic, play areas, children moving about in the test room or screening personnel giving instructions) will make screening more difficult and could result in false positives. The screening room should also have at least a table, two chairs and an electrical outlet.

Screening audiometer
The minimum requirements for selection of a screening audiometer are:

- portability: it is important the audiometer can be moved between locations. It should be sturdy so that damage is not caused by packing and unpacking each day. This is even more important when the screening is performed in the schools, as the equipment will be brought with the screener each day
- tones: the audiometer should be able to produce pure-tone stimuli through headphones
- sound level: the audiometer should be able to test down to 20 dB HL
- calibration: the audiometer should be capable of being calibrated locally

Additional considerations when deciding on an audiometer

- battery-operated: if the environment will not have consistent electrical power supplied, then a battery-operated audiometer should be strongly considered.
- some audiometers contain additional features outside the minimum requirements (for example, bone condition, speech testing). These are typically more expensive and unnecessary for screening purposes.

The screening audiometer should be calibrated yearly to ensure that the correct stimuli and levels are being delivered.

Headphones
It is recommended that the sound is delivered via headphones to each child to get ear-specific information. It is recommended that headphones are the over-the-ear style or alternatively in-the-ear style. Insert earphones (with foam tips that slide into the ear canal) are another possibility, but these are often not accepted by young children and more expensive as the foam tip is thrown away after each child. Ensure that the headphones selected are appropriately sized to fit young children.
**Tympanometer**
A device for tympanometry or otoscopy is not standard equipment for a screening programme. These methods are part of clinical investigation and require a medically trained screener.

**Forms and documentation**
The following forms and documents should be prepared (more information on the contents of these documents is available in section f below and Appendix 2):

- information leaflets to be provided to parents prior to hearing screening
- consent form to be collected from the parents if screening is performed in school, that is, without the parents present. The local policy regarding informed consent should be followed. Information needs to be available to the screener on how to contact the parents in cases where the child has failed hearing screening. Consent may also be collected to allow sharing information to healthcare providers in the case of a failed hearing test
- test sheet to document the individual results of the hearing screening
- referral letters to parents/caregivers and healthcare providers

**Sanitation**
It is very important that the equipment is clean and disinfected between each child, to prevent infections from spreading from child to child. Sanitary disinfection wipes or sanitary disinfection solution with disposable clothes should be ready prior to testing. All equipment should be cleaned regularly, and the headphones should be wiped clean after each test.

e. **Referral**
A child that does not pass the CHS should undergo audiological examination to determine the severity and type of the HI. A sensorineural HI may be treated with amplification, but many of the referred children will suffer from middle ear disease, which necessitates ENT examination. Ideally, the child should be referred to an institution that offers both audiology and ENT services. Alternatively, the child is referred for audiometry, to be followed by ENT consultation if that is indicated. Local existing practice should be considered to determine the referral path. It should be clear who is responsible for making the follow-up appointment.

- Parents should be made immediately aware of the results and the recommendations for referral.
• The recommended procedure is that the screener directly schedules an appointment with a qualified audiology clinic. The follow-up clinic (audiology or ENT) should be notified of the results of the hearing screening (if legally possible).
• If the audiology or ENT clinic is responsible for making the appointment, the information regarding the child’s screening test result in addition to the contact information of the parent/caregiver should be provided to the clinic (note that this is subject to local laws pertaining to the sharing of information. See Chapter 4 for more information on legal considerations).
• If the parents are responsible for making the follow-up appointment, it must be very clear how and where the follow-up appointment should be made. Contact information should be provided for the clinic where the appointment should be made. Information should be provided both written and verbally.
• Additional information should be provided to the parents why it is important that they follow up after a hearing screening referral. A phone call may be scheduled after a set duration (2-3 weeks later, for example), to ensure and document that the parents did make the follow-up appointment.
• The outcome of the hearing test should be documented in the child’s individual health record (if available) and should also be communicated to the primary care practitioner.

f. Communication

i. Information for parents
Information about the screening programme is important, and can be provided with information leaflets and/or by personnel at the healthcare centres and schools. This subject is covered in chapter 10 and specific advice on information leaflets can be found in Appendix 3.

ii. Public awareness
Communicating the arguments for CHS to the government, policy makers, healthcare providers, educational settings and citizens (parents) is a key factor in the early planning. The more aware the public is about the importance of screening, the higher chance of sustaining an effective screening programme.

iii. Information for care providers
Information about the hearing screening programme must include all stakeholders who will be responsible for or involved in healthcare and children’s early development.
Information can be disseminated through leaflets, presentations at professional society meetings, educational programmes and healthcare board meetings.

iv. Monitoring and reporting
As with newborn hearing screening, quality assurance and the systematic monitoring of programme performance and outcome are essential for a childhood screening programme. All elements of the pathway should be monitored to ensure the programme meets its aims and screeners should be well trained and regularly assessed to ensure their ongoing competency.
Part IV: practical implementation: vision screening
7. VISION SCREENING BEFORE AGE FOUR YEARS

Chapter editors: Anna Horwood, Maria Fronius

a. General background
Identifying and treating reduced visual acuity (VA) in early childhood is the main purpose of screening. Testing VA using logarithmic tests cannot be done accurately in very young children due to their lack of cooperation and cognitive immaturity. Early childhood vision screening is broadly divided into two areas:

- Firstly, neonatal vision screening which aims to detect major ocular pathology and risk of severe vision loss in the first weeks of life. It has very different objectives from vision screening beyond early infancy and does not target the reduced visual acuity and amblyopia that is the target of later screening. With the exception of section c, the majority of this chapter is devoted to neonatal screening.
- Beyond the neonatal period, many children under 4 years of age will be unable to do a linear logarithmic VA test reliably, so between infancy and 3-4 years amblyopia may be suspected or detected, but only poorly quantified. There is significant controversy about whether, when and how, children should be screened (see section c ‘vision screening from infancy up to 4 years’ below and chapter 8 ‘Photoscreening’). Section c outlines the issues, but the consensus from the EUSCREEN study is that by introducing screening before accurate VA testing is possible, costs are increased for only modest improvements in outcome.

b. Neonatal vision screening
The main purpose of vision screening in the neonatal period is to detect ocular pathology and risk of severe vision loss, not the reduced visual acuity and amblyopia that is the target of screening at a later age. A large amount of visual development occurs in the first six months of life, so testing in the neonatal period, whilst essential, is a very poor predictor of later visual problems such as refractive error or amblyopia. Infants are born with very limited visual acuity, poor ability to detect contrast, a wide range of refractive errors, inactive focusing (accommodation), immature binocular vision, unstable eye alignment. They are attracted to faces, lights/windows and high contrast images, and may be very slow to change fixation to new targets (‘sticky fixation’). During typical development different visual processes have different developmental trajectories:
• Visual acuity improves dramatically due to neural and ocular growth from logMAR 1.5 (6/180) or worse at birth to logMAR 0.4 (6/15) at 12 months and logMAR 0.2 (6/9.5) or better at five years \(^{106}\) (for details of notation, see Appendix 1).

• A wide range of refractive errors found at birth grow towards normal (emmetropisation). Refractive errors outside a broad envelope may not emmetropise, and those beyond certain age-related limits may persist or develop into later life. Emmetropisation occurs mostly in the first two years of life, then slows and is largely complete by teenage years. In some children the emmetropisation process is defective, (for example in children with Down syndrome, prematurity or developmental delays) so their early refractive error does not normalise. It is not possible to predict with any certainty whether an infant with a refractive error will emmetropise or not.

• Myopia (short sightedness) is mostly absent in early childhood but develops and increases later. The earlier the onset of myopia, the more myopic the child is likely to be, increasing the risk of developing high myopia later in life, the highest risk factor for visual impairment second to age.

• Binocular vision is very rudimentary at birth and stereo vision is not present. “Adult-like” motor control and depth perception develop relatively suddenly and are relatively mature by four months of age, followed by much smaller changes in later infancy and childhood. If binocular vision does not develop normally, many children will develop strabismus beyond the neonatal period, although it is not clear whether very early onset strabismus is a cause or consequence of lack of binocular vision development.

For these reasons, only screening for the most severe sight-threatening conditions is possible or indicated in early infancy (the first six months of life).

i. Pre-implementation considerations and preparations
Consideration of the political, cultural, geographic, economic and demographic elements in preparation for implementation are covered in chapter 4 of this manual. Neonatal screening for the most common sight-threatening conditions is common in most countries, so infrastructure considerations are mainly to do with tailoring existing services maximizing coverage, efficiency and reducing loss to follow up. If a completely new service is to be set up, primary considerations are listed below:

• whether the proposed programme is local, regional, or national, and how reporting will be fed upwards to national datasets.

• funding – both for initial implementation and for sustainability.
• what kind of maternity care expectant mothers receive e.g. will provision have to be made for babies who leave hospital soon after birth, or are born at home.
• how will babies needing special care be screened? Premature infants have additional visual risks (see next section) and need to be placed on alternative care pathways.
• will the visual screening be carried out by staff carrying out other health checks e.g. hips, hearing, or by those with specialist training.
• whether the necessary follow-up diagnostic testing facilities exist in terms of appropriate venues and equipment and if so, how these are accessed. Conditions such as congenital cataract and retinal tumours are rare and may be treated by tertiary centres requiring many hours travel, which may be impossible or unaffordable for some parents, so will provision be necessary to support them.
• will special efforts be necessary to ensure that parents understand the importance of the screen and, particularly, the urgency of rapid early diagnosis and treatment.

ii. Types of vision screening in the neonatal period
Newborn vision screening targets severe sight-threatening ocular diseases such as cataract, neonatal ocular infections, corneal opacities and ocular tumours. It is vital that these are detected very early because they either can be life-threatening, or lead to a very severe form of amblyopia (‘stimulus deprivation amblyopia’) which can be prevented by appropriate, and often intensive, treatment which must be started within the first weeks of life. These conditions are rarer than other forms of amblyopia (for example the prevalence of congenital cataract is less than 0.05%\textsuperscript{107} and of neonatal tumours is less than 0.00008%\textsuperscript{108} compared with amblyopia prevalence of around 3%\textsuperscript{109}).

Screening of specific at-risk groups
Some children are at more risk of poor vision than others. Children born prematurely or of low birth weight are specifically at risk of retinopathy of prematurity (ROP) which occurs due to abnormal development of the retina and its blood supply associated with the pre-term delivery and neonatal intensive care. ROP is a leading cause of childhood blindness if left untreated. ROP screening in the neonatal period is offered to premature or very low birth weight infants only, and involves regular detailed retinal examinations after dilating eye drops, carried out by experienced paediatric ophthalmologists. It is therefore much more intensive and targeted than general neonatal screening and will not be covered in detail in this document.
Children at risk of metabolic, genetic or inherited diseases which affect the eyes, for example phenylketonuria, deaf children and children with disabilities, may also need specific testing throughout infancy. Refractive error does have a genetic component, but
many early refractive errors will emmetropise, so neonatal screening for refractive error is not indicated.

### iii. Objective setting

Neonatal screening is common in many countries but the timing of these screenings varies (as evidenced by the EUSCREEN Country Reports). Neonatal vision screening can take place in maternity units or in the community, and may be repeated in the first weeks of life to ensure that difficult-to-test infants are tested properly and that emergent conditions which may be minimal in the immediate neonatal days, such as infections, developing cataracts or haemangiomas are detected and referred. Testing is commonly carried out by general medical or paediatric personnel such as paediatricians, neonatologists, GPs, nursing or midwifery staff in the course of more general health checks.

### iv. Target conditions

For neonatal screening the target conditions are ocular media opacities (corneal opacities, cataract and ocular tumours), conditions which cover the pupil (lid ptosis, large lid haemangiomas) and signs of ocular infections (red or swollen eyes). Any of these can prevent clear images reaching the retina and prevents vision developing normally. Such abnormal visual experience is extremely harmful and needs prompt treatment. Some, such as retinal tumours, can be life-threatening.

### v. Location

The screening may take place in a maternity unit if the infant is in the unit for long enough for a reliable test to take place. In units where mothers are discharged soon after birth, or if birth takes place at home, it might be better for the test to take place during other health checks in the neonatal period in the community or on a home visit. As with all screening that depends on parents bringing their infants to be checked, uptake depends on parental awareness, acceptance, willingness and ability to attend. Where neonatal screening does not already exist, public information campaigns may be necessary to increase parental uptake of screening. Neonatal vision screening shares many similarities with neonatal hearing screening (see chapter 5). Coordination is necessary between maternity and community neonatal support networks.

### vi. Information for parents

Neonatal vision screening is generally quick, and often carried out during other neonatal checks by nurses, midwives, paediatricians or GPs. The consent process is usually part of
consent to general neonatal checks. Any opt-in system is likely to result in lower uptake of the screening from the most vulnerable groups. For more information see chapter 4e.

This basic screening is an opportunity to deliver basic eye care advice and alert parents to warning signs to watch out for in later infancy. These include:

- a white pupil
- strabismus emerging or worsening after three months of age. Occasional intermittent strabismus in the first weeks of life is common and should only be referred if still present at four months of age
- wobbling or unstable fixation (nystagmus or roving eye movements)
- anything that prevents either eye seeing e.g a persistently closed eye
- many children have watery and intermittently sticky eyes in infancy. Most will resolve spontaneously over the first year of life. Parents should be informed of how to seek advice for this or other issues

If a referral is made, parents must be made aware of the significance of the finding and that follow-up for diagnostic testing is important and urgent.

Unless parents are aware of some specific inherited condition, a family history of eye problems or glasses is frequently unreliable due to poor public awareness of different types of eye condition.

**vii. Information for follow-up care providers**

Ophthalmologists or others receiving referrals should be given clear details of each referral made: name, contact details, date of birth, reason for referral, any information they may need about triage of appointments (for example mild versus severe defect). Referral of conditions, such as congenital cataract or tumours may be to specialist centres out of area, so mechanisms should be in place to follow up referral outcomes.

**viii. Screening personnel and training**

Neonatal screening is frequently carried out by trained medical personnel during general neonatal checks. Using eye trained personnel may be less cost effective, especially in community settings or smaller units, when only a few children need screening at a time.

Training materials and instruction of these professionals should be overseen or delivered by ophthalmology services and clear referral procedures should be defined. Record keeping and communication become more complex if multiple organisations and record
systems are involved e.g. hospital and community services, than if health records are more integrated, so great attention should be paid to:

- Identifying children to be screened and any that might be missed e.g. home deliveries
- How many are screened from this population (coverage)
- Reporting outcomes and services receiving referral to parents
- Audit and monitoring systems (collect data and report on coverage, referrals, true positives, false positives)
- Follow up data from referrals so that monitoring of outcomes can take place

ix. **Minimum theoretical/practical requirements after training**

All screeners should have an understanding of the conditions that the screening targets, and have a basic knowledge of their significance and management after referral. They should be able to perform a basic external examination of the eyes, test the ability to fix and follow and to check for a normal red reflex in the pupil. The target conditions are rare, so once the techniques have been taught, training is likely to involve the use of photographs, online resources or model eyes.

High quality training and assessment is essential and should ensure that screeners:

- understand the principles of screening and the difference between screening and diagnostics
- recognise and understand the potential risks and harms, limitations and benefits of screening
- fully understand the workings of the chosen equipment, its use and care
- have extensive hands on experience with the equipment, a period of supervised practice and a competency check before independently screening babies
- are knowledgeable about the policies and procedures of the hospital or clinic in which they are screening and how the screening programme fits in to routine practice
- are knowledgeable about and confident with the screening protocols
- are knowledgeable about the full screening pathway
- understand and can accurately document results and use the data management system
- can communicate sensitively and clearly with parents
- understand about sight-threatening vision conditions, their impact on development, and the interventions which are available
• are confident and calm dealing with babies and new parents
• understand the importance of working as part of a team with both other members of the screening programme and other professionals

x. Alternative training plans
When planning a new screening programme, it may be considered preferable to train many screeners at once, which lends itself to training days and group teaching. Once a programme is established, regular update/refresher days need to be planned to maintain quality standards, team building and motivation. New staff may need to be trained individually, with or without online resources. It is important that if trained in the field by another screener, high standards of the trainer are monitored and assured and bad habits do not creep in. Screeners may be specialists or senior trainees in other medical fields e.g. neonatal medicine, with high staff turnover due to training rotations, so ongoing, high quality training of all new staff must be ensured.

xi. Resources for training materials
As well as face-to-face training, written and online learning materials should be provided and regularly updated. Every new screener should have a supervisor or mentor for day-to-day advice if necessary. Most screeners will work in isolation from other screeners, so regular opportunities to meet or share experiences are recommended. In remote areas, this might need to be online.

xii. Follow-up of screening personnel and training
As a screening programme becomes established, expertise and community acceptance become embedded. Regular evaluation will help determine the communication needs and the interval between training and re-training. Feedback to individual screeners about the diagnostic outcome of their referrals is important in terms of quality assurance and screener confidence.

xiii. Protocol: test choice
The tests generally include:

• external observation, looking for any corneal opacity, a white, atypical or obscured pupil, abnormal iris pigmentation or anomalies such as coloboma or aniridia, nystagmus, abnormal redness, sticky eyes, lid abnormalities, albinism
• ability of the infant to fix and follow the examiner’s or the mother’s face as it moves slowly within the central visual field. Many newborns prefer to look at bright lights
or windows in preference to a stranger’s face and will maintain fixation as their body is gently rotated, so this is also acceptable

- 'red reflex' testing. When looking through any ophthalmoscope set at zero a red reflex from the retina will be seen in the pupil. This demonstrates clear ocular media between the cornea and the retina (however, the red reflex test will not detect peripheral retinal abnormalities such as peripheral tumours). A corneal opacity, cataract or other media opacities such as vitreous anomalies or central ocular tumours will show as an absent, dark or dim reflex. Central lens or corneal opacities show up as a black dot in the red reflex. It is very important that testers are familiar with the range of normal reflexes because eye and skin pigmentation can cause a normal reflex to be anywhere between bright red in very blond children to a very dull, dusky reflex in children with dark skin.

- Brückner Testing. The Brückner Test is an extension of the red reflex test, and requires very little extra training. Instead of using the ophthalmoscope to look at one eye, the tester also sits more distantly so that the ophthalmoscope beam straddles both eyes. The two eyes are more easily compared and if the reflex is brighter at the top or bottom of the pupil, and especially if this differs between the eyes, it may indicate a refractive error that might need more careful monitoring.

xiv. Protocol: rescreening steps

Some infants will be asleep, crying or inattentive at the time of testing so may need to be tested at another visit. If infants are discharged from maternity units before the screen, systems must be in place to make sure they do not miss the screen.

xv. Protocol: pass/refer criteria

The infant should exhibit:

- Normal external appearance.
- Ability to fix a face or bright light as it moves slowly in the central visual field.
- Clear red retinal reflex in each eye, symmetrical between the eyes.

If these are not all demonstrable, re-testing or referral is indicated.

xvi. Protocol: follow-up

Referral of children suspected of a defect should be to local ophthalmology services and should be urgent. A decision must be made whether a direct referral is made to the service, or whether parents are expected to seek care themselves (which risks higher loss to follow up and should be avoided if at all possible). Mechanisms should be in place that referrals are followed up. Ophthalmologist involvement is vital to successful evaluation, so referral and feedback mechanisms should be as minimal and efficient as possible to prevent loss of data. For example an existing
database can be used for data reporting and referral, or a simple return postcard provided. In regions where private providers offer care, loss to follow-up and feedback issues need to be considered carefully. Tracing outcomes from screening is more difficult if community/specialist communication is not routine, healthcare data is not centrally shared, or if parents are left to make their own diagnostic appointments.

**xvii. Communicating results to parents**
The importance of the referral should be made clear to the parents so that diagnosis and prompt treatment can be as soon as possible. Parents must understand that delay in referral can be sight-, or even life-, threatening and must not wait until the child is older. As with neonatal hearing screening, this should be handled sensitively, with a mechanism for parents to access support and advice beyond the screening event.

**xviii. Monitoring**
Efficient monitoring of a screening programme is necessary to be able to carry out effective quality assurance, evaluation and reporting. Regular, appropriately-funded evaluation should take place, including assessment of coverage, training of screeners, performance of screeners, method of screening, referral criteria and results. More detailed information on monitoring can be found in chapter 11.

Note that any data registry should comply with applicable legislation (see chapter 4e) and that, for newborn screening, quality evaluation is especially difficult because referrals are rare and many professionals will make very few, if any, referrals.

**xix. Adapting an existing programme**
Most countries have some type of neonatal vision screening, but adaptations and efficiencies may still be possible or necessary. For example, changes in when or where the test takes place, and by whom. Before change is implemented, evaluation of current services must take place, so that any effects of the change can be properly monitored.

**xx. Overcoming barriers**
Barriers to setting up or improving any screening programme should be identified at the earliest stage, in relation to local circumstances. Identification and strategies to overcome them are critical to success. They may be very low level (local communication or transport issues), mid-level (training or quality assurance) or high-level (strategic or funding). A careful risk register of all possible barriers and how they will be handled and overcome should be kept and regularly updated.
C. Vision screening from infancy up to 4 years

The EUSCREEN Country Reports show that many countries screen children’s vision between 6 months and 4 years of age, but there is a wide variation in practice. Some children are not tested at all during this period, and referrals are made only in the presence of signs or symptoms causing parental or professional concern; while others are screened annually, using a wide range of tests and test combinations. Most assessments rely on orthoptic tests, such as cover tests, corneal reflection assessment, ocular motility testing, stereotests, prism tests and gross VA assessment; looking for strabismus and any clinical sign of reduced acuity in one or both eyes. Stereotests administered as a single screening test, on the premise that amblyopia and strabismus result in poor stereovision, have also been advocated \(^{112}\), but poor sensitivity means they have not been widely adopted. More recently, photoscreening or autorefraction looking for refractive risk factors for amblyopia are being added to some of these assessments (see chapter 8). All these tests generally target risk factors for amblyopia, rather than amblyopia itself. Referral rates of 53\% were reported in a study using a battery of VA, binocular vision and photoscreening tests in 4-year-olds\(^{113}\). There is often very poor reporting and availability of outcome data, so comparisons are difficult or impossible.

There are specific issues relating to testing young children that make such screening of limited value in terms of most of the WHO recommendations for screening (see Chapter 2a).

- VA is often inaccurate, unreliable and poorly quantifiable because young children cannot do linear logarithmic tests. Young children are often inattentive, uncooperative or will not tolerate uniocular testing.
- Tests may be timed to coincide with vaccinations, hearing or other health tests, so children may be tired or apprehensive on the day.
- Testing of young children is a highly skilled process, and results from even the most skilled testers are more variable. VA assessment is often carried out by clinic nurses, health visitors, GPs or paediatricians with restricted eye testing expertise and who may use poor technique\(^{114}\).
- Because these tests need specialist skill to interpret and children can be difficult to test, sensitivity, specificity and PPV for amblyopia are low, and a high proportion of children may be referred for further assessment, while milder amblyopia may be missed.
- Early refractive errors can change rapidly, or normalise, because emmetropisation is active, especially before 2 years of age.
- Some conditions, such as accommodative strabismus, amblyopia and anisometropia develop during this period, so test results can change quickly. A pass one day may be a fail a month later.
• Children are not often in compulsory nursery or education, so parents must bring children to be tested, resulting in low or poor coverage particularly of the most at-risk children in disadvantaged groups, or where public health awareness is poor.

• More screening events cost more, but once children are referred, costs rise even further. The patient journey to discharge after amblyopia treatment is longer, because children are rarely discharged until after the most active phases of the critical period.

• Cost effectiveness calculations up to the point of diagnosis for these early and multiple screenings may be possible in areas where there is good community data, but often the costs lie beyond screening, borne by state health services or parents for much longer. Data sharing between primary and secondary care may be patchy or difficult.

• Audit is very difficult because even if a final VA after treatment is testable, a comparable test result at referral was not possible. A child may be known to have been amblyopic on referral, but precisely how amblyopic they were, or how much they have improved, is often unknown.

• Many children with strabismic amblyopia present due to parental concern about an obvious strabismus, not via screening, so many screened children may already be under secondary care on the screening visit. However the other main causes of amblyopia such as refractive error, may only be detected by VA or refraction, and are not detected by orthoptic tests.

The World Health Organization Screening programmes: a short guide outlines the general issues very well. Decision-makers must decide whether multiple, early and imprecise tests provide more benefit than reducing screening interventions to later, more accurate tests from the age of four years. Early screening is more difficult, less precise, and leads to longer overall treatment of supervision costs. The advent of photoscreening, possible in very young children (see chapter 8) has highlighted these controversies further. Although amblyopia outcomes are better if treatment is started early, differences are small and outcomes are still generally good even if treated later, as long as treatment is carried out within the critical period. For example, the large UK ALSPAC cohort study compared children screened 6 times up to 37 months, with a group tested just once at 37 months. Amblyopia treatment outcomes were good in both groups (both better than a mean of 0.2 logMAR) and the intensively screened group only saw an average of 3 letters better than the later, single screened group)\textsuperscript{115 116} found little effect from removing a screening at 6-9 months, and modelled\textsuperscript{117} that omitting a further screening at 24 months would also not lead to significantly worse outcomes. Moving screening from 3-4 years including orthoptic testing, to a VA test alone at school entry 4-5 years in the UK made little difference to outcomes of amblyopia treatment, but because parents did not have to bring their children.
to be tested, population coverage increased dramatically\textsuperscript{110}. This clear advantage may not apply in countries with significantly later school entry age unless most children attend nursery or kindergarten before formal schooling.

Looking for strabismus, refractive error and other risk factors for low vision in very young children may change what actually becomes the target condition. Although a screening service may say it targets amblyopia and significant low vision, by referring children who are \textit{at risk} for low vision, rather than children who actually \textit{have} low vision, many more children will be referred and then receive treatment for a non-amblyopic condition.
THINK BOX: WHICH CHOICE WOULD YOU MAKE?

REFER WHEN LOW VA CAN BE PROVED FROM A SINGLE VA TEST (4-5 YEARS) - E.G. THE UK MODEL:
- ONLY CHILDREN WITH ACTUAL LOW VISION RECEIVE TREATMENT
- AMBLYOPIA AND EVERYDAY LOW VISION REMAIN THE TARGET CONDITIONS
- MILD, NON-AMBLYOGENIC CONDITIONS WILL NOT BE REFERRED AND SO ONLY BE TREATED AS THEY PRESENT LATER
- LOW COST - FEWER REFERRALS, HIGH PPV FOR THE TARGET CONDITION
- TREATMENT FOR GENUINELY AMBLYOPIC CHILDREN MAY NOT START UNTIL LATER IN THE CRITICAL PERIOD, SO OUTCOMES MAY BE MARGINALLY WORSE, BUT ARE MARGINALLY WORSE OUTCOMES SIGNIFICANT TO AN INDIVIDUAL’S FUNCTIONAL OR QUALITY OF LIFE, OR AT A POPULATION LEVEL?
- RISK OF HARM RESTS ON THESE MARGINALLY WORSE OUTCOMES AND POSSIBLE ADVERSE EFFECTS OF MILD CONDITIONS

OR

REFER EARLIER FROM RISK FACTOR SCREENING (INACCURATE VA TESTS / ORTHOPTIC TESTS / PHOTOSCREENING AT UNDER 4 YEARS) (COMMON IN MANY HIGH-INCOME COUNTRIES):
- CHILDREN WHO MIGHT HAVE LOW VISION RECEIVE TREATMENT TO MITIGATE OR PREVENT AMBLYOPIA
- RISK FACTORS BECOME THE TARGET CONDITION FOR THE SCREENING
- MARGINALLY BETTER AMBLYOPIA TREATMENT OUTCOMES
- CONDITIONS OTHER THAN LOW VISION AND AMBLYOPIA WILL BE REFERRED AND TREATED (MILD REFRACTIVE ERRORS, NON-AMBLYOPIC, COSMETICALLY INSIGNIFICANT STRABISMUS, CONVERGENCE OR STEREOVISION DEFECTS
- EVIDENCE THAT THESE CONDITIONS ARE SOCIALLY SIGNIFICANT IS STILL EQUIVOCAL
- ONCE REFERRED, AMBLYOPIC CHILDREN NEED MORE APPOINTMENTS FROM EXPENSIVE SERVICES AND LONGER TREATMENT AND SUPERVISION
- MUCH MORE EXPENSIVE - TO PARENTS AND HEALTH SERVICES. ARE YOUR COUNTRY AND POPULATION WILLING TO PAY FOR IT?
- RISK OF HARM RESTS ON COSTS AND POTENTIAL FOR OVER-TREATMENT OF INSIGNIFICANT CONDITIONS.


8. PHOTOSCREENING

Chapter editor: Anna Horwood

a. Introduction
Vision screening can be broadly divided into testing for the primary signs of amblyopia and low vision (by testing visual acuity and eye alignment), which is a skilled task and imprecise in children under four years of age; or looking for the risk factors for these conditions (significant refractive errors, strabismus and media opacities) by objective and semi-automated methods such as autorefraction or photoscreening. Screening using stereotests to look for reduced stereopsis which can indicate amblyopia, is another form of screening (see chapter 7 section a-ii). The rationale behind early screening for risk factors is that by correcting them early, amblyopia can be prevented or mitigated. Semi-automated risk factor screening can be done earlier than VA testing and sometimes more easily. Autorefraction takes images of a child’s eyes, which are then analysed by software to estimate refractive error and sometimes evaluate eye alignment. Autorefraction frequently arrives at an actual measure of refraction i.e. a glasses prescription, but in the context of this manual we will be discussing photo- or auto-refraction only as used in the screening context and will be referred to as “photoscreening”. Photoscreening can be used on much younger children than visual acuity measurement (which requires much more cooperation from the child), because the only cooperation required of the child is to briefly look at the camera.

A major decision for commissioners of services is whether vision screening is targeting low vision, or for the larger number of children with risk factors for low vision, or both. Although early and automated testing can seem an attractive option for those funding public healthcare, relative costs and benefits over the whole patient journey may be less clear cut. It is very important for funders and planners of services to understand the controversies.

As mentioned in the previous chapter, the EUSCREEN Country Reports suggest that in many cases photoscreening is being added to some existing local screening services for the younger children for whom VA testing is imprecise. Thus within a country, some services will be looking for low vision, while others will be looking for not only low vision, but its risk factors as well. Where private providers (e.g. pediatricians) are screeners, it is frequently offered as a ‘billable extra’ to mandated tests, so children whose parents chose to pay for this option are screened and treated for risk factors, while other children will be screened for low vision only. This makes any local or regional audit very complex, and
reduces the equity of opportunity that are WHO and EU aims, and also risks introducing a profit motive for providers of screening or care. Both photoscreening and visual acuity measurement have merits, so decision makers must decide which is most appropriate for their situation. Setting up either type of screening service will involve many of the stages outlined in chapter 9, but this chapter outlines some of the issues that may influence which modality to choose. The EUSCREEN model will help compare relative costs, particularly the significant effects of adding photoscreening to existing services.

b. Photorefractors and autorefractors
Most automated screeners use the principle of photorefraction. Autorefractors usually test one eye at a time, while photoscreeners generally test both eyes at the same time, so can also detect some types of strabismus. Early studies with equipment no longer available began in the early 1980’s but more devices have been commercially available since the mid-1990s. The child simply looks at some form of sensor (usually infra-red) and an algorithm calculates an estimate of refractive error from the characteristics of the retinal reflex produced from an infra-red light source. Photoscreeners can be set up to give an estimate of actual refractive error (i.e. used as an autorefractor and the refraction reading used by the screener to decide whether referral thresholds are exceeded) or as a pure screening tool to be administered by lay screeners with a simple ‘pass/refer/untestable’ result. Most are supplied with factory-set referral criteria, based on evidence-based guidelines such as those recommended by American Association of Pediatric Ophthalmology and Strabismus (AAPOS). These can result in unacceptably high referral rates and some services have adjusted these to optimise results, for example in Germany and Flanders. In most cases these settings can be adjusted if different levels of sensitivity and specificity are required, or if the target condition is not only amblyopia risk factors, but also specific levels of refractive error, for example developing myopia.
Photoscreening can sometimes be carried out with additional lenses or filters to extend the equipment operating ranges or compensate for sub-optimal light levels in the testing environment.
A newer method of automated screening – birefringence scanning - uses a different principle based on detection of foveal fixation, which is generally defective or eccentric in an amblyopic eye. This test has potential to be more specific for amblyopia and strabismus, but at the time of writing there still are limited published data. It should be noted that new technologies are being developed such as eye tracking systems, that could possibly be used for vision screening in the future, although at this point little is known about the public health advances these technologies offer.
All photoscreening methods are designed to be child-friendly, portable and to be operated by minimally trained personnel. Testing only requires a child to look steadily for long
enough for the reading to be obtained. This usually takes a few seconds, so it is often possible to get an accurate estimate of refraction even in infancy. There is a large literature on photoscreening and autorefraction, but it is important to note that sensitivity, specificity data are generally reported in terms of success in detecting the risk factors for amblyopia, not low vision or amblyopia itself. Visual acuity screening literature, on the other hand, reports on success in detecting the conditions themselves. Therefore, direct comparisons between photoscreening and visual acuity measurement are frequently difficult.

c. Early versus later detection of amblyopia

There is strong evidence to show that amblyopia can be prevented, and is more easily treated, earlier in the critical period of visual development, and certainly before seven years of age. There is little doubt that all screening for amblyopia before this age reduces preventable and generally permanent loss of vision. Detection of risk factors is often advocated in order to detect and treat amblyopia earlier, before the amblyopia is so firmly established, or where skilled screeners are not available. Both visual acuity screening and earlier photoscreening will detect amblyopia before it is too late to treat, but the argument between early versus late (for example 2 versus 4 years) screening is much less clear than the argument between screening and no screening at all. There is some evidence that earlier detection has some advantages in terms of somewhat better outcomes, more rapid or easier treatment of amblyopia, and prevention of a few cases of strabismus, but these relative advantages are more modest (see previous chapter). For example early detection may result in a line better on a vision chart, a shorter period of wearing an eye patch or a small number of cases of strabismus prevented. These advantages could also be counteracted by more hospital visits or family difficulties caused by years of enforcing many reluctant young children to wear glasses or patches. The wider availability of photoscreeners has highlighted the debate between earlier versus later detection of amblyopia and refractive errors. More very young children will have amblyopia risk factors than will go on to develop reduced visual acuity, amblyopia or significant refractive errors. This is because some young children have refractive errors which will resolve spontaneously due to emmetropisation in the first years of life. This is particularly the case for hypermetropia (long sight) and astigmatism in infants which may not persist into later childhood. Emmetropisation is still very active in the second year of life so many infants have moderate refractive errors that will resolve. Beyond two years of age fewer children with a significant refractive error will grow out of it completely, but it may reduce to levels below a screening threshold. The degree of emmetropisation varies among children and some children may even have increasing hypermetropia and these in particular would be prone
to develop accommodative strabismus and amblyopia\textsuperscript{127}. It is possible that children with increasing rather than decreasing hyperopia or anisometropia are particularly at risk of amblyopia and strabismus.

Some refractive errors are more 'amblyogenic' than others, such as hypermetropia over approximately +3.00D, hypermetropic anisometropia (one eye more long sighted than the other), and significant astigmatism. Mild hypermetropia or myopia (short sight) more rarely lead to amblyopia. Myopia is rarely present in early infancy, typically develops in later childhood and adolescence, and myopic children have clearer vision for near so rarely develop amblyopia. Hypermetropia is a particular screening problem because not all even significantly hypermetropic children (e.g. +5.00D), will have low vision\textsuperscript{128} and it can also be missed by photoscreening\textsuperscript{129}; although they might struggle with prolonged close work.

\textbf{At the time of writing, we do not know the relationship between the presence and level of early refractive risk factors and the likelihood of developing amblyopia in an individual child. We also do not know how much glasses for mild refractive error in the pre-school years help general development or lead to better long-term outcomes; or conversely, lead to more stress, cost, or social stigma.}

d. Limitations of the evidence base

i. Photoscreening to detect refractive error

The availability of earlier detection by photoscreening has highlighted some deficiencies in the evidence upon which decisions must be made.

The World Health Organisation offers guidance for conditions for which screening is recommended (see chapter 2a). While amblyopia fulfils most of these, because it is preventable and must be treated in the critical period of visual development, it is less clear that these criteria apply for early detection of refractive error which does not cause amblyopia, such as mild myopia or hypermetropia.

Vision concerns may differ across the world. The distribution of refractive errors varies between ethnic groups and national priorities may vary. For example, myopia is very common in East Asian populations\textsuperscript{130}; hypermetropia and amblyopia more common in Caucasian populations; and astigmatism common in South Asian and some native American populations.

Decision-makers considering what form of screening to adopt should consider their local distribution of refractive errors and thus their prevalence of amblyopia.
Refractive error is largely unpreventable, and there is only weak evidence at the moment that mild uncorrected refractive errors degrade school performance in the very early years of schooling (although future research may change this opinion in due course).

ii. **Stand-alone photoscreening or combined with visual acuity testing**

Much of the published literature reports the use of photoscreening as a stand-alone test, often only administered at one time point in a child’s life\(^\text{131}\). Most reports do not consider uptake of follow up for accurate diagnosis or treatment outcomes. Consideration of photoscreening versus other screening modalities such as visual acuity testing is rare. In particular, the total cost of a patient journey, or lifetime costs, in relation to differences in outcome for early vs later screening, is rarely considered.

In contrast to the impression of photoscreening use reported in the literature, the EUSCREEN data show that, in specific regions in many countries, photoscreening is used as an additional test within a combination of tests, or carried out on very young children before subsequent visual acuity testing carried out when older, or is repeated. Adding photoscreening rarely replaces tests already being done, and is often done by more expensive testers trained to also test vision. If paid for as an additional private test, there can be an unfortunate incentive to repeat photoscreening in some practices. This may lead to higher costs for both screening and treatment. Adding photoscreening is likely to lead to more, and earlier referrals. More children are given glasses, both to correct refractive error and to try to prevent or mitigate amblyopia development. These children are then often kept under observation and treatment until their VA can be tested later, and are often screened again with a VA test, though many of these children now are already undergoing treatment. Early referral of children with amblyopia risk factors means that children also need more specialist visits because they may still be followed to visual maturity, whatever the age they are referred. Many more glasses will be prescribed to young children: after five years of photoscreening in Flanders, Belgium the number of 4-year-old children wearing glasses had risen from 4.7% to 6.4%\(^\text{132}\). Although treatment outcomes may be slightly better, this is by a smaller margin than might be expected\(^\text{133 134}\).

**Decision makers must weigh the relative advantages and disadvantages of visual acuity screening which is only accurate in children over 4 years of age versus earlier or concurrent photoscreening.** Some of the costs and disadvantages of photoscreening may be long term or more hidden because long term treatment and outcome data lies outside public health databases or control. The EUSCREEN model may help inform these decisions.
**THINK BOX**

IF YOU PHOTOSCREEN AT AGE 3, MANY CHILDREN WILL BE REFERRED BECAUSE OF RISK FACTORS (AND SOME DUE TO UNTESTABILITY). MANY OF THESE CHILDREN WILL THEN BE GIVEN GLASSES, OR OBSERVED UNTIL THEIR VA IS TESTABLE AT AROUND 5 YEARS OF AGE. SOME AMBLYOPIA WILL PROBABLY BE PREVENTED, BUT MANY CHILDREN MOVE EARLY FROM THE COMMUNITY INTO THE SECONDARY REFERRAL SYSTEM AND START INCURRING TREATMENT COSTS.

AT AGE 5, MOST OF THE SEVERE CASES (THOSE WITH REFRACTIVE RISK FACTORS ALREADY SCREENED AT 3, PLUS THOSE OBVIOUS STRABISMUS, LOW BILATERAL VISION WHICH PRESENT TO HEALTHCARE DUE TO PARENTAL CONCERN) WILL NOW ALREADY BE UNDER TREATMENT, SO ADDITIONAL VA SCREENING WILL NOW ONLY PICK UP SMALL NUMBERS OF ADDITIONAL MILD PROBLEMS, AND FROM A POPULATION WITH (NOW) A LOWER PREVALENCE OF AMBLYOPIA BECAUSE THE EARLY TREATMENT PREVENTED A PROPORTION OF CASES. THE COST OF THIS SECOND TESTING, FOR A RELATIVELY SMALL NUMBER OF ADDITIONAL CASES DETECTED, MAY MAKE THIS "DOUBLE SCREEN" THE MOST COSTLY COMBINATION OF ALL. ALTHOUGH RE-SCREENING CHILDREN ALREADY UNDER TREATMENT IS UNNECESSARY, IT CAN BE MORE ADMINISTRATIVELY CHALLENGING TO FIND OUT WHO NOT TO SCREEN IN A CLASS, ESPECIALLY IF CHILDREN ARE NOT WEARING THEIR PRESCRIBED GLASSES, SO MANY CHILDREN ARE SCREENED TWICE. SOME TESTS AND EVEN REFERRALS MAY BE SUPERFLUOUS, BUT STILL INCUR COSTS (EXTRA ADMINISTRATION, SAME STAFF, TRAVEL, EQUIPMENT).

e. Advantages and disadvantages of photoscreening

i. Advantages of photoscreening

- Testing is often possible at any age from infancy, so this is a clear advantage over visual acuity testing which is only accurate from around 4 years of age (see discussion in previous chapter).
- Earlier referral of at risk children, so amblyopia and strabismus outcomes may be better.
- Each test takes only a minute or two so many children can be tested in one session. However, some highly efficient VA screening services delivered by orthoptists can also test many children in a session\(^{135}\).
- Modern commercially available photoscreeners are designed to be administered by minimally trained screening personnel so staff and initial training costs are much
lower. Where skilled testers who can gain experience in testing many hundreds of children are not available, photoscreening may be the only viable option.

- Costs per screen are reported to be low because of rapid testing time, and being delivered by lower paid operatives, especially if equipment costs are not considered.
- Automated, so greater consistency between screeners.
- Photoscreening will detect refractive error as well as risk factors for amblyopia. This may be a consideration if refractive error is included as one of the target conditions for the screening.
- Estimates are possible of refractive errors in anisometropia, myopia and astigmatism without needing dilating eye drops, which are the gold standard requirement for accurate refraction in children, but not possible in a screening situation.
- An oft-heard argument for early detection and correction of refractive error is that it will aid general development and educational attainment. While this seems likely for the few children with severe vision problems who cannot access the size of print and close work tasks they need to do, it has not been established if a delay of a year or two in correction of milder refractive error carries any proven long-term harm if they can still engage in age-appropriate toys and print, even if it is slightly blurred.

ii. Disadvantages of photoscreening

- Equipment, maintenance and replacement costs are higher than for visual acuity screening (a photoscreen device can cost up to €7,500 and may need replacing every few years, many times more expensive than a VA test). Some companies offer rental or lease arrangements for equipment. If many screening sites can share one device, this cost may be acceptable, but the device needs to be carried, and set up every time, from site to site, increasing wear and tear. If one device per site is needed (for example if screening is carried out by paediatricians, every paediatrician in a city will need one), costs increase dramatically and many hundreds of devices will be required.
- Photoscreeners are not as accurate at measuring hypermetropia compared to the other refractive errors. It can be missed or underestimated if a child compensates for their refractive error by accommodating (focusing) briefly during the test. Thus, one of the major risk factors for strabismus and amblyopia can still be missed.
- Other conditions known to cause low vision will not be detected by photoscreening such as nystagmus, microstrabismus, retinal abnormalities.
- There will be many referrals per target case of amblyopia. Referral rates from photoscreening in young children are frequently reported to be close to 20% or
more\textsuperscript{139}, compared with around 5-8\% for good visual acuity screening services, in populations where the prevalence of amblyopia is around 3\%.

- A substantial amount of young children will be untestable because they will not look at the sensors for long enough for a reading to be obtained. The 'untestable' rate, if tested before 2 years of age, can exceed 12\%\textsuperscript{140}. Most screening programmes would repeat screen or refer these children for diagnostic assessment, leading to additional costs.

- Some children with risk factors will not develop amblyopia and will eventually be discharged without treatment. This is particularly significant if babies are tested, because a larger proportion of them will emmetropise. They will need comprehensive testing and often follow up before decisions to treat or discharge are made. A significant proportion of children will never receive glasses or only get them at a later date\textsuperscript{141}. Follow up and treatment costs may therefore be high in the longer term.

- Children referred from photoscreening with genuine amblyopia or low vision enter healthcare services earlier. Because, whatever the age of referral, children with amblyopia need supervision until the critical period of visual development is over, they will need more visits to more expensive services, for possibly only modest improvement in outcome.

- Services need to be willing and able to receive, treat and monitor the larger number of referrals. In countries where skilled paediatric ophthalmic services are limited, very high false positive rates and the many children with milder refractive errors could be a burden on already stretched services. Public health thresholds for concern may differ from professional standards. Once referred, ophthalmologists may apply lower treatment criteria than those used for screening referral\textsuperscript{142}, so children may eventually get glasses for a condition that would not have failed screening. For example a child referred as an untestable baby might be given glasses for -1.00D of myopia at age four, which is not an amblyopia risk factor and would be unlikely to hold them back at school at this age.

- Equipment limitations.
  - Data capture may be inaccurate or impossible in the case of ambient lighting levels being too high/low or if the child has small/large pupils
  - Most photoscreeners have a limited operating range to detect large refractive errors if an estimate of refraction is required
  - False readings can occur due to certain eyelid features or curly eyelashes obscuring the pupil margins
  - Some specific pigmentation of the iris and retina may make the pupil margins undetectable to the camera and the estimate of refraction unreliable
The photoscreeners use internal mean calibration factors informed by validation studies. There may be individual differences in calibration factors, which may differ between ethnicities with lighter and ethnicities with darker eyes. These latter points all increase false positive or repeat screens. The last three points may mean that some photoscreening is less reliable in some non-Caucasian populations.

Parents may be less likely to follow up the screening visit if told the child “might have a problem”, rather than if they are told (or see) that the child actually cannot see. This is particularly important in countries with low awareness of the importance of children’s eyesight, low trust in healthcare providers, poor cultural acceptance of children in glasses, suspicion of a profit motive, or logistical difficulties in accessing specialist follow up where parents might need to be persuaded to make a long expensive journey to a specialist.

f. Current controversies

- Do the visual, social and developmental benefits of early detection and referral for a few children outweigh the additional equipment, referral and treatment costs associated with lower positive predictive value and longer treatment/observation times for many others?
- How much does earlier detection reduce the long term prevalence, incidence, severity and treatment times of amblyopia cases?
- In particular, does one good visual acuity assessment which does not depend on parents keeping screening appointments, at an age when it is accurate lead to worse public health outcomes than more frequent, additional or earlier photoscreening?
- Should photoscreening be repeated, and if not, what is the optimal testing age? Anecdotally, many experts in screening consider that multiple photoscreenings improve sensitivity and specificity, but more visits mean higher costs.
- Photoscreening may be an option when no skilled testers are available, but could more investment in training a dedicated group to be skilled VA testers be an alternative option? This could lead to lower long-term costs by reducing false referrals?
- If refractive error and amblyopia are the target conditions for vision screening, how important is it to correct modest refractive errors which make only a line or two difference on a vision chart, but would not prevent a child's activity in the preschool years, compared to on school entry?
- When children enter formal schooling at different ages, does the age that glasses are prescribed make a visual and/or educational difference?
• There is some evidence that the trajectory of emmetropisation could be a stronger predictor of amblyopia than a single photoscreening result. In other words, a child who is growing out of their hyperopia in their first years is less at risk of both strabismus and amblyopia than a child who is not, or where it is even increasing. This implies that two measures of refractive error one or two years apart might help identify these children and would argue for repeated photoscreening from infancy into childhood. However, there is limited data to indicate the cut-off points for the increased risk, and photoscreening is particularly bad at detecting precise measures of hyperopia. An “increase” of 1.00D in hyperopia over a year could be genuine, but it could equally be test-retest variability as the child accommodated more for the first test than the second. Costs of the additional screenings would be incurred, and many more children would need full diagnostic assessment and follow up, so at the moment this does not appear to be a cost effective approach to screening. More data is required in this area as it is likely to be a high cost-option and a clear benefit of such an approach would need to be demonstrated.

g. Questions a potential buyer of a photoscreener should ask if considering purchase

• What is/are the target condition(s)? Is the priority to detect amblyopia or to detect refractive error?
• What referral criteria are the factory settings? Can they be tailored for your population, the age of children being tested, and screening requirements? In the case of Flanders in Belgium, the referral criteria needed to be adjusted following excessive referrals.
• Is the local population likely to be willing or able to access follow-up and treatment if their very young child is referred?
• Are there robust procedures in place to evaluate follow-up, prescribing practices and long term outcomes in terms of uptake, improvement in vision, acceptability and costs post-referral?
• Will adding photoscreening to your existing screening programme improve long term outcomes? Who will bear the costs of additional equipment and higher referral rates, and are increased costs justified?
• Are local care providers willing to see a high proportion of false referrals in young children which may occur?
• Which photoscreener? What is the operating range for accurate estimates of refractive error? How tolerant of different pupil size, light levels, child eye colouring is the equipment?
**THINK BOX**

**PHOTOSCREENING**
- EXPENSIVE EQUIPMENT
- LOWER COST STAFF AND TRAINING
- EARLIER REFERRAL
- MANY MORE REFERRALS
- MORE FALSE POSITIVES AND EQUIVOCAL RESPONSES
- MARGINALLY BETTER OUTCOMES OVERALL (PARTICULARLY FOR A FEW SEVERE CASES)
- INCREASED TREATMENT AND MONITORING COSTS
- RESOURCE INTENSIVE FOR HEALTHCARE POST-REFERRAL

**LATER VA SCREENING**
- CHEAPER EQUIPMENT
- NEEDS SKILLED TESTERS WITH MORE INTENSIVE TRAINING
- LATER REFERRAL AND TREATMENT
- LOWER REFERRAL RATES
- FEWER FALSE POSITIVES OR EQUIVOCAL REFERRALS
- SHORTER TREATMENT PERIOD AND LOWER TREATMENT COSTS
- TREATMENT STILL POSSIBLE, BUT STARTS LATER SO MARGINALLY WORSE OVERALL OUTCOMES THAN FROM EARLIER REFERRAL (ESPECIALLY FOR A FEW SEVERE CASES)

**h. Conclusions**

Photoscreening is an alternative approach to vision screening and appears to be a low-cost and attractive option to decision-makers and commissioners of screening services. The available literature suggests, however, that visual acuity screening beyond four years of age is more cost effective overall, especially if public funds subsidise not only the screening but also subsequent treatment costs. Photoscreening referral rates are high, many referred children will not be amblyopic, or not be given glasses immediately; and some amblyopic and hypermetropic children will still be missed. Higher referral rates, poorer positive predictive value and longer treatment times for early photoscreening referrals, may load
higher costs onto the whole patient journey in the long-term; currently without clear evidence of significantly better outcomes at a public health level. The EUSCREEN interactive model will help in this decision-making. By using different combinations of visual acuity measurement and photoscreener episodes it will quickly become clear that its costs are always higher, primarily because the machine costs 100x more than a VA chart and secondarily because treatment costs are higher due to longer treatment times and more children being given more glasses. Adding photoscreening for infants and children to existing services testing VA when older may be the most costly of all, because more children will be referred earlier, falsely referred and treated and observed for longer, while the community costs of VA screening later are still incurred.
Chapter editor: Maria Fronius

9. VISION SCREENING BY MEASUREMENT OF VISUAL ACUITY (FROM AGE FOUR YEARS)

a. Introduction
Although vision screening is generally recommended for the reasons outlined in part I and part II, there is still no consensus about the timing and frequency of the screening, the tests that should be used, and even the target condition. Prior to setting up any screening programme all these issues should be considered. The EUSCREEN cost-effectiveness model can help decision-makers make appropriate and cost-effective decisions in relation to some of their local, regional or national circumstances.

b. Implementing a new programme
In the interest of equity and ethics it is important that all children have the opportunity to be screened. Due to different local circumstances, for example between urban and rural areas, different solutions may be necessary, even within a country or a region. If a new screening programme is implemented, then it is important to consider how everyone can access the screening. This is particularly important in areas that are difficult to access. In order to achieve the best coverage it is important to consider where children of the target age are most likely to be encountered. In countries with an early school entry age this may be best achieved if the screening were to take place in school. It could be in preschool in other countries. If coverage is expected not to be high enough to be considered sufficient, combining visual acuity screening with other important medical appointments such as vaccinations should be considered (see also chapter 4b). Some countries have child healthcare centres where physicians and nurses screen all children for general health conditions, including vision disorders. In other countries, paediatricians and nurses/assistants in private practice may be in charge of vision screening. In countries with an appropriately early school entry age (before age six), visual acuity screening may be combined with a general school entry health assessment which exists in some countries.

Once a screening programme is in place, it is important to regularly evaluate it, and be prepared to modify or implement change processes where necessary (see also chapter 11). The EUSCREEN cost-effectiveness model can assist in modelling alternative scenarios.
c. Programme objectives and targets

i. Objective setting
Communities, screeners and professionals receiving referrals need to be clear about the objective of the programme and the target condition(s) in their specific healthcare setting. High income countries, or those with good public awareness of eye care may be prepared to accept and support greater costs for health services, resulting from earlier or multiple testing and many referrals for mild or borderline problems, or for conditions such as intermittent exotropia or defective binocular vision that are not amblyogenic. However, long-term population-level outcomes may not be significantly better than from a single later screen event, so these additional costs should be considered carefully. Removing a screening episode that a community or profession has come to expect can be unpopular.

Lower-income countries may only have the capacity to screen once and may have to prioritise the most at-risk groups and more severe cases. Even high-income countries may prioritise elsewhere. Public acceptability of the screening may be low due to poor health awareness so uptake may be poor. The EUSCREEN cost-effectiveness model can assist decision makers in evaluating different options. Currently there are two main alternatives with published evidence-bases: a visual acuity test, with or without additional tests such as a cover test or a stereotest or earlier autorefraction or photoscreening, again with or without basic orthoptic assessment\(^\text{144}\). There are also some automated testing technologies being developed which can detect strabismus or absence of foveal fixation.

Amblyopia is the common target condition for vision screening after the age of three years, but is important to establish whether strabismus, and refractive error without amblyopia such as in myopia are also target conditions. If all potential visual deficits, such as mildly reduced stereopsis or occasionally intermittent exotropia are chosen as the target condition, referral rates, and so costs, will be much higher\(^\text{145}\).

Even if amblyopia is the target condition, other conditions will be detected during screening, such as pathology, non-amblyogenic refractive errors, and strabismus. **Incorporating additional orthoptics tests to detect strabismus or poor binocular vision has a weak evidence base (see chapter 7) and unless carried out by trained orthoptists, is often carried out poorly**\(^\text{146}\).

Hyperopia is a particularly controversial topic. Even moderate hyperopia (+3.00 to +6.00 DS) may only reduce VA slightly\(^\text{147}\), and without cycloplegic eye drops, it may evade photoscreening if children accommodate during testing. While it is possible that such hyperopia might interfere with schooling and is a major risk factor for esotropia, the
evidence of causal associations is currently weak. Only a dilated eye examination will identify all hyperopic children, but this stops being a screening test and approaches a full eye examination. Whatever the screening test, some hyperopic children may remain undetected, and decision-makers must decide how much effort and resources should be devoted to detecting these children, and whether it is cost-effective.

A clear decision needs to be made when vision needs to be assessed - as early as possible, repeatedly, or later, at fewer, or a single, screening event(s). This decision may well depend on capacity, other health intervention timings, and capacity to deal with onward referrals.

ii. Referral threshold

The referral threshold used will depend on age-related normative data for the specific test and age range. Visual acuity of >0.2 logMAR in one or both eyes is a common referral threshold. This may be due to amblyopia, refractive error or pathology, which can only be diagnosed after referral to a specialist. 0.2 logMAR is a common threshold because smaller deficits carry few lifetime adverse consequences and using stricter criteria will include children with no visual abnormalities but who have acuity at the low end of the range of normal vision on validated tests. The range of normal vision will vary with age, and all screening services should consider these age norms when determining referral criteria. Normal VA for children over 5 years on some tests is 0.1 logMAR, but if worse than 0.1 is chosen as a referral criterion, referrals will increase and it is not clear whether children with 0.2 logMAR vision are disadvantaged compared to those with 0.1.

A standard and valid pass threshold is that three out of five letters on a line must be seen to pass that line. This is scientifically valid and an easy rule for screeners with less specialist training to follow. The VA notation can be either in decimal (most common in Europe), fraction (in feet or metres e.g. 20/20 or 6/6) or logMAR values (for a detailed explanation, see Appendix 1). Using logMAR VA values allows for each letter on a line to have a numerical value e.g. only one letter seen on a 0.2 line of five letters will equate to 0.28 logMAR VA, and 4 out of the 5 letters would be 0.22 VA in logMAR notation, but in a screening context with a pass/fail criterion the three out of five letters to pass a line is recommended. It is easy for confusion to occur if decimal and logMAR notation are used by different professionals, so training and communication must be consistent, and the notation always has to be specified. The opportunity to re-screen at a later date an unco-operative or a borderline fail child (for example identifying 4 out of 5 letters in one eye and 2 out of 5 in the second eye in a child getting bored) within the screening age ‘window’ will reduce false referrals. It may be more
cost-effective to re-screen children with inconclusive results rather than to refer them directly to a specialist. Some countries may decide that their secondary referral infrastructure could not cope with many referrals of mild problems e.g. children with equal vision of 0.3 logMAR, or those with only one line difference in vision between the eyes. They may choose to adopt a different referral threshold to prioritise more severe cases, either in the early stages of a new screening programme until secondary services develop, or in the longer term if resources are scarce.

In cultures where spectacle wear is less accepted, parents and children are more likely to notice a difference after treatment if the referral threshold is slightly worse vision, which might help to raise acceptability of the screening service in the community in the longer term. For example a child or parent may notice little functional difference between 0.2 and 0.3 VA, so not feel the screening was worth it, but a noticeable improvement in function might be discussed as a benefit in conversations among parents.

An alternative strategy is testing for refractive error risk factors which predict low vision and amblyopia. However, the relationship between having a specific refractive error at any age and the chances of being truly amblyopic is currently unknown (for more detailed information on this subject, see chapter 8). More children will have refractive risk factors than will become genuinely amblyopic, but all are likely to be offered treatment or observed over time once referred.

d. Screening locations

It is best to screen where there are most children of the appropriate age. This is often when attendance at preschool or school is advised or mandated by the state, or at clinics or community centres where all children come for health checks or immunisations. This practical consideration to maximize coverage may override testing at the most visually optimal time to start treatment. The EUSCREEN cost-effectiveness model can help inform these decisions. The implementation study in Romania highlighted that different solutions might be necessary in urban compared to rural areas. In densely populated settings many can be tested by a nurse covering a large population in a defined locality, while in a sparse rural population an experienced travelling tester visiting small, widely dispersed settings might be the most effective option.

While preschool screening might be considered preferable due to potentially better treatment outcomes, unless preschool attendance is high and screening can take place there, early testing often relies on parents bringing their children to be screened. This may affect attendance, which in turn will impact upon the efficiency and cost-effectiveness of the screening programme itself. Poor community awareness of the importance of eye care,
and transport difficulties can also result in reduced uptake of the screening programme and the children most at risk are the most often missed because they do not attend\textsuperscript{150}. This can lead to significant inequalities in access to care. For example, while one child might have a better outcome to amblyopia treatment if referred a year earlier, 40\% of the children may not be screened at all if testing relies on parents bringing their children to a test, so ten children with the target condition may be missed. By screening a year later in school, it may be better to accept the marginally worse outcome for the one child detected later, but screen closer to 100\% of a community’s children (eligible population) and pick up more amblyopes overall. Final outcomes can be very similar despite later referral\textsuperscript{151} if school entry age is sufficiently early.

**EXAMPLE**

THE EUSCREEN \url{COUNTRY REPORTS} HIGHLIGHT HOW NATIONAL COMPULSORY EDUCATION LAWS MAY DETERMINE WHERE MAXIMUM COVERAGE CAN BE ACHIEVED. IN SWEDEN WHERE CHILDREN MAY NOT START FORMAL EDUCATION UNTIL AGE 7, SCREENING IN SCHOOL MAY BE TOO LATE FOR EFFECTIVE AMBLYOPIA TREATMENT. IN THE UK, CHILDREN START SCHOOL AGED 4-5 YEARS SO IF A PROBLEM IS DETECTED TREATMENT CAN BE INITIATED MUCH EARLIER. DIFFERENT COUNTRY REGIONS MAY HAVE DIFFERENT RULES WHEN CHILDREN START SCHOOL E.G. IN INDIA, SO A DECISION IN ONE STATE MAY NOT APPLY TO ANOTHER. TESTING IN KINDERGARTEN OR NURSERY MAY ONLY BE ACCEPTABLE IF ALL CHILDREN ATTEND (E.G. ISRAEL, HAS FREE NURSERY PROVISION WITH HIGH ATTENDANCE), OR IF THERE IS GOOD NATIONAL HEALTH SURVEILLANCE DATA WHICH CAN TRACE CHILDREN NOT IN SCHOOL OR NURSERY AND PROVIDE AN ALTERNATIVE SCREENING OPTION.

The actual screening setting should be a quiet room with good light, but close to where the children are situated, if within a school setting (see Appendix 1 for detailed tips for screeners).

**e. Pathways**

**i. High- vs low-risk children**

Some children are at more risk of poor vision than others. Children born prematurely have a much higher risk of both retinal pathology, refractive error and strabismus. Many regions
screen all premature or low birth weight children soon after birth for retinopathy of prematurity (ROP) and may put in place additional screenings throughout childhood. Children with disabilities and special educational needs are also at high risk of visual deficits, so may be targeted for full visual assessment rather than screening (see also chapter 7a).

ii. Opt-in vs opt-out consent
Opt-out consent is preferable because the default for parental non-action is that the child is still screened (see chapter 4e for more information).

f. Coordination
Coordination and goodwill are vital to the success of any screening programme. The wider community needs to understand the reasons why vision screening is important and parents need to be prepared and able to access treatment if referred. The programme itself must be well organised, and secondary care providers must be able to see and care for referrals. They should also agree to provide feedback on referral and treatment outcomes so that the screening programme can be evaluated (see chapter 11). In some countries or regions, orthoptists or optometrists may be able to deal with some or many referrals, but their relationship to more specialist paediatric ophthalmology services needs to be defined, for example which more complex cases need upward referral.

g. Communication

i. Information for parents
Whole communities including schools, educational boards/authorities, parents, community leaders and ‘influencers’ (such as general practitioners or religious leaders) can help when planning screening programmes. They can provide help and support in many ways, such as promoting the need for the vision screening; identifying ways to better engage with hard-to-reach communities; and help to encourage families to attend the screening appointments. There are many ways in which this can be achieved, including involvement of local media or social networks, or community outreach events. Ideally this should happen before the vision screening programme starts (see chapter 10 for further information).

Information for parents should be in a format they find accessible (appropriate level of language, translation available if necessary, infographics or web-based as appropriate). For
a new service, specific community efforts may need to be made to make sure parents understand why vision screening is important.

Most amblyopia is unilateral, and most children will be asymptomatic, so parents may not accept their child has a potential vision problem. In areas where trust in healthcare is poor, trust in the screening service may need to be built carefully. In many successful screening services, this has taken many years, and may depend more on acceptance within parent communities, than formal information.

Thought should be given to the amount and type of information given to parents of referred children about why they have been referred, how to encourage them to seek treatment, but without causing excessive anxiety.

Parents need to be able to understand how to, and be able to, access the pathway for treatment locally if their child is referred.

The parents need to understand that the screening is not a complete eye examination, so other (non-target) eye conditions may be present and be missed. Conditions may also develop later, but the screening may have been carried out before those conditions had developed. Parents also need to understand that some children ‘fail’ screening, but are found to have no vision problems at diagnostic examination/testing (i.e. false positives). It may be difficult to convey this information to parents. Information resources may need to be piloted and modified to ensure that they too are easy to understand, and include all necessary information. These too should be monitored and evaluated regularly. Parents need to be informed how their data will be handled, stored and accessed (see chapter 4e).

ii. Information for follow-up care providers

In preparation of a new screening programme follow-up care providers should be informed about its objectives and their future role. Ophthalmologists or others receiving referrals should be given clear details of each referral made: name, contact details, date of birth, reason for referral, any information they may need for triage of appointments (for example mild versus severe defect). Their involvement is vital to successful evaluation, so referral and feedback mechanisms should be as minimal and efficient as possible to prevent loss of data. For example an existing database could be used for data reporting or sending reminders, or just use simple return postcards. In regions where private providers offer care, without any mandate to report back, feedback issues need to be considered carefully. The threshold for glasses prescription may vary between ophthalmologists. Prescription
guidelines should be agreed if possible, for example to prevent visually trivial or unnecessary prescriptions.

h. Screening personnel

There may be an existing pool of suitably trained professionals who could screen, such as orthoptists (who consistently have been shown to screen with a true positive rate of over 90%152) or optometrists, but for maximum efficiency of resources less skilled personnel may need to be trained. For example, an orthoptist travelling between schools may be able to screen all children in a large school intake in one morning, but for many reasons this may not be logistically possible in some regions, so people with a basic medical background and good communication skills with children make good screeners, for example school nurses. It is desirable that they are managed or supervised by someone already skilled in the practicalities of vision screening, and in some regions this might mean importing such personnel from other areas to set up and monitor a new screening programme.

**THINK BOX: WHO IS GOING TO SCREEN?**

**TRAVELLING SCREENER COVERING MANY SITES**
+ QUICKLY BECOMES EXPERT BECAUSE SCREENS HUNDREDS OF CHILDREN
+ CONSISTENT SCREENING
+ MAY BE ABLE TO ACT AS VISION EDUCATOR FOR COMMUNITY
- DOES NOT KNOW LOCAL CIRCUMSTANCES AS WELL
- ADVANCE PREPARATION/INFORMATION AND POST SCREENING INFORMATION ON RESULTS WOULD HAVE TO BE DONE BY SOMEBODY (LESS EXPERIENCED) ELSE OR MULTIPLE VISITS WOULD BE NECESSARY
- INCREASED TRAVELLING TIME AND EXPENSE IN RURAL AREAS
- MAY NEED DEDICATED FUNDING FOR A POST
+ INCREASED RESPONSIBILITY FOR SUCCESS OF THE SCREENING SERVICE

**LOCAL SCREENER E.G. SCHOOL OR GP PRACTICE NURSE**
- MAY NOT SEE MANY CHILDREN PER YEAR SO MUCH LESS EXPERT
+ LOCAL KNOWLEDGE OF SOCIAL, ECONOMIC, LOGISTICAL CONSIDERATIONS
+ INCREASED TRUST IF EMBEDDED IN THE COMMUNITY
i. Training screening personnel

   i. Minimum theoretical/practical competencies after training

   All screeners should have an understanding of the target conditions and their management after referral. They are likely to be acting as ambassadors for good eye care, so need to be enthusiastic about their role. Parents and teachers may look to them for basic advice. Good training and ongoing feedback about their performance is vital to develop and maintain skills and to keep their enthusiasm about doing a good job. Training should include both theoretical and practical teaching, as well as formal and certified assessment of competence at the end of training. Screeners should be trained to use the equipment accurately to gold standard levels. This includes the use of logarithmic progression charts, ensuring correct testing distance, effective monocular occlusion, as well as being able to spot when a child may be struggling with the test (for more practical advice see Appendix 1).

   Training should include experience of interacting with children of the age they will be screening. Successful screening often depends on good communication skills with children as much as being able to administer any particular test. If online resources are available, they are very useful for training and future reference.

   ii. Alternative training plans

   At the outset of a new screening programme, many people may need to be trained at once, which may be more efficiently delivered via training days and group teaching. Once a programme is established, regular update/refresher days need to be planned to maintain quality standards, team building and motivation. New staff may need to be trained individually. It is important that if trained in the field by another screener, high standards of that trainer are assured and bad habits are not handed down to trainees.
iii. Resources for training materials
As well as face-to-face training, written and online teaching materials should be provided and regularly updated. Every new screener should have a supervisor or mentor for day-to-day advice if necessary. Many screeners will work in isolation from other screeners, so regular opportunities to meet or share experiences are recommended. In remote areas, this might need to be online.

iv. Assessing screeners’ performance
Any test is only as good as its testers. Visual acuity testing on young children is a very skilled procedure and needs well-trained and experienced testers. The referrals made by each screener should be evaluated and underperforming screeners re-trained. To achieve a complete evaluation of results, clear (and preferably mandatory) reporting back from secondary care-providers is vital. Giving screeners feedback about the accuracy of their referrals, and if possible, outcome of treatment, can help maintain motivation and quality.

Experience of the tester is key to accurate results so each tester needs to have tested many hundreds of children to become fully proficient. Locally sited screeners e.g. school nurses in small rural communities may find it difficult to build up such experience.

In the training phases, screeners should be monitored more closely and appropriate feedback given.

v. Follow-up of screening personnel and training
Regular evaluation will help determine the communication needs and the interval between training and re-validation of individual screener’s competency.

j. Protocol

i. Test choice
The choice of test is determined by the target condition (amblyopia), reduced vision from any cause including amblyopia, or risk factors for amblyopia (see Appendix 1 on VA testing). The two main alternatives with the clearest published evidence-base are a visual acuity test (with or without additional tests such as a cover test or a stereotest), or earlier autorefraction or photoscreening.
Visual acuity tests should be as close as possible to the gold standard Landolt C test, but suitable for the targeted age-group. There are many different tests designed to approach these standards and some are designed for digital displays. See Appendix 1 for detailed discussion of test choice but essential criteria are a linear logarithmic size progression test, with rows of letters or symbols with proportional spacing between letters and rows and validated, published age-related norms. These tests allow each letter to have equal value and relationship to each other. There are various commercially available tests with these characteristics\(^{153}\). It is recommended to choose a test for which normative data are available for the envisaged age range of children to be screened. Snellen charts, which have different numbers of symbols per row and inconsistent progression of letter size between rows, are not advised. Single letter or symbol tests (especially if the letters are not surrounded by ‘crowding bars’), and unvalidated picture tests should also not be used because results from these tests are less precise (see Appendix 1 for more detailed information).

Each eye should be tested separately, ensuring effective occlusion of the other eye with an adhesive patch or well-fitting occluded glasses that a child cannot peep over. The child should be carefully watched throughout the test because a child who cannot see will naturally try to peep.

The EUSCREEN Country Reports show that many current vision screening programmes, however, do not use a single test, or a single test event. Many screening programmes use a combination of different tests, at different ages, tested by people with different levels of expertise, with different referral criteria and in many different combinations. Some countries screen annually throughout childhood and adolescence, while others only twice. The EUSCREEN study has highlighted that poor follow-up, audit and reporting of referrals, uptake and outcomes make it extremely difficult to assess the efficacy of comparative schemes and leads to wide disparities in the costs per case detected. Most screening services develop by adding tests to existing batteries and once screening has been set up, removing tests or screening episodes of limited value can be very challenging.

Some screening services specifically target strabismus, but large angle strabismus usually presents before screening due to parental concern. Small angle strabismus, which is just as amblyogenic as large angles can be easily missed by lower skilled testers. So few additional amblyopes are detected by screening for strabismus that would not be detected by a VA test. Binocular tests such as ocular motility assessment, stereotests and prism tests have low specificity for amblyopia\(^{154}\). If a child has good visual acuity, conditions such as asymptomatic convergence insufficiency, small angle strabismus and ocular motility defects not already noticed by parents, are unlikely to result in treatment.
Screening programmes need to be clear whether amblyopia is the prime target condition for the screening, or whether they also want to detect conditions such as refractive error or strabismus which are not necessarily amblyogenic.

**ii. Rescreening steps**

The opportunity to re-screen a child who struggles with the test will reduce false positive referrals considerably and so save costs post-screening, although a special visit to re-screen one child in a school may not be justified and direct referral be more efficient use of resources. Shy children, those very new to the classroom situation or those with poor attention by the time the second eye is tested may fail the screening without having a visual problem. A repeat screen a few weeks later (or even later in the day) may be more successful. Experienced screeners learn to be able to differentiate an apparently unco-operative child who genuinely cannot see, from one just getting bored, but the option of a re-test is valuable. Conversely, some children clearly fail the first time by saying “I can’t see that” so would not benefit from a repeat screen. Children unable to be tested on a second visit should be referred.

**iii. Pass/refer criteria**

The pass criterion depends on the test used and the age of the child and needs to be related to normative data for the particular test used. A common pass/refer criterion is >0.2 logMAR in 4-5 year olds in each eye with no more than one line difference between the eyes, but it also needs to be decided whether children who do not pass are to be referred straight away or whether there will be an option of a repeat screen.

A decision must also be made as to whether visual acuity should be tested further (to a child’s individual threshold) once it reaches the pass threshold of for example 0.2 logMAR. Further testing of children who see better than the threshold will take longer and also lead to other complications.

**THINK BOX: TEST TO PASS THRESHOLD OR TEST TO INDIVIDUAL THRESHOLD?**

Suppose that children are tested to their individual threshold (Option A) and a child passes the test with VA of 0.0 logMAR (excellent) in one eye and 0.2 (just pass) in the other. The child still has a difference in visual acuity between both eyes that would be defined as amblyopia.

If the same child had been tested to the pass threshold only (Option B), they would have passed the screening. If option A is chosen, should that
CHILD WITH GOOD VISION IN ONE EYE AND JUST SUFFICIENT VISION IN THE OTHER EYE BE REFERRED AND TREATED?

IF OPTION A IS CHOSEN, THE CONSEQUENCE WILL BE THAT THE PROGRAMME WILL REFER MORE CHILDREN THAN IF OPTION B IS CHOSEN, WHEN ONLY CHILDREN WHO DO NOT PASS THE TEST ARE REFERRED. SOME OF THE CHILDREN ADDITIONALLY REFERRED IN OPTION A WILL BE TREATED WHEN THEY WOULD NOT BE IN OPTION B. OPTION A WILL THEREFORE BE MORE EXPENSIVE.

NEITHER OPTION IS RIGHT OR WRONG, BUT WHICH OPTION IS CHOSEN DOES AFFECT THE COSTS AND MOST LIKELY ALSO THE COST-EFFECTIVENESS OF THE SCREENING PROGRAMME. THIS SHOULD BE TAKEN INTO ACCOUNT WHEN DECIDING WHICH OPTION TO CHOOSE.

If photoscreening is used in addition to a VA test, clear rules should be outlined in the protocol for every plausible scenario. If every child is also photoscreened, will children with amblyopia risk factors but adequate VA still be referred? Will the photoscreen only be used for borderline cases, or will VA only be tested on children who fail photoscreening? Referral rates may differ widely as a consequence of the criteria chosen, with potentially very different cost implications. The EUSCREEN model may help with these decisions.

**iv. Follow-up**

After screening the results should be recorded and passed on appropriately in the upward referral and evaluation chain. Referral data should be entered on an appropriate database, checked and audited.

Part of the screening evaluation trail should include following up children who failed screening to establish how many sought referral, obtained a definite diagnosis, received treatment, how long they had to wait for a diagnostic appointment, and if possible, what the outcomes of the treatment were.

**k. Communicating results to parents**

After screening, the outcome of the screening should be reported back to the parents if they are not present at the test. If the child fails the screening test, the parents should be advised to take the child for diagnosis and advised how to proceed. If the child passes the screening test, the parents should be made aware that this does not rule out current minor deficits or future eye problems (see also chapter 9-g-i).
If the parents are not present during screening, for example when screening takes place at school, they have to be informed of the result by letter. Additional communications such as reminder letters or telephone calls are likely to have a positive effect on follow-up rate\textsuperscript{155}. Additional measures to increase follow-up may be necessary in low SES populations\textsuperscript{156}.

The evaluation process should consider whether parents actually received and understood the importance of the initial letter to say their child has failed the screen. In communities where screening has not previously taken place, some mechanism for encouraging uptake of referrals may be necessary. Good links with local nurses, teachers and GPs may facilitate this (but ensuring that data protection issues have been considered). Parents must be informed about (and consent to) where their child’s data will be held and shared with others.

\section{Equity}

A decision must be made about what to do about children who are not screened (e.g. travelling or home-schooled families), or who do not make or attend the diagnostic appointment following referral, and how much effort will be made to make sure they access treatment. Local systems should be agreed about how to follow up these families. A primary principle of screening is equity of access for all, and in practice this may mean that the most effort needs to be targeted to disadvantaged groups who are least able or willing to access care. In countries with poorer health infrastructure, low public health awareness and large remote rural populations, this can be a significant problem that should be considered from the outset.

\section{Monitoring}

Efficient monitoring of a screening programme is vital to be able to carry out effective quality assurance, evaluation and reporting. Regular, appropriately-funded local and central evaluation should take place, including assessment of coverage, training of screeners, performance of screeners, method of screening, referral criteria, diagnostic uptake and long and short-term outcomes. More detailed information on monitoring can be found in chapter 11. Note that any data registry should comply with applicable legislation (see chapter 4e).

Those evaluating screeners should be aware that children who are the youngest of their age cohort may find the tests more difficult, so, for example, more borderline or referred children might arise from a visit early in a school year than later, however good the screener.
n. Adapting an existing programme

Most high- and middle-income countries already have some vision screening recommendations and there may be many different local schemes already in place. Low-income countries may have such schemes provided by outreach charitable organisations. Therefore an existing scheme, whose proponents may already have invested heavily in it, may need to be adapted and its stakeholders be persuaded that change is required. Disinvestment in one scheme in order to develop another can be very challenging. The EUSCREEN model may help provide evidence of relative cost-effectiveness of different alternatives, but accurate data and cost-efficiency predictions are the key to driving change\textsuperscript{157}. Once a decision has been made that change is desirable it is important to retain communication, goodwill and motivation between all involved. Small, incremental changes with careful audit can lead to highly efficient services.
Part V: communication and monitoring
10. PUBLIC AWARENESS AND COMMUNICATION

Chapter editors: Birkena Qirjazi, Anna Horwood

The way the population perceives a screening programme is exceptionally important when a new programme is starting. As with all aspects of screening, local circumstances should be taken into account when developing means of communication. A health ‘profile’ of the population the communication will be aimed at (parents of children to be screened) needs to be known and taken into account. Questions that should be answered are:

- what is the level of health literacy of the population?
- is the population accustomed to preventive healthcare, or are they used to only going to the doctor when obviously ill?
- what is the level of trust the population has in medical professionals?
- is healthcare embedded in children’s education? Are there, for example, school nurses?

If the answers to any of these questions would be a barrier to uptake, acceptance or access to follow up, these issues should be addressed before implementing or modifying a service. Pilot projects are recommended before any large scale change is implemented. In general, communication should deliver accurate, practical and concise information, worded in simple and clear language. Whatever medium of communication is used, public communication should always give clear and accurate messages and avoid complex sentences and specialist language.

Any communication should also take into account ethno-cultural values, and beliefs. Different groups will respond differently to various communication methods.

EXAMPLE

WHEN IMPLEMENTING HEARING SCREENING IN THREE COUNTIES IN ALBANIA, IT WAS FOUND THAT IN GENERAL, IN CITIES SOCIAL MEDIA SUCH AS FACEBOOK WERE AN EFFECTIVE WAY OF COMMUNICATION. IN REMOTE TOWNS AND VILLAGES TELEVISION AND RADIO WERE MORE EFFECTIVE.
All communication strategies should be included as part of the screening programme budget. Communication materials take time to be produced and disseminated. It is important that these are considered as part of the programme’s planning. Both the cost and time required to produce communication materials should be considered before deciding whether these are suitable for a specific screening programme.

a. Public awareness barriers and facilitators

There are three categories of people to be addressed:

- medical staff at child healthcare centres and medical services for children (GPs, paediatricians, ENTs, school nurses, etcetera)
- general public (parents, preschool- and school teachers, other caregivers)
- administrative and decision-making professionals

General public (parents)

Creating awareness among the general public is a long and ongoing process, which will need continuous input. It is very important though, because low parental awareness, attitudes, misunderstanding and mistrust of a screening programme are significant barriers to participation158.

Different forms of mass communication should be utilised to reach different parts of the population. The medium with the biggest impact is television, especially national channels that broadcast in a vast area. Using television can however be expensive and require extra funds. Radio channels and local television channels can be cheaper alternatives. Given the increasing importance of social media in many people’s lives, using social media as a communication channel could be considered.

Word of mouth from parents of successfully treated children can be very powerful, so case studies, audio or video clips or verbatim quotes can be very valuable and it advisable to incorporate these in communication media.

One should be aware of the possibility that participation in a screening programme may be negatively influenced by activity on the internet in general, and social media in particular. The latter may discourage participation or even propagate disinformation, as has been the case with agitation against vaccinations159.
Leaflets and posters may also be a good way of communication. People can take leaflets home and read them when it suits them. In areas where literacy levels are low, infographics may need to be included in leaflets. It should be noted that when leaflets are simply distributed at a location, people often will not pick them up of their own accord so a more active approach to bringing the leaflets to people’s attention may be required. Maternity hospitals’ lobbies, gynaecologists’ waiting rooms, hospitals and health centre corridors and waiting areas are especially suitable because in these locations expecting parents can be reached so they have the opportunity to learn about screening in advance.

When health institutions have projection screens in the lobbies, these can also be used to inform the public about a screening programme by for example showing a screening test. Leaflets with facts, pictures, instructions and so forth can be distributed to mothers after delivery and before leaving the hospital together with other information they receive. This can also be done in mothers’ or children’s health centres. It should be noted that leaflets distributed nearer the time of the screening are more likely to be read than if in a general bundle given out when, for example, a child starts school.

Advocacy groups of parents of children with hearing or vision problems can also be relevant partners in communicating a screening programme. In some countries these groups are very well organised and play an active role, both as information providers as well as lobbying for issues important to them. In some cases, however, these groups have opinions on how hearing or vision problems should be handled, that are different from commonly accepted medical practice. Some organisations of deaf people, for example, do not see deafness as a condition that needs to be cured and therefore oppose certain interventions such as cochlear implants (CIs). Therefore their positions on screening and follow-up should be understood first. However, even if the positions of these groups differ from what the programme advocates, they can still be involved in parts of the screening and follow-up that they do not oppose. If their positions are compatible, the parents’ associations can also be partners in communication with the public.

Medical staff
When starting a screening programme, the medical staff also needs to be addressed, because they are in direct contact with the public and the information they deliver is crucial. They are involved at all stages of the journey from screening to long term outcomes and are also generally respected community influencers. A pregnant woman and a young mother have regular checks with various medical workers; therefore the information given by them regarding the screening should be clear and uniform. An informed health worker can be a facilitator while an uninformed one can be a barrier.
When a new programme is starting it is understandable that some healthcare workers without previous experience with screening are not aware of all the intricacies involved in screening or of the implications of the condition they will be screening for. Many may not know much about screening and for example be unaware of what to do when a child does not pass the test.

This is why it is very important to ensure that as many health workers in the area as possible, and not just the screeners, learn about the screening programme: why it is necessary, how it is done, where the screening tests are offered, what is to be expected from the tests and what follows. They should also have a general idea about clinical pathways. This is particularly important for GPs and personnel working in mother and child centres.

This information can be disseminated in different ways: educational days, special informative sections within an established medical conference or congress or inclusion of the information in general educational curricula for health workers. In countries where Continuing Medical Education (CME) is obligatory, efforts should be made to incorporate the screening information in the existing CME structure. Certificates or diplomas should be awarded at the end of the training courses or seminars, to provide testimony of training to a satisfactory standard.

Administrative and decision-making professionals
For advice on communication with administrative and decision-making professionals, see chapter 4.

b. Communication plan and materials
The general communication plan should be tailored to the needs of the area where screening will take place, in accordance with the funds available and developed well in advance.
Considering the fact that it will take time to effectively communicate the screening programme and influence the public's perception, it is important to plan different communication activities for an extended period of time.

Written and verbal information should be provided before and at the screening appointment, to avoid unnecessary anxiety and misconceptions about screening. It is of paramount importance that parents get the right message. Especially when parents are informed their child failed the screening test and they may experience anxiety and stress.
These negative effects may be countered by providing adequate information and education on follow-up testing\textsuperscript{161}.

The establishment and continuation of a screening programme largely is an issue of available funds and public support for a programme can be a significant asset in acquiring funds. Therefore high levels of participation in the programme are important.

In many new or adapted programmes, great effort is often put into communication at the inception of the programme, but communication also needs to be regularly updated and refreshed and adapted as new parents engage with the service. Low attendance may, for example, be an indication that the communication strategy is not effective in reaching the target audience. Like all other aspects of a screening programme, the communication strategy should be evaluated regularly. Questionnaires for parents can be used to evaluate whether the communication methods chosen have been effective or whether there is a need to modify the communication. Alternatively, before commencing communication parental focus groups or telephone interviews could be set up to help determine the best ways to overcome local communication issues.

Along with the communication plan the materials to be used should be developed such as leaflets, posters, television, social media and radio spots and so forth. For all these it is important to keep the information clear and short and the language simple.

\begin{itemize}
    \item the condition being screened for (hearing or vision loss)
    \item information on how common and serious the condition being screened for is
    \item why screening is done (early detection of conditions, detection of conditions that would not be noticed in everyday life)
    \item the benefits of early detection of the condition
    \item an explanation of the screening test and how it is performed
    \item what happens if the child does not pass the screening test (a second test, referral)
    \item the importance of diagnosis and treatment following not passing the screening test
    \item screening is not infallible: false positives and false negatives
    \item screening is a snapshot: a negative result does not rule out hearing or vision problems occurring at a later stage
    \item possible adverse effects of screening
\end{itemize}
11. MONITORING, QUALITY ASSURANCE, EVALUATION AND REPORTING

Chapter editors: Inger Uhlén, Jill Carlton, Jan Kik

a. Introduction: context and importance
Monitoring, quality assurance, evaluation and reporting are important parts of a screening programme. The World Health Organization states that “Monitoring and evaluating screening programmes at regular intervals are essential.” Without good quality data, it is impossible to assess the effectiveness of a screening programme.

However, one of the most important conclusions of the EUSCREEN study is that, even in countries where screening programmes are otherwise well-organised, there appears to be a lack of data collection and data availability. Even when data are collected, these are often inaccessible and generally do not seem to be aggregated and analysed. Considering this unavailability of data, it is not surprising that quality assurance, evaluation and reporting are not being systematically undertaken in most countries, if at all.

Quality assurance is a continuous process that should take place at all steps in the screening pathway. Each step in the pathway can be compromised by insufficient quality. Evaluation takes place at the end of a screening cycle to assess the results of the programme, to determine whether the objectives have been delivered on and to identify possible problems and areas for improvement. Reporting also takes place at the end of a cycle, to account for the results of the programme and provide advice to policy makers based on these results. Effective monitoring of a screening programme is necessary to be able to carry out quality assurance, evaluation and reporting.

b. Monitoring
The importance of monitoring cannot be overstated. It is imperative that when implementing a screening programme monitoring of the programme is included.

A prerequisite for effective monitoring is high quality data collection: complete and consistent registration of all relevant steps in the screening process. These include the
screening itself, and repeat screening if applicable, as well as referral and treatment (if applicable).
A good quality database is an absolute necessity, where all relevant data are registered by personnel capable of ensuring the quality of the data. The database is the central ‘hub’ of the screening programme in this respect, as illustrated in the flow chart.

Another general requirement for monitoring is that, within a programme, screening is performed everywhere according to the same protocol and data are registered in the same way in order to be comparable. Centralised management of the screening programme may make this easier.
Consistent and uniform registration of data is important. Throughout the programme, consistent terminology should be used, as well as consistent definitions. Screening results have to be written down in uniform values (specified in the screening protocol) and the
database should only accept values in the correct format (for example only ‘1,0’ and not ‘1’ or ‘1.0’ or ‘one’). The database should also use mandatory fields, dropdown fields and logic checks (to prevent errors such as a screening date prior to a child’s date of birth) as much as possible to further minimise the risk of data entry errors.

All data should be timely, complete, unique, valid, consistent and accurate. A checklist that can assist in assessing data quality can be found here.

It is very important that not only the results of screening are registered, but also the results of follow-up (diagnostic assessment). Without this, the quality of the screening cannot be assessed (rate of false positives). Additionally, the results of treatment have to be registered in order to make it possible to analyse the cost-effectiveness of a screening programme.

The above means that a screening programme should not only incorporate effective measures to ensure high follow-up, but also to ensure the results of follow-up are reported and registered. An example of a database structure, for vision screening, can be found in Appendix 4.

In EU countries, all data must be registered in compliance with the GDPR (see also chapter 4e on legal considerations). Results have to be verifiable, though, in case of suspected mistakes or even fraud. This means results have to be traceable to screener/child by using codes with all personal identifying information omitted – codes and connected personal information have to be stored separate from the database.

**EXAMPLE**

IN THE NETHERLANDS, ALL ORGANISATIONS WHO PERFORM NEONATAL HEARING SCREENING HAVE ACCESS TO THE SAME DATABASE, CANG (CENTRAL ADMINISTRATION SYSTEM NEONATAL HEARING SCREENING). THE ENTIRE DATA REGISTRATION PROCESS IS DIGITAL: SCREENING RESULTS ARE UPLOADED STRAIGHT FROM THE SCREENING DEVICES TO THE DATABASE. THIS PROCESS ENABLES REAL TIME QUALITY ASSURANCE. IF APPLICABLE, RESULTS OF DIAGNOSTIC EXAMINATIONS AND INTERVENTIONS ARE ENTERED IN THIS DATABASE AS WELL. BECAUSE THE DATA THUS COLLECTED ARE UNIFORM AND RELIABLE, THESE CAN SUBSEQUENTLY BE EMPLOYED FOR EVALUATION AND REPORTING PURPOSES. AN EXAMPLE OF A REPORT CAN BE FOUND HERE (IN DUTCH ONLY).

It is also important to notice that a database is only as good as the data entered. These should be correct and complete. Great care should be taken to ensure that all data on screening, referrals and treatment are collected because without these data effective
monitoring is not possible. This requires competent and knowledgeable administrative staff. It is also very important that everyone in the screening pathway not only knows **which** data should be registered, but also **why** these data should be registered. When people know the purpose of what they are doing, they will do it more conscientiously than when they have no idea why they have to do something.

### c. Setting benchmarks and defining Key Performance Indicators (KPIs)

Benchmarks provide critical context for the goals of a screening programme. Benchmarks establish what ‘normal’ results would be for a specific screening programme (for example, newborn hearing screening) in a comparable context (for example, a country or region with a certain level of development, standard of living and population density). By comparing the results of a screening programme with the benchmarks it is possible to say whether the programme is performing as would be expected, or below or above expectations.

Benchmarks are measured through Key Performance Indicators (KPIs). KPIs are numeric measures of performance for specific parts of a screening programme. For most screening programmes KPIs would include coverage, referral rates, follow-up rates and treatment results. Some KPIs can be programme-specific, for example, a specific KPI for an NHS programme would be the number of children screened within a certain number of days after birth. An example of KPIs for a newborn hearing screening programme can be found [here](#).

### d. Quality assurance

Quality assurance is a means to assure and improve quality throughout the screening pathway.

This includes the assessment of the delivered quality and well as identification of specific problems and barriers and measures to overcome these.

The screening protocol should provide written, verifiable standards for screening and referral. All professionals who are part of the screening pathway should be intimately familiar with these standards and training and feedback should be based on these standards. **Responsibilities should be clearly defined and all professionals should be accountable for the part of the screening pathway that is their responsibility.**
Regular data analysis is recommended to check for outliers in the data such as excessive referral rates. This can partly be automated by building alerts into the database that automatically message a supervisor when inconsistent data are entered (for example when a child with screening values that warrant referral is registered as having passed the test, or the opposite). Once the possibility of database (entry) error is ruled out, this should be investigated. The same goes for anomalies such as screeners with consistent very low or very high referral rates or erratic screening results.

All screeners should, at regular intervals, receive feedback on the quality of their referrals based on the results of the diagnostic examinations of the children they referred.

While quality assurance is obviously important, it should be kept in mind that an abundance of quality assurance can prove counterproductive. If too much emphasis is put on preventing children with the target condition from passing the test, for example, screeners may become anxious or defensive and, unconsciously, to go too far in erring on the side of caution, leading to very high rates of false positives. There should be a reasonable balance between sensitivity and specificity and care should also be taken to prevent screeners from becoming demoralised.\textsuperscript{163}

There are no universally accepted definitions of quality assurance, but below are two examples of approaches to the concept:

New Zealand’s National Screening Unit identifies the following four dimensions of quality:\textsuperscript{164}  
- equity and access: the extent to which people are able to receive a service on the basis of need, mindful of factors such as socioeconomic factors, ethnicity, age, impairment or gender
- safety: the extent to which harm is kept to a minimum
- efficiency: the extent to which a service gives the greatest possible benefit for the resources used
- effectiveness: the extent to which a service achieves an expected and measurable benefit

Muir Gray and Austoker identified these five preconditions for successful quality assurance:\textsuperscript{165}  
- the right culture
- the existence of explicit standards of good performance
- an information system that allows each professional and programme to compare their performance with that of others and with the explicit standards
- authority to take action if a quality problem is identified
• clear lines of responsibility in managing the process of quality assurance itself

➢ Further reading: *Quality assurance in screening programmes*.

e. Evaluation

Evaluation is assessing the performance of a screening programme in the broadest sense and determining how well it is achieving its goals. Evaluation is performed by analysing the available data and comparing the actual results with predetermined KPIs (the targeted results).

Evaluation can be expanded by complimentary quantitative or qualitative research, for example questionnaires for or interviews with professionals in the screening pathway, or parents of screened children. Such additional research can shed more light on issues identified through the data analysis. The extent of the evaluation is of course also dependent on the available means.

The information generated on effectiveness and cost-effectiveness of the programme can be used to inform policy makers and decision makers.

Although evaluation is not the same as quality assurance, appropriate evaluation will be able to assist with quality assurance and quality improvement by identifying aspects of the programme that need to be revised or improved. When changes in the screening programme are implemented, based on observed issues, the effects of these changes should also be monitored and evaluated, to assess if these changes achieved the desired effects.

➢ Further reading: *Evaluating health promotion programs: introductory workbook*.

Note that all aspects of a screening programme should be evaluated. Not just the screening itself, but also for example the communication of the programme to the public, the organisational structure, the reduction in prevalence of the targeted condition in the eligible population, and so forth.
f. Reporting and dissemination

The data analysis performed for evaluation can however also be used for reporting and dissemination. Reporting is providing an account of the results of the screening programme. This is done based on analysis of the data and can be concise or prolific, depending on the available data and the target audience.

Reporting
The primary audience of reporting will be governments and other stakeholders, especially those who contributed monetarily to the realisation of the programme. These parties will obviously have an interest in the results of the programme and, especially, its cost-effectiveness. Based on the results that are being reported on, policy advice can also be provided on the future of the screening programme. Once a screening programme has been established, reporting can be done periodically. This will of course make it possible to compare results from subsequent cycles and gain insight into whether the results of the programme are improving.

Dissemination
In addition to reporting aimed at governments and stakeholders, reports can be written for the general public. These may be adapted as far as content and language are concerned to make them accessible to a wider audience, and may serve to disseminate knowledge of screening among the general public. Reporting on the results of the screening programme to the general public also contributes to the public's faith in and general acceptance of and support for the programme. This is important because public support is imperative to the success of a screening programme.

g. Checklist

Below is a short checklist with questions to address before commencing monitoring (and therefore before implementing a screening programme):

- Are there sufficient funds for monitoring?
- Are qualified personnel available to perform the monitoring tasks?
- Is it clear who is responsible for all aspects of monitoring?
- Is there a database of sufficient quality in place and, if technical problems should occur, is support available?
- Has the scope of the monitoring been defined (strictly based on collected data during the screening or with additional research to gain more insight in relevant processes)?
• has enough attention been paid to making sure all data collection is compliant with relevant privacy legislation?
• are all professionals who are part of the screening pathway aware of their responsibilities?
• is there a clear "chain of command" or paper trail, so that policy makers and funders can have confidence in the data they use - but also know where it then goes (for example to ministries or publications)?
GLOSSARY

amblyopia  reduced visual acuity as a result of reduced visual stimulation during the 'critical period' of visual development between birth and approximately seven years of age. It is commonly due to strabismus, anisometropia, high hypermetropia and astigmatism. Treatment involves restoring clear vision with glasses (or occasionally cataract or other surgery) and often providing stimulation to the defective eye with eye patches or atropine eye drops. Amblyopia treatment is very successful under seven years of age but becomes more difficult or impossible to treat much beyond this age. Amblyopia is the main target condition for vision screening in childhood.

anisometropia  a difference in the refractive error in either eye. Amblyopia is common in hyperopic anisometropia, but less so in myopic anisometropia.

astigmatism  the eyeball or lens is more curved in one meridian than the other so vision is always blurred in one or both of these meridia. Astigmatism can be myopic, hyperopic or 'mixed'. Amblyopia is common in significant astigmatism because there is no natural region of clear vision.

auditory neuropathy spectrum disorder  a hearing disorder in which the sound information is not transmitted sufficiently by the auditory nerve to the brain.

cochlear implants  surgically implanted neuroprosthetic devices that provide a person with moderate to profound sensorineural hearing loss a modified sense of sound.

Continuing Medical Education  a form of continuing education that helps those in the medical field maintain competence and learn about new and developing areas of their field (voluntary in some jurisdictions, mandatory in others).
cover test  a test to determine the presence and amount of ocular deviation

coverage  the part of the eligible population that is screened and has a result documented, usually expressed as a percentage

critical period  time window wherein the growing brain is most malleable and shows heightened responsiveness to external environment influences; a period of plasticity in response to visual experience when neuronal circuits can be modified by experience

early childhood  the period from birth to eight years old, a time of remarkable growth with brain development at its peak

emmetropia  zero refractive error

ENT  Ear, Nose and Throat surgery; the area of medicine that is concerned with disorders of the ear, nose, throat, head and neck (also otorhinolaryngology)

evaluation  a systematic determination of a subject’s merit, based on an established set of criteria

false negatives  screening results that are negative while in fact the subject does have the condition being screened for

false positives  screening results that are positive while in fact the subject does not have the condition being screened for

GDPR  General Data Protection Regulation; EU directive 2016/679 concerning the protection of personal data

gold standard  the diagnostic test that is the best available under reasonable conditions

GP  general practitioner; a medical doctor who treats acute and chronic illnesses and provides preventive care and health education
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>health literacy</td>
<td>the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions</td>
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<tr>
<td>HI</td>
<td>hearing impairment; a partial or total inability to hear (also HL)</td>
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<tr>
<td>HIC</td>
<td>High Income Country; a country with a gross national income per capita of $12,376 or more in 2018</td>
</tr>
<tr>
<td>HL</td>
<td>hearing loss; a partial or total inability to hear (also HI)</td>
</tr>
<tr>
<td>HMIC</td>
<td>High Middle Income Country; a country with a gross national income per capita between $3,996 and $12,375 in 2018</td>
</tr>
<tr>
<td>hyperopia</td>
<td>long sight (also hypermetropia). Light would naturally focus 'behind the retina', so a child either has to make extra focusing effort to make images clear, which can cause a strabismus (squint) and so strabismic amblyopia, or risk amblyopia from long-standing blurred vision</td>
</tr>
<tr>
<td>Key Performance Indicators</td>
<td>measurable values that demonstrate how effectively key objectives are achieved (KPIs)</td>
</tr>
<tr>
<td>lay screeners</td>
<td>persons who perform screening who do not have a professional medical background</td>
</tr>
<tr>
<td>LIC</td>
<td>Low Income Country; a country with a gross national income per capita of $1,025 or less in 2018</td>
</tr>
<tr>
<td>LMIC</td>
<td>Lower Middle Income Country; a country with a gross national income per capita between $1,026 and $3,995 in 2018</td>
</tr>
<tr>
<td>logMAR</td>
<td>the logarithm of the Minimum Angle of Resolution; the logarithmic value of the letter size given as a decimal value</td>
</tr>
<tr>
<td>LTF</td>
<td>loss to follow-up (also LTFU); subjects who after screening, for whatever reason do not receive another screening, diagnostic examination or treatment (if these are applicable)</td>
</tr>
</tbody>
</table>
marginalised groups  vulnerable populations outside of mainstream society that face systematic social exclusion; often ethnic minorities but can also apply to for example the homeless and drug users

myopia  short sight. Light naturally focuses in front of the retina. Distance vision is reduced, but few myopic children will be amblyopic because near vision is clear

negative predictive value  what proportion of subjects identified by the test as not having the condition actually do not

nongovernmental organisations  organisations independent of any government. Usually non-profit and active in humanitarian or social areas

NHS  neonatal (or newborn) hearing screening; aimed at the early identification, intervention, and follow-up of infants with hearing problems, also known as early hearing detection and intervention (EHDI)

ocular media opacities  cataract, corneal defects

optotype  letter or symbol used for visual acuity testing

otorhinolaryngology  the area of medicine that is concerned with disorders of the ear, nose, throat, head and neck (also ENT)

otitis media  a group of inflammatory diseases of the middle ear

positive predictive value  what proportion of subjects identified by the test as having the condition actually do so

ptosis  a drooping eyelid. If the pupil is covered, dense amblyopia is common

preschool  educational institution for early childhood education (ISCED level 0) before compulsory education starts, either publicly or privately funded and operated (also known as kindergarten, nursery school, pre-primary school or playschool; terminology varies by country)
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>primary care provider</td>
<td>provider of day-to-day healthcare, who acts as the first contact and principal point of continuing care for patients within a healthcare system. Often a general practitioner (GP), but can also be a nurse, physician assistant or other medical professional</td>
</tr>
<tr>
<td>QALY</td>
<td>quality-adjusted life year; a measure of disease burden that takes into account both quality and quantity of life. QALYs are used to economically assess the value of medical interventions. Read more <a href="#">here</a>. See also: utility. A concise explanation of these and related concepts can be found <a href="#">here</a>.</td>
</tr>
<tr>
<td>refractive error</td>
<td>long sight (hyperopia), short sight (myopia) or astigmatism. In early childhood specific types of refractive error (hypermetropia and astigmatism) can lead to amblyopia. More children will have refractive error than will have amblyopia</td>
</tr>
<tr>
<td>risk factors</td>
<td>in vision screening, certain levels of refractive error are associated with higher incidence of amblyopia. The screening is for the risk factor, not low vision or amblyopia itself. Currently, we do not know the precise relationship between the presence and level of early refractive risk factors and the likelihood of developing amblyopia in an individual child</td>
</tr>
<tr>
<td>sensitivity</td>
<td>a screening test’s ability to correctly designate a subject with the disease as positive</td>
</tr>
<tr>
<td>SES</td>
<td>socioeconomic status; economic and sociological composite measure based on income, education and occupation. Usually broken down in low, middle and high</td>
</tr>
<tr>
<td>specificity</td>
<td>a screening test’s ability to correctly designate a subject without the disease as negative</td>
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</table>

stakeholders persons or organisations with an interest in a policy, for example legislators, governments, ministries, NGOs and foundations
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>stereotest</td>
<td>stereopsis test; a test where slightly different images are shown to each eye, such that a 3D image is perceived if stereo vision is present</td>
</tr>
<tr>
<td>strabismus</td>
<td>squint; crossed or diverged eyes. A constant unilateral strabismus will commonly lead to amblyopia</td>
</tr>
<tr>
<td>target condition</td>
<td>the condition a screening programme aims to detect</td>
</tr>
<tr>
<td>uptake rate</td>
<td>the percentage of subjects who, having been sent an invitation for screening, attend and undergo a screening in response to that invitation</td>
</tr>
<tr>
<td>utility</td>
<td>the value assigned by a subject to his or her general health state; usually a number between 0 (equalling death) and 1 (equalling perfect health). See also: QALY. A concise explanation of these and related concepts can be found here.</td>
</tr>
<tr>
<td>VA</td>
<td>visual acuity; the clarity of vision</td>
</tr>
<tr>
<td>well babies</td>
<td>newborns with no identified health concerns; babies who require minimal nursing and medical care</td>
</tr>
<tr>
<td>World Health Organization</td>
<td>a specialised agency of the United Nations with a broad mandate to act as a coordinating authority on international health issues, founded in 1948 (website)</td>
</tr>
</tbody>
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Appendices
1. CHILDHOOD VISION SCREENING AFTER THE NEONATAL PERIOD - PROCEDURE

Choice of test

The gold standard test for adult VA testing is generally considered to be a logarithmic Landolt C test. Any VA test used for screening should approach this gold standard as closely as possible. The Landolt C test is, however, difficult for use with children. Most adult clinical charts use letters, which have been chosen to be of similar visual difficulty and based on the Bailey-Lovie principles. We do not recommend any specific test charts, but it is important that any test used has published validated age norms and adheres as closely as possible in terms of logarithmic space-to-optotype ratio, as in the Bailey-Lovie chart, recommended by the ICO in 1984 or according to the European ISO 8596 Standard (EN ISO 8596:2017). The European Standard for Vision Measurement states a VA chart should contain at least 10 lines of optotypes. Many charts with a logarithmic progression maintain a consistent ratio between optotypes and spacing of letters and lines, proportional to the optotype size (see Figure 1). Visual acuity measured with these logarithmic progression charts can be recorded in logMAR, fractional or decimal notation (see notation section below). Decimal progression and Snellen charts do not have the same proportional difference between lines at different points on the chart (see Table 1 and Figure 4) and are being phased out of the scientific literature, orthoptics and ophthalmology. Charts with a decimal linear scaling from 0.1 (low visual acuity), 0.2, 0.3 etc. up to 1.0 (good visual acuity) are not appropriate because they do not follow a logarithmic progression and could lead to wrong decisions about failing the test and referral. They should be avoided clinically, although in many countries this change has not been widely adopted.

Tests designed for pre-literate children can use the Tumbling E format, letters or symbols which can be used with matching cards. Some use a flip booklet format with a single row of letters surrounded by crowding bars e.g. Keeler logarithmic crowded test, so that young children do not get confused by too many letters on the chart. The 'Tumbling E' is somewhat easier for young children, although somewhat less in quality than the Landolt C. Some symbol tests such as the LEA symbols and Kay Pictures are calibrated against the gold standard adult tests (Landolt-C) and thus also a possible choice. In countries with early school entry age, young children may be familiar with letters, so letter charts may be feasible for these children (crowded logarithmic tests). Most children will be able to use a matching card even if they cannot name letters or symbols. Single letter tests should be avoided as they compare very poorly to linear logarithmic tests, particularly in amblyopia.
Picture charts such as the Amsterdam Picture Chart, do not compare well to logarithmic charts, are not well validated, and may contain pictures that modern children may not recognise e.g. old fashioned cars, so should not be used\textsuperscript{169}. Some pictures may also be culturally specific and disadvantage children from other ethnic backgrounds. Many digital screening options use laptops or tablet devices to present a letter chart. The best have been well calibrated as above so are an alternative option. Small screen size on portable equipment can be a limitation, necessitating making testing distance closer than physical charts need to be. The closer the testing distance, the more critical it is that children do not move closer to look intently at small letters. \textbf{Whatever test is chosen it is important that it has been validated, uses a linear optotype format adhering as closely to the gold standard tests above, and has published visual acuity norms and confidence limits for different age children.} A definition of what is abnormal VA must be based on the confidence limits for normal vision for the age of child and the test.

\textit{Figure 1: illustrates acceptable tests using the logarithmic format}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{logarithmic_tests.png}
\end{figure}

\textbf{IF PICTURE TESTS ARE USED FOR CHILDREN WHO CANNOT DO A LETTER TEST E.G. LEA SYMBOLS OR KAY PICTURES, IT IS IMPORTANT TO UNDERSTAND THAT THE SYMBOL CONSTRUCTION DIFFERS FROM THE CONSTRUCTION OF ADULT TESTS, IN THAT THE PROPORTIONS OF LINE THICKNESS TO SPACE IS DIFFERENT. E.G. LEA SYMBOLS ARE DRAWN FROM A 7X7 GRID AND KAY PICTURES FROM A 10X10 GRID (FIGURE 2). THEY MAY BE WELL CALIBRATED AGAINST GOLD STANDARD TESTS, BUT EVEN IF VALIDATED, THEY MAY DIFFER FROM OTHER OR ADULT TESTS (FOR EXAMPLE THE KAY PICTURE TEST TENDS TO RETURN SLIGHTLY BETTER ACUITIES THAN THE LEA OR LANDOLT C, SO REFERRAL THRESHOLDS MIGHT NEED TO BE DIFFERENT)}\textsuperscript{170}.

\textit{Figure 2: construction of Snellen symbol, LEA test symbol and Kay Pictures symbol}
Test distance may be between 3 and 5 metres and some tests are calibrated for more than one distance, but most specify a single distance. In younger children the closer test distance may improve cooperation, but the closer the testing distance, the more important that it is adhered to exactly.

*Figure 3: child vision tests based on logarithmic principles (LEA, HOTV and Kay Pictures)*
Charts illustrated in Figure 4 are not advised because they do not adhere to any or all of the Bailey-Lovie logarithmic principles in terms of symbol construction, equality of recognisability, line or character spacing.

Checklist when deciding on which test:
- Is it a logarithmic chart?
- Is it as close to a gold standard test as possible?
- Has it been validated against a gold standard test with published age-related norms?

In practice, it makes sense to decide on a first line choice of optotype (e.g. letters or E tests), but to also have an alternative optotype (e.g. LEA symbols) which can be used if a child does not cooperate with the first line optotype if a re-test would be difficult to rearrange e.g. in remote rural areas.

It is, however, critical to understand that inaccuracy of screening is more likely to be due to the tester, not the test. So even if automated methods are adopted, children still need supervision to ensure attention, motivation and co-operation and to prevent attempts to peek around an occluder.

**Visual crowding**

In amblyopia the recognition of optotypes in a line of letters or a word is more difficult than for a single letter (‘the crowding effect’) and letters at the beginning and ends of lines may be more recognisable. Very close spacing of optotypes may hamper cooperation in young children due to physiological crowding.

Crowding is a normal phenomenon, but it is greatly exaggerated in amblyopia, therefore presenting one single optotype or few optotypes with large spaces between them may lead
to underestimation or missing of amblyopia. According to ISO 8596:2017 each line must have at least 5 optotypes. Crowding can also be standardised by adding a high contrast frame around the optotypes (e.g. the Keeler crowded logarithmic test flip booklet, which only presents one size of letters at a time).

**Notation**

Mean “normal” visual acuity in an adult is visual acuity 1.0 = 0.0 logMAR being 1’ arc angular visual resolution equal to the size of the gap in a 5’ Landolt-C optotype with 3 out of 5 guessed correctly. Visual acuity can be expressed in many different ways and conventions often vary between countries. Snellen notation expresses letter size as a fraction of testing distance, with good vision being e.g. 6/6 (metric e.g. UK) or 20/20 (feet e.g. US) or its decimal (e.g. 1.0, as used in much of Europe). LogMAR notation results in 0.0 meaning good vision and 1.0 poor, while in decimal notation 1.0 is good and values near 0.0 are poor (see Table 1).

Table 1 also shows that, for example, the difference between decimal VAs of 0.1 and 0.2 is much larger in logMAR terms than between decimal 0.4 and 0.5. VA charts with linear scaling of decimal values 0.1 are not appropriate because they do not follow a logarithmic progression, and could lead to wrong decisions about failing the test and referral. This can very easily lead to confusion, especially if logMAR notation is used by screeners in a country where decimal notation is the norm and clinicians still use decimal notation. Modern visual acuity charts often show several notations for the same line, and it is important to read the correct one (details about different visual acuity notation on visual acuity charts are shown in the Table 1 below).

LogMAR is the internationally recognised standard. Great care must be taken in training, recording and communication so confusion does not arise. It is important that the screening records always show which optotypes were used, which spacing between them and which type the visual acuity notation is.
It may be helpful to provide in the screening forms all visual acuity levels shown by the respective chart for the right and left eye separately, so that the obtained values can be circled or underlined - or clicked in case of electronic records.

There is an international consensus that logMAR notation is the gold standard, but in many countries decimal or Snellen notations are still the norm in clinical practice. To avoid confusion, for referral after failed screening it makes sense to use the notation known to the ophthalmologists in that country, and possibly logMAR notation additionally (clearly specifying which value is which notation). Training of screeners and those auditing any reported outcomes must ensure the correct notation is used.

**Pass/referral criteria**

The criterion for passing or failing a visual acuity screening test has to be specified. It depends on the children’s age and the visual acuity chart used (especially the spacing of the optotypes within a line, or the 'crowding') and needs to be related to normative data for the particular test used and age of the children. Normal ranges in children typically show slightly lower acuity and wider confidence limits.

ISO 8596:2017 states that to pass a line three out of five letters on the line must be identified correctly. This is scientifically valid in tests like the Landolt C or tumbling E because a test with 4 possibilities best measures (highest specificity) at 62.5%, because it is halfway between 100% good at large E’s and 25% good at small E’s. Thus a child seeing 3, 4 or 5 letters on the 0.2 line would pass the test and be recorded as having a VA of 0.2.
According to some literature, children aged four pass the test when visual acuity of both eyes separately is 0.2 logMAR or better, with one line (0.1 logMAR) or less difference between the two eyes. Children aged five pass the test when visual acuity of both eyes separately is 0.1 logMAR or better with one line (0.1 logMAR) or less difference between the two eyes. In practice, when a year-group of children are tested e.g. 4-5 year olds which straddle two different criteria, the more lenient is often chosen e.g. 0.2 logMAR. Services must decide whether to repeat screen or refer children on the referral borderline or those who were too immature to understand the test. A 'repeat before referral' policy saves expensive false referrals and may only mean a few weeks delay for the few genuine cases. These criteria should be revisited during regular evaluation. This is particularly important when testing the youngest children who may 'fail' due to loss of concentration (especially of the second eye tested).

If a child does not reach the 'pass' criterion and the screener decides that cooperation was good, the child may be referred for ophthalmological assessment. If the screener decides that the failure was possibly due to lack of cooperation or fatigue, retesting may be done with the same optotypes or with a second line of optotypes on another occasion, starting with the other eye if necessary. If understanding the task is the problem, an easier test e.g. LEA symbols, could be tried. This could be later in the same day, or on a subsequent visit within a specified period. Experienced testers are much more accurate than novice screeners, and skill and confidence are helped by regular audit and feedback from outcomes.

**Additional orthoptic tests**

Many screening services in Europe use additional orthoptic tests, such as cover tests, motility assessment, binocular vision or stereo tests. Many of these tests require a high level of skill. Small defects are easy to miss so sensitivity and specificity are low, especially if not carried out by trained orthoptists. Larger defects usually present to ophthalmology services before screening anyway due to parental concern.

Evidence of additional cost-effectiveness of adding these tests in improving the detection of amblyopia is limited. In 2013 the UK recommended a single visual acuity screen without additional orthoptic tests.

Decision makers need to agree on referral criteria if cost-effectiveness of an amblyopia screening service is to be maintained. For example, are asymptomatic children with non-amblyopic small angle or intermittent strabismus, reduced stereopsis or convergence insufficiency a target for the screening, or is the service concentrating on low vision and amblyopia. Small changes to referral criteria or adding/removing a test may make significant differences to referral rates and costs. Countries may make different decisions. Some countries (often those with high incomes) have a high acceptance of screening and easy access to medical care. Referral of mild, or
non-sight-threatening defects such as intermittent exotropia or slightly defective binocular vision might be acceptable and affordable for parents. Other countries have poorer public health awareness, few paediatric ophthalmology services, and accessing them could be a huge financial burden to very low-income parents. Here, a decision might be made to only screen for the most severe problems. Detecting mild problems which do not impact on a child’s education or future employment prospects may be an unaffordable luxury. One of the reasons that amblyopia fulfils the WHO criteria as a screenable condition is that untreated unilateral amblyopia can lead to blindness and a large burden on families and society if the better eye is lost in later life, and especially old age. This is not the case for conditions such as strabismus, mild myopia, or weak binocular vision.

**Preparation for the testing**

Administrators or screeners should establish visit dates with the school, clinic or kindergarten and confirm room bookings and lists of children to be tested. Decide how children who are absent on the test day will be tested within the screening timescale. If not embedded in the community, the screener should establish rapport with local staff and make sure they know what will happen, so they can explain to children and parents and reinforce support for the screening.

Ask staff to tell the screener about any child who might need specific handling (shy, hyperactive, special needs, non-native language speaker). Establish what provision will be made for children with special needs or disabilities. Some countries mandate that all such children are tested more fully, but in other countries these children may not even be in school. There may be national guidelines mandating more detailed assessment of children with some disabilities or genetic conditions.

Inform parents (and if applicable preschool or school teachers) about the planned screening and get informed parental consent or refusal (see chapter 4e).

Depending on the location, parents or teachers may prepare the children for testing. Images of the test symbols used (for example LEA or Tumbling E’s) may be put in the envelope of the letter inviting the parents for the screening so that they can practice with their child beforehand at home. This reduces the number of failed measurements.

Prepare a quiet and secure room, large enough (depending on the test distance for the visual acuity chart used) for assessments, with the possibility to present the visual acuity chart at eye height of the children. The European Standard for Visual Acuity Measurement ISO 8596 recommends that the chart’s luminance (‘brightness’) should be between 80 and 320 cd/m². Basically, the charts should be well and adequately illuminated in a normal daylight conditions medical examination room (the examination room of an ophthalmologist is usually darker). The chart should not be illuminated with extra light spots. Avoid direct sunlight or shadows on the chart. The luminance of the visual acuity chart can be measured using a luminance meter if necessary.
An appropriate space for testing should:
- be quiet and free of distractions
- be close to where the children will be collected from
- have good lighting
- have suitable chairs

Suggested equipment required in screening sessions:
- visual acuity test(s)
- key card(s)
- device for covering the non-tested eye (tape or occlusive glasses)
- list of children to be screened
- confirmation of parental consent or refusal, depending on whether an opt-in or opt-out consent policy is used (see chapter 4e)
- recording method (paper or digital)

The distance from the child's eyes to the visual acuity chart can be marked with a mark on the floor.
The screener should receive a list of children to be screened, with information about children with special needs or comprehension problems who might need help or more specialist testing.
If the testing area is not close to the children, for example across a playground or upstairs, availability of a helper (classroom assistant/parent/older responsible child) is very useful to fetch the children to make most efficient use of the screener's time.

Procedure of visual acuity assessment in children
Start by confirming identity and consent, and that the child understands the screener. If a child already has glasses they should be worn during the assessment.
The child may sit on a parent's lap, but may also sit or stand alone. The child should not lean forward excessively or sit on the tip of the chair. Ideally, if practically and financially feasible, two people should be present to screen children aged 4–5 years: the screener to undertake the test and the other person to sit by the child to offer encouragement, confirm results on the key card if used, and to supervise the child, to ensure the child does not lean forward, keeps head straight, and does not peep. This helper could be a classroom assistant, volunteer parent or even a responsible older child.
Explain to the child in comprehensible terms what is expected of him. Practice the measurement first binocularly at a short distance, for example 40 cm, to ensure the child understands the task, then begin the actual test monocularly. If they do not understand, move onto an easier test such as a validated picture test, and record clearly that that was
done. If a re-test would be possible, a later attempt at the same test may be preferable than a less accurate result from an easier test.

Always start with the same eye (right eye), unless it is a repeat examination, then start with the 'suspected' eye.

Provide a method for secure covering of the non-tested eye, for example two pairs of occluded glasses frames of different colour, where the right or the left eye is covered so that peeping is not possible. Sticky eye patches prevent peeping more reliably, but many children dislike wearing them so cooperation may be lost.

Never use the child’s or the parent’s hand for covering the fellow eye as a tiny gap between fingers may allow the occluded eye to still be used and amblyopia or low vision can be missed.

Keep looking at the child and never turn your back at the child. Observe the child carefully before and during testing – abnormal head position, eye alignment, eye movement, opacity of cornea or lens, hanging eyelid (ptosis) may reveal pathologies.

Point from below at the optotypes with a finger or a black pen, leaving a similar space to the optotype as lies between the optotypes. Make sure the whole optotype is clearly visible to the child. Encircling the optotype with a pen once is permitted, but do not cover the surrounding optotypes, because in the case of amblyopia, this will provide unrealistically good results and amblyopia may be missed.

Start at the top line. According to ISO 8596 the optotype must be presented no longer than 10 seconds, however young children may need longer to respond. In the case of an incorrect answer, indicate another optotype. If three of the five optotypes are named correctly, go to the next line. Proceed to the last line where three of the five optotypes are named correctly. That is the visual acuity to be recorded. If a child can clearly see the upper lines of a chart, it may be permissible to check fewer larger letters (e.g. one central letter per line) to maintain co-operation for the lines closer to the child’s threshold, when all letters on the line must be tested so the 3/5 criterion can be applied (see section on pass/fail criteria).

The visual acuity value determined should be recorded immediately after testing each eye, using a consistent notation. Recording is sometimes done giving a logMAR value based on each letter seen. All documentation should use the convention of showing the right eye first.

Some children with strabismus, ocular motility defects and abnormal head postures will not have reduced VA. See section on orthoptic tests above.

Encourage the child to guess in case of uncertainty, and use encouraging feedback even if a letter is wrongly identified. Make sure that any accompanying person or (if needed) interpreter does not give hints as to the correct answer.

Make sure that evaluation procedures do not suggest one screener is 'better' just because the children they tested were, on average, slightly older.
**Useful advice**

- Make sure the correct child is being tested. Confirm with someone responsible, because many children will respond to other children's names or have the same name.

- In large communities where more than one visit is planned per year, it can be best to test the oldest children in the age cohort on one visit and leave the younger ones until the later visit. In small communities, children at both ends of the screening age range will need to be tested on the same visit.

- Decide whether to test a child alone or in a small group (two to four children). If a group is brought into the room together, be very sure that the children not being tested cannot see or memorise the test chart or 'help' the child being tested. A shy child will be helped by watching a more confident one perform the test. Time can be saved by teaching the test to the group, rather than individually, but a disruptive, distracted or crying child might distract the others.

- Be prepared to be flexible.

- Make sure that the chosen occluder – patch or occluded glasses cover the eye properly and any attempts to peep can be spotted quickly. A child with an amblyopic eye will think it perfectly normal to try to peep around an occluder or find a peephole near the nose, so a face turn during testing is a warning sign.

- Children with an amblyopic eye may look confused when the good eye is covered up but will rarely say they cannot see.

- If an amblyopic eye is tested first, the child may just appear to be uncooperative. By moving quickly onto the other eye, it is easier to decide if it is general poor cooperation or a genuine vision problem in the eye tested first.

- Get into a habit of testing the same eye first every time (usually the right eye). If the order changes frequently, after 20 children the tester might forget that only one eye was tested. If using occluded glasses, use different colours and always use the same colour first.

- Never say “shall we cover up one eye now?” – an obvious reply is “No”. In an uncooperative child a good strategy is to say “which colour glasses shall we put on first?” The child has then been given some control of the test, but understands that both eyes still get tested. Putting a patch or glasses on a toy might help persuade them to wear a patch. If the child has an obvious strabismus (squint / crossed eyes), or a ptosis (droopy eyelid) that eye is likely to have poorer vision.

- Make sure the children know it is a game, and that nobody will be angry with them if they cannot see a letter. Make sure they are encouraged constantly, for every letter. If they get a letter wrong do not tell them they were wrong. You can say “are you sure?” or “good try – now let’s do another one”. 
• Encourage 'intelligent guessing'. So say “what do you think it might be?” “have a try, even if you are not sure”. A child who genuinely cannot see a letter will often guess wildly or look away while guessing, while a child at their threshold acuity will keep fixating when having a try. Children do not realise that adults have to make similar guesses during any eye test.
• If a child seems to be struggling at their threshold, say “is it too little to see?” – they often look relieved and say “yes”, when they would not have told you they could not see it if you had not asked.
• Experienced screeners develop a 'feel' for a child with a genuine problem compared to one who is just scared or uncooperative. It becomes more obvious with experience, but it really helps if testers get feedback about the referred children, so that they learn from their right and wrong decisions.
• Make sure that parents, teachers, GPs, nurses know where they can go for support and advice once the screener has left. Encourage teachers, GPs and satisfied parents to share their experience of screening and getting treatment for poor vision that they had not expected – especially if there was a good outcome.
2. CHILDHOOD HEARING SCREENING AFTER THE NEONATAL PERIOD - PROCEDURE

Pure tone screening audiometry
Recommended screening level at preschool age (3-5 years) is 25 dB -35 dB HL, depending on the pre-established target condition. Hearing levels are in decibel, dB. The screening frequencies are 1000, 2000, 4000, 6000 and 500 Hz. The minimum requirements are for frequencies 1000 Hz, 2000 Hz and 4000 Hz. 6000 Hz is not always included at this age. 500 Hz may be screened at a level 5 dB higher than the other frequencies if the target condition does not include temporary hearing impairment (otitis media). 500 Hz may be excluded from the test sequence if necessary. For school age children (6-7 years), the recommended screening level is 20-30 dB up to 6000 Hz, also depending on the pre-established target condition. The available capacity for diagnostic assessment may play a role in determining the screening level, since a lower level means more referrals and therefore a need for more diagnostic assessments.

1. Check the equipment: before testing for the day, the tester should test the equipment to make sure the sounds are at the right volume for each frequency. The tester should listen to each frequency that will be tested at 40 dB HL. If the tones are not at the correct level, then the equipment should be inspected to make sure all connections are in place and the settings are correct.

2. Preparation: pure tone audiometry is a behavioural test that requires cooperation and participation from the child. It is important that the child is well rested and fully focused during the screening.

3. Instruction: Prior to performing the hearing test, the child should learn the task and show that they understand the instructions.

4. Sound stimuli: pure tone audiometry is performed with headphones. The sound is a pure tone sine wave. Warble tones may be used in younger children for better attention.

5. Headphones: Put the headphones (TDH39) on the child’s head. It’s important that they are comfortable and well placed covering the opening of the ear canal.

6. Test protocol: Start with the right ear or the best ear if there is a suspected HI in one ear. Start with frequency 1000 Hz at a well audible level, 40 dB. Give the child instructions and check that they are well understood.

7. Response from child: in response to a sound the child should be instructed to perform some kind of action. Pushing a button does not work well with small
children and instead they can build with blocks, put a ring on a peg, or raise their hand.

8. If the child cannot hear 40 dB, increase with 10 dB stepwise until the child gives a response. Increase to maximum 60 dB (this is a screening situation). Check that the child understands the instruction. If there is no response to 60 dB, try other frequencies or the other ear.

9. If the child responds to 40 dB, change to screening level 25 dB (30 dB). Present the stimulus twice with a duration of 1-2 seconds at an interval of 3-5 seconds. If the child responds to both stimuli there is a pass. Continue and test the next frequency in the same way: 2000 Hz at 25 dB, 25 dB HL 4000 Hz, 25 dB HL 6000 Hz, 25 dB HL 500 Hz.

10. If the child can only hear one stimulus, present a third tone. If the child can hear it, the screening is passed for the first frequency.

11. If the child cannot hear the third tone, the child has not passed.

12. Continue with other frequencies and the other ear.

13. Referral criteria: No pass at 2 frequencies 500 – 4000 Hz in the same ear or >40 dB at 1 frequency 1000- 6000 Hz.

14. Retest: the screening result must be evaluated according to cooperation of the child or health status that may affect the ears. If the child fails the hearing screening, a retest should be performed frequently before referral.

**Play audiometry**

Same procedure as above, but with a play activity in response to sound instead of pushing a button. Prior to the test, the tester should prepare a few activities for the child to use to indicate a response. If one activity is not interesting to the child, another activity can be suggested.

**Inconclusive test results**

Normal speech development indicates normal or near-normal hearing. However, a child with a refer result from hearing screening, despite normal speech and no obvious hearing problems, should always be referred for further evaluation.
3. INFORMATION LEAFLETS

Information leaflets are important, and sufficient attention should be paid to them. Existing leaflets can be used as examples or templates, but it is best to create information leaflets locally, tailored to the local context as much as possible. In general, leaflets should employ straightforward, understandable language, but this holds especially true for leaflets intended for use in areas where literacy may be limited, such as low SES areas. Depending on the local demography, it may also be necessary to have leaflets available in more than one language or use infographics.

An information leaflet should at least include:

- the disorder being screened for, specified in terms of the relevant adverse health outcome (hearing or vision loss). It should also include background information on how common and serious the disorder is
- the health gains from screening in terms of the benefits of early detection of hearing or vision problems
- an explanation of the screening test: what it is, how it is performed, the percentage of cases that are generally detected, and the percentage of unaffected children who test positively (false positives)
- the next step: what happens if the test is positive (a second test, referral)
- possible adverse effects of screening

The leaflet should also mention that a negative result does not explicitly rule out the condition being screened for. The general public are often unaware that passing screening does not guarantee ‘normality’. All screening tests are fallible. A positive test result means the child has a high chance of having the condition, but not a 100% chance. Similarly, a negative test result means the child has a high chance of not having the condition, but also not a 100% chance. It is important to make clear that passing screening means that a child had adequate hearing or vision at the point in time he or she was screened. The condition may also develop or worsen at a later age.

It is also important to briefly mention data collection: to make clear that data are collected and processed safely and inform parents of their rights (see also chapter 4e). For people who want to know more about this, the leaflet can refer to more detailed online information.

The leaflet should also include a phone number and an email address in case people wish to ask questions about the screening programme.
EXAMPLES
AN EXAMPLE OF AN INFORMATION LEAFLET EXPLAINING HEARING SCREENING FOR PARENTS CAN BE FOUND HERE, AND A LEAFLET EXPLAINING VISION SCREENING HERE.

➢ *Further reading: Information leaflets in medical screening.*
### 4. DATABASE STRUCTURE EXAMPLE FOR VISION SCREENING

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#### 1. SCREEN

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<tr>
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<td>LIST OF TESTS</td>
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<td>NOTATION TYPE</td>
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<tr>
<td>LEFT EYE</td>
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<td>-----</td>
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### 2. REPEAT SCREEN

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<tr>
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<td>LIST OF TESTS</td>
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<td>NOTATION TYPE</td>
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| RIGHT EYE | X,X |
| LEFT EYE  | X,X |
| SCREENING RESULT | PASS | REFER |
| PARTICULARITIES | NONE | CHOOSE FROM LIST OF PARTICULARITIES |

---

### 3. DIAGNOSTIC ASSESSMENT
HEALTHCARE ORGANISATION | PRE-ENTERED, BASED ON LOGIN

LOCATION | PRE-ENTERED, BASED ON LOGIN

DIAGNOSTIC PROFESSIONAL CODE | PRE-ENTERED, BASED ON LOGIN

TICK BOX IF LTF | IF KNOWN, CHOOSE FROM LIST OF REASONS FOR LTF *

DIAGNOSIS DATE | DD/MM/YYYY

DIAGNOSIS TIME | XX:XX

METHOD OF DIAGNOSIS | LIST OF METHODS

MEASURED VA NOTATION TYPE

RIGHT EYE | X,X

LEFT EYE | X,X

DIAGNOSTIC ASSESSMENT | NO CONDITION

TREATMENT PRESCRIBED | NONE

4. TREATMENT

TICK BOX IF LTF | IF KNOWN, CHOOSE FROM LIST OF REASONS FOR LTF *
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TREATMENT END DATE | DD/MM/YYYY
---|---
TREATMENT END RESULT | CHOOSE FROM LIST OF RESULTS

* list only appears when LTF box is ticked
** additional checkups can be added as necessary
5. REFERENCES


2 Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, England, Estonia, Faroe Islands, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Israel, Italy, Kosovo, Latvia, Lithuania, Luxembourg, Malawi, Malta, Moldova, Montenegro, North Macedonia, Northern Ireland, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Rwanda, Scotland, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey.


170 O'Connor AR & Milling A (2020): Normative data for the redesigned Kay Pictures visual

171 Anstice NS, Thompson B (1997): The measurement of visual acuity in children: an