ASSESSMENT OF THE PREVALENCE OF VISUAL IMPAIRMENT ATTRIBUTABLE TO REFRACTIVE ERROR OR OTHER CAUSES IN SCHOOL CHILDREN

PROTOCOL
AND
MANUAL OF PROCEDURES

November 2007
FOREWORD

Population based surveys using a standardized protocol, sometimes suitably adapted, are the gold standard for studying the prevalence, causes and determinants of eye diseases causing visual impairment and blindness in different parts of the world. The collation and analysis of such survey data have provided information necessary for the estimation of the global magnitude of blindness and visual impairment. These data have also provided the basis for priority setting in intervention programmes.

The survey protocol and data collection instruments presented here were developed by WHO in collaboration with, and under financial support from, the National Eye Institute, National Institutes of Health, USA. Published studies have been carried out in countries as varied as Nepal, China, Chile, India, South Africa, and Malaysia. Most recently, the protocol is being carried out in Brazil and a third location in China.

This document presents a Protocol and Manual of Procedures which represents the latest refinement of the original protocol, incorporating experience gained in earlier studies. The two principal revisions are 1) defining sampling clusters on the basis of schools rather than geographic areas 2) requiring cycloplegic refraction only in children with visual impairment. There is often a tendency to overload a study protocol to include items which may not have direct relevance to the area of study. Moreover recommended technological methods may be of a level of sophistication that is not affordable or available in many developing parts of the world. This is not the case with the current document.

The current protocol is aimed at obtaining valid, core information that is of practical value in the planning, implementation and monitoring of refraction and other eye care services and in subsequent evaluation. It represents what has evolved over its implementation in the above mentioned countries, and is directed towards addressing the following specific aims:

- Estimation of the prevalence of visual impairment in school children
- Assessment of refractive error and the principal causes of visual impairment
- Evaluation of refraction services and outcomes

We appreciate the NEI’s support and collaboration in the preparation of this document and trust that national authorities, including National Coordinators of Prevention of Blindness/Vision 2020 programmes, will find the protocol easy to follow and reasonably simple to implement.

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WHO-Geneva
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1. INTRODUCTION

1.1 Objective/Aims

The overall objective of this study is to estimate prevalence of vision impairment and associated refractive error and the use of corrective spectacles in school children.

- Children of selected ages will be identified for visual acuity measurement and in-school basic eye examination, including cycloplegic refraction in those with visual impairment. This information will provide for estimation of the prevalence of visual impairment and associated refractive error.

- As a reflection/indicator of eye care the extent to which children with vision impairing myopia and other refractive error are wearing corrective spectacles will be evaluated.

Socio-economic and demographic characteristics should be considered in identifying schools that are broadly representative of the study area/region.

1.2 Existing Data

(This section should be completed by presenting an overview of data and findings from previous surveys and other relevant data pertaining to the country/area of interest.)

1.3 Significance

Clinical evidence suggests that refractive error (RE), including amblyopia and strabismus, are common ophthalmic disorders in children. However, despite the recognized importance of correcting refractive anomalies in children, there are few reliable studies on the type and prevalence of the various anomalies encountered. RE, and particularly myopia, places a substantial burden on the individual and on society. Myopia can have a potential negative impact on career choice, ocular health, and sometimes self-esteem. School-age children constitute a particularly vulnerable group, where uncorrected RE may have a dramatic impact on learning capability and educational potential. Data on RE prevalence and the utilization of corrective spectacles among school-age children are needed for eye health care planning.

2. STUDY DESIGN
2.1 Study Population

Previous population based Refractive Error Study in Children (RESC) surveys have conclusively shown that refractive error (myopia) is mainly a problem among children attending schools. Further, these studies have also shown that myopia is also related to the educational / socio economic status of the family, probably related to the emphasis on reading and other near vision tasks associated with school performance. Accordingly surveys utilizing house to house enumeration of children are not necessary in areas where essentially all children attend school. In these areas of high attendance, school-based sampling will provide data essentially equivalent to that obtained with geography based sampling. (School attendance data within the study area should be reviewed to support this claim). School based sampling has practical implications since it is much easier to carry out.

Considering the association with socio economic status (SES), the study population should emphasize the inclusion of middle to high SES level schools. However, for representativeness it is important that children from low income areas are also included, where supposedly myopia will not be as prevalent because of less intense educational activities. It may be necessary to recruit low SES children from public schools and middle/high SES children from private schools.

Epidemiological research has clearly shown that myopia is related to increasing age, in all populations. Accordingly the refractive error problem will be more prevalent among older children. In countries where a high percentage of children 16 and older are not attending school it is advisable that the study population be recruited from selected classes/grades from middle schools (generally with the children between the ages of 10 and 15). However, depending on the purpose of the survey, children beginning with the first grade could be included.

2.2 Sampling Plan

Cross-sectional samples of school children of selected ages are obtained through random cluster sampling. In some studies, SES or grade level stratification may be desirable. Stratification by grade level may be necessary to ensure an appropriate sample size for each year of age (grade level).

Clusters are defined on the basis of individual classes within each grade. The sampling frame, thus, consists of these class-based clusters within SES or grade level stratum.

The following steps are followed in the creation of study clusters:

a) Review the geographic boundaries of the study area. The study area should encompass at least 5,000 children within each year of age (i.e., within each grade level).

b) Identify all public and private schools within the study area along with enrollment numbers for the appropriate age related grades. The sampling frame is a listing of class-based clusters within each school with the number of children in each.
c) Select the required number of clusters (classes) within each stratum using simple random sampling with equal probability. Because all children in a selected cluster will be enumerated and included in the study sample, clusters are selected with equal probability. With equal probability, cluster (class) size does not influence the chance that a child will be included in the study sample.

2.3 Study Sample Size

The sample size is based on estimating the age specific prevalence of myopia in the study population. The sample size requirement with simple random sampling is calculated as

\[ N = \left( \frac{Z}{2} \right)^2 \frac{(1.0 - P)(P)}{B^2} \]

where \( P \) is the anticipated prevalence of myopia, \( B \) is the desired error bound, and \( Z = 1.96 \) for a 95% confidence interval. Illustrative age cohort sample sizes are shown below:

<table>
<thead>
<tr>
<th>Anticipated prevalence (P)</th>
<th>Sample size with ( B = 10 % )</th>
<th>Sample size with ( B = 15 % )</th>
<th>Sample size with ( B = 20 % )</th>
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<tbody>
<tr>
<td>10 %</td>
<td>3,457</td>
<td>1,537</td>
<td>864</td>
</tr>
<tr>
<td>20 %</td>
<td>1,536</td>
<td>683</td>
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<td>30 %</td>
<td>896</td>
<td>398</td>
<td>224</td>
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<tr>
<td>40 %</td>
<td>576</td>
<td>256</td>
<td>144</td>
</tr>
<tr>
<td>50 %</td>
<td>384</td>
<td>171</td>
<td>96</td>
</tr>
</tbody>
</table>

Available data should be taken into account in choosing the anticipated prevalence rate.

The sample size must be adjusted for the anticipated absenteeism and nonparticipation rate -- which should not exceed 10\% to ensure minimal bias in study results. The sample size must also be increased to accommodate inefficiencies associated with the cluster sampling design. An increase on the order of 100\% is appropriate in situations where the study sample will consist of a small number of relatively large clusters.

To illustrate the sample size calculation, with an anticipated prevalence of 30\% and a 15\% error bound, 398 children would be required for each age cohort with simple random sampling. Assuming a
10% nonparticipation rate, the sample size increases to 438. Allowing for a 100% clustering design effect increases the sample size requirement to 876. A study aimed at children of ages 11 through 14 (i.e., encompassing four grade levels) would thus require a total sample of 3,504 children. If the average cluster (class) size in the sampling frame was 35 children, it would be necessary to randomly select 100 classes for the study sample. With two SES strata, 50 classes would be selected within each stratum. If stratification was based on grade (age), 25 classes would be randomly selected from each of the four grade levels.

3. FIELD & CLINICAL PROCEDURES

3.1 Recruitment

Before selecting the study area and preparing the sampling frame, the cooperation of the local education authorities must be ensured. Considerable effort may be necessary to obtain the cooperation of school officials and parents. Schools selected for inclusion in the study sample should be visited by the Study Investigator to explain the purpose of the study to the school administration. During the visit, data describing the demographic and socioeconomic status of the school population and class sizes should be obtained. Prior to starting the study, an informational session for teachers and parents and or guardians of children in the selected classes may also be necessary.

3.2 Enumeration Procedures

Enumerators will visit each selected school to identify by name, age, and gender all children in the study grades/classes (Annex I). Parent/guardian name and contact information should also be collected for each child.

3.3 Informed Consent

An invitation for the free eye examination to be offered at the school and an Informed Consent Form (annex II) will be sent home with each eligible child. This direct contact with each parent will note the scheduled date for the vision screening and eye examination. Parents will be informed about the objectives of the study and the details regarding the eye examination of the child. Parents will be encouraged to ask questions before they sign the consent form. If the child's parent is illiterate, provision should be made to include the signature of a literate witness, preferably selected by the illiterate parent.

3.4 Ophthalmic Examination Procedures
Before the scheduled examination date at each school, the child identification section (child name, school #, grade #, class #, child #, age, and gender) of a RESC Eye Examination Form (Annex III) is filled in for each eligible child. This partially completed form is then transferred to the school examination site for use as children begin the examination process.

Study children will be examined in their respective schools according to a predetermined schedule. Examination data are recorded using the RESC Eye Examination Form.

As a means to increase the examination coverage, children failing to attend the vision screening/examination, for any reason, should be offered an examination at a mutually convenient later date in the school.

The examinations process is as follows:

a) **Child Identification:** The appropriate RESC Eye Examination Form is retrieved and the name, age and gender of the child are verified prior to examination.

b) **Vision Assessment:** Distance visual acuity is measured with a retro-illuminated LogMAR chart with five optotypes on each line (Precision Vision, Villa Park, Illinois). Visual acuity measurements begin at a distance of 4 meters with the top line (20/200). The child is asked to read the letter one by one of the line. If four or more optotypes are read correctly, the child is then tested by dropping down to line 4 (20/100). If one or no optotypes are missed, the testing is to resume at line 7 (20/50), continuing to line 10 (20/25) and finally line 11 (20/20). If at any level the child fails to recognize at least four optotypes, the line immediately above the failed line is tested, until successful. If the top line at 4 meters is missed, the child is advanced to 1 meter with progression down the chart as described above. The lowest line read successfully is assigned as the visual acuity for the eye undergoing the testing. The right eye is tested first, then the left eye, each time occluding the fellow eye. Care should be taken to ensure that the occluded eye is not pressed. Also, the tested eye should be observed to prevent squeezing/squinting (pinhole effect) while reading the optotypes. Acuity is measured first with spectacles, if the child wears them, followed by measurement of uncorrected (unaided) vision. Visual acuity testing will generally be done by an ophthalmic technologist or optometrist.

c) **Binocular Motor Function:** All ocular alignment assessments will be performed without spectacles. Initially ocular alignment is determined using corneal reflections (Hirschberg). This is to be followed by a cover/uncover test using an occluder and performed at 0.5 and 4 metres. The left eye is covered first and the right eye is observed to detect any corrective movement while the child fixates an accommodative target at the required fixation distance with both eyes open. The cover is then removed and then the right eye is covered to detect any movement in the left eye. If a strabismus is detected, this should be classified as constant if it is present at all times for both fixation distances. If detected at only one fixation distance or not present at all times, it should be classified as intermittent. The strabismus then should be further classified as esotropia (outward movement of the uncovered eye), exotropia (inward movement), or vertical tropia (upward or downward movement).
In all other children without tropia, an alternate cover test using an accommodative target will be performed to fully dissociate the eyes and reveal any phoria. To detect phoria, one eye is covered and then after a few seconds the occluder should be moved directly to the other eye, again after 1-2 seconds, the occluder should be moved back to the original eye. Repeat the sequence a number of times (minimum 2-3) and ensure that at least one eye is covered for the duration of the alternate cover test. If corrective re-fixation movement of the eye is detected consistently as the cover is removed from the eye, then a phoria has been detected. The phoria should be classified as an esophoria (outward movement of both eyes as they are uncovered), exophoria (inward movement) and vertical phoria (upward or downward movement). If <2 prism diopters is detected, then the condition is classified as orthophoria.

Measurement of phoria and tropia will be performed using the objective prism cover test. The prism strength will be increased until no movement of the eyes on cover is observed (neutralisation). The prism strength is then further increased until there is reversal in the direction of the tropia/phoria., and then decreased until neutralisation is seen for the second time. The measure of the total strabismus or phoria size will be recorded as the amount of prism power required to neutralise the deviation for the second time. This measurement will take place for both distance and near fixation where relevant.

The presence of nystagmus (involuntary rhythmic oscillations of the eyes) should be noted. This assessment, the cover tests and prism cover tests will generally be performed by an ophthalmic technologist, orthoptist or optometrist.

d) **External and Anterior Segment Examination**: Eyelids, conjunctiva, cornea, iris, and pupil are examined with a magnifying loupe and torch light by an ophthalmologist. The recording of abnormalities is important as documentary evidence to support the assignment of a principal cause of impairment by the examiner. Significant abnormalities include:

- Eyelid: ptosis, defective closure of eyelid, entropion, trichiasis, irregular eye lid margin, meibomitis, blepharitis, hordeola, etc.
- Conjunctiva: Bitot spot, signs of trachoma, other forms of conjunctivitis, phlyctenule, episcleritis, etc.
- Cornea: corneal opacity/scarring in the pupillary area, pterygium involving the pupillary area, keratoconjunctivitis, corneal foreign body, keratoconus, microcornea, buphthalmos, anterior staphyloma, etc.
- Pupil (iris); absence of pupillary reflex, iris coloboma, anterior or posterior synechiae, aniridia, etc.
- Other anterior segment abnormalities. (Please specify)

b) **Cycloplegic Dilation**: In children with unaided visual acuity 20/40 or worse in either eye, pupillary dilation and cycloplegia (in both eyes) are attained using the following: 1 drop of a topical anesthetic eye drop in both eyes, after waiting 2 minutes to achieve ocular surface anesthesia, 2 drops of 1% cyclopentolate are administered 5 minutes apart to each eye. After an additional 15 minutes, if a pupillary light reflex is still present when observed with a bright torch light without magnification, then a third drop can be administered as required.
After a further 15 - 20 minute interval, pupils are considered fully dilated if 6 mm or greater and cycloplegia is considered complete if pupillary light reflex is absent. In some children both dilation and cycloplegia may not be achieved: dilation may be less than 6 mm but cycloplegia complete, or dilation ≥ 6 mm with incomplete cycloplegia. Cycloplegic dilation is generally performed by an ophthalmic technologist, orthoptist or optometrist.

c) Cycloplegic Refraction: In eyes with successful cycloplegia, refraction is performed with either an autorefractor or retinoscope. Autorefraction is carried out according to the manufacturer instruction manual, including daily calibration. A minimum of 5 readings with valid confidence rankings as per the manufacturer’s instructions should be obtained for each eye. Retinoscopy is carried out using a streak retinoscope in a semi dark room, with the examiner at a distance of 0.75 meters and a +1.50 diopter lens in the trial frame. The additional spherical, cylindrical power and axis necessary to neutralize the shadow movement is noted. Retinoscopy is performed either by an ophthalmic technologist, orthoptist, optometrist, or ophthalmologist.

d) Best Corrected Visual Acuity (Subjective refraction): Using the refraction measurement as the starting point (when available), best corrected visual acuity with subjective refraction is determined. In cases where visual acuity of 20/32 or better is not achieved in both eyes, visual acuity testing may be repeated with the addition of a pinhole in front of the subjective correction lenses. Best corrected visual acuity is determined either by an ophthalmic technologist, orthoptist, optometrist, or ophthalmologist.

e) Media and Fundus Examination: Examination of the lens, vitreous and fundus is performed with a slit lamp and direct/indirect ophthalmoscope in children with an unaided visual acuity of 20/40 or worse in either eye. The recording of abnormal findings is important as documentary evidence to support the assignment of a principal cause of impairment. This examination should be conducted by an ophthalmologist. Significant abnormalities include:

- Lens: Cataract (trivial findings such as blue dot and sutural cataract may not be noted), aphakia, pseudophakia, posterior capsular opacity, subluxated or dislocated lens, partially absorbed lens, etc.
- Vitreous: vitreous opacity, vitreous haemorrhage, etc.
- Fundus: congenital anomaly, optic atrophy, macular degeneration, macular scar, macular oedema, coloboma, chorioretinitis, vascular retinopathy, diabetic retinopathy, abnormal cup:disc ratio, myopic fundus, retinitis pigmentosa, retinal detachment, etc. Abnormal fundus findings should be recorded by either fundus drawings or photography.

f) Ocular biometry: Measurements of axial length (AL) of each eye, anterior chamber depth (ACD), lens thickness (LT) and vitreous chamber depth (VCD) are performed using an A scan. Instill one drop of local anesthetic in each eye. Enter the child’s ID in the machine. After 2 minutes commence readings with the child seated and checking that the on-screen settings are set to; PHAKIC and AXIAL 1550m/s. While measuring take care that the probe is perpendicular to the cornea and not to indent the cornea. Obtain 5 readings within a standard deviation (SD) of 0.12mm and ascertain that the scans have all the key features. Delete any scans that appear erroneous, and
repeat until 3-5 acceptable measures are obtained. Write the ID number of the child on the printout and then attach it to the examination form.

An alternative method of ocular biometry is the IOLMaster (Ziess). No anesthesia is required. Calibration should be performed at regular intervals as per the manufacturer’s instructions. For each child enter their name, date of birth and ID number into the database. For all measurements follow the manufacturer’s instructions as supplied in the manual and measure the right eye first. Make 5 valid AL measures, with a minimum of 3 being regarded as acceptable if a child is uncooperative. Each reading is consider valid if the signal-to-noise ratio (SNR) > 2, and the graph appearing on the screen has a distinctive tall principal spike (reflection at the retinal pigment epithelium surface) and several low secondary spikes. Note that the IOLMaster allows a maximum of 20 readings for each eye in a day. For measurements of ACD, 5 measures are taken automatically. If the readings are not consistent, with differences of more than 0.15mm, or an error message is displayed, the measurement will be repeated. After the last measurement on the left eye, the results will be printed and attached to the child’s examination form. (Note that the IOLMaster will only store 100 separate data files at any one time. Any additional entries will cause the automatic deletion of existing files).

g) Cause of Impairment. A principal cause of impairment is assigned for eyes with uncorrected (unaided) visual acuity 20/40 or worse. Refractive error is assigned as the cause if acuity improves to 20/32 or better with subjective refractive correction -- with or without pinhole. The cause of impairment is assigned by the examining ophthalmologist.

Children with presenting visual acuity 20/40 or worse in the better eye improving with refraction should be provided with spectacles, free of charge. Medical treatment for minor ophthalmic problems should also provided free of charge at the time of examination. Children requiring further management should be provided with an explanation and referred to the hospital/clinic nearest their home.

Each data form should be reviewed for completeness and accuracy before the clinical team leaves the examination site.

4. TRAINING AND QUALITY ASSURANCE

In order to ensure data integrity and reduce observer variation in data collection to a minimum, the following measures will be taken: pre-testing of all the survey forms and procedures; special and adequate training of all staff; a pilot study to ensure familiarity with all aspects of the protocol in a realistic field/clinic setting; regular monitoring and supervision of the staff performance throughout the field/clinic work to circumvent unintentional deviations from the protocol.
4.1 Staff Training

The Study Investigator should identify personnel for each of the study components. In some instances it may be necessary to hire personnel for specific duties. Intensive training should be provided to explain the purpose of the study, clinical methods and procedures, completion of study data forms, and quality assurance techniques.

Enumeration Team.

The enumeration team is responsible for listing all children in the selected classes. The denominator for prevalence rate calculations is based on the enumerated population. Hence accuracy of the prevalence estimates depends on the completeness of the enumeration and the examination response among those enumerated.

Ophthalmologists and Ophthalmic Assistants/Technologists/Optometrists.

It is important that the training of ophthalmic professionals include field experience. Field training is particularly important for staff without previous exposure to similar field work. They are required to become familiar with all details of the field procedures and clinical data collection forms.

Ophthalmic Assistants/Technologists should be trained in vision testing under field conditions. Additional responsibilities such as calibration and maintenance of equipment should also be discussed in detail.

Data Entry and Management Staff

The data management staff should be trained in the use of data entry, data cleaning and statistical analysis software. These software tools have been developed based on the conduct of similar surveys in several countries. Data entry and management associated with the pilot study will ensure staff familiarity with all aspects of data process.

Inter-observer agreement between clinical staff in visual acuity testing and refraction can be evaluated in a formal fashion through test-retest measurements during the training period. Standardization of clinical methods and procedures for ophthalmologists, optometric technologists, and optometrists is also an important part of training.

4.2 Pilot Study

It is recommended that a pilot study be conducted to familiarize the staff will all aspects of the study, and identify problem areas requiring attention prior to the implementation of the full study. The pilot study should be carried in a representative school not included in the study sample. During the pilot exercise both enumeration and clinical procedures should be carried out as per the protocol, data forms should be completed and data computer entered. Data cleaning and analyses programs should also be run. Based on the pilot study experience and findings, remedial training and other actions should be addressed as necessary.
4.3 Visual Acuity/Examination Response Rates

Another indicator of quality in a field survey is the visual acuity testing and examination response rates. The higher the response rates the more valid the study becomes, recognizing that findings from studies with low response rates can be open to a lot of speculation. Achieving high response rates may be a challenge considering that the vast majority of children will have normal vision and some may not have an interest in participating in a survey such as this. A high clinical response rate, on the order of 90%, should be the target.

5. DATA MANAGEMENT

5.1 Data Entry

Data entry software displays the data form on the computer screen, with built-in logical branching, as appropriate. The software has various checks for data completeness, data ranges, and data consistency. If feasible, data entry could be conducted daily, along side the daily field work. Once data collection and entry are completed for an entire school/cluster, additional data cleaning and consistency check programs should be run.

Changes/corrections on an original data collection form, made either in the field or in the central office, will be shown in ink by crossing out the original data and recording the new data beside it. The change will be initialed and dated by the person making the change. Over writing shall be avoided.

The data entry operator should keep back-up copies of entered data, on a daily basis. Back-up data sets will be stored in an appropriate location.

The data entry software is developed in EpiInfo. Data sets will be transferred for statistical analysis with standard routines available in STATA.

5.2 Data Analysis

The following primary analysis will be conducted for the study aims.

- Estimation of prevalence of visual impairment and refractive error in school aged children:

The distribution of the uncorrected, presenting and best corrected visual acuity will be reported by visual acuity categories with confidence intervals. The distribution of spherical equivalent refractive error among those with vision impairment will be tabulated by age and gender. The association of
myopia or hyperopia with the child's age, gender will be explored with multiple logistic regression. Principal causes of visual impairment (visual acuity 20/40 or worse) will be summarized.

- Evaluation of refractive services among school aged children:

  The percentage of children wearing glasses by uncorrected visual acuity categories will be tabulated. Comparison of best corrected with presenting visual acuity will provide information on the acuity improvement that can be obtained through the provision of appropriate corrective spectacles, including the further improvement that can be achieved among those already wearing glasses.

6. SERVICE PROVISION & ETHICAL CONSIDERATIONS

Because this survey is an epidemiological research project, it is important that strict ethical considerations are met. The study protocol has been reviewed and approved by the WHO Ethical Review Committee. It should also be submitted for review by the Institutional Review Board (IRB) of the implementing organization/institute. The informed consent process must be rigorous and complete (Annex II). It should be made clear that children/parents are under no obligation to participate, and that personal identifiers in the data are kept confidential.

As a benefit to participating children, necessary eye care services should be provided, free of charge, by the implementing organization/institute. Children with presenting visual acuity 20/40 or worse in the better eye improving with refraction should be given spectacles free of charge. Medical treatment for minor ophthalmic problems should also be provided free of charge at the time of examination. Children requiring further diagnostic assessment or treatment should be provided with an explanation and referred to the hospital/clinic nearest their home.
ANNEX I

GRADE/CLASS ENUMERATION FORM
# CLASS (CLUSTER) ENUMERATION

<table>
<thead>
<tr>
<th>Child #</th>
<th>Child Name</th>
<th>Age</th>
<th>Sex</th>
<th>Parent/Guardian Name</th>
<th>Home Address</th>
<th>Tel #</th>
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Scheduled Examination Date: ____/____/____
ANNEX II

INFORMED CONSENT FORM
I am (researcher name), working for (organization). We are studying the vision status of school children.

**Purpose:** In children it is quite common that a number of them may have impaired or low vision and may not be able to see the blackboard clearly in a classroom. Such children may not be able to perform well in studies because of this impaired vision. Impairment because of myopia, or short sightedness, can easily be corrected by wearing appropriate devices such as glasses. Many children or parents may not know about the presence of such problems. In (country/area) we do not have reliable data on the magnitude of this problem. After examining a large number of school children we will know the extent of the problem. This will help in planning adequate eye service for school children by government or school authorities. To obtain such important information we invite your child to have his eye examined by an ophthalmologist and team from (organization).

Your child will receive a free complete eye examination that includes routine tests of the eyes and vision. If your child participates in the examination he/she may require the instillation of eye drops (Cyclopentolate 1 %), which may cause temporary glare and difficulty in reading printed materials for up to one day. The examination may last ten minutes to one hour. This is a routine procedure performed for eye examination by ophthalmologists/optometrists in their daily clinical practice.

**Benefits:** The examination will detect if your child has any abnormalities. If your child has defective vision which can be corrected by glasses he/she will be given free glasses. If medical/surgical treatment for your child’s eyes is necessary, you will be given an explanation and your child will be referred to an appropriate hospital/clinic.

**Confidentiality:** The examination information will be kept confidential and will not be given to anyone outside the study. Your name and your child’s name will never be used in any reports.

**Right to refuse or withdraw:** Your child's participation is voluntary and he/she can withdraw from the study after having agreed to participate. Your child is free to refuse any aspect of the examination. If you have any questions you may ask now or later. If you wish to ask question later, you may contact the following: (name, address, telephone number/email)

This study has been approved by WHO Ethics Review Committee and the Institutional Review Board.
(IRB) of *(organization/institute)*. This committee's task is to make sure that research participants are protected from harm. If you wish to find more about the IRB, contact *(name, address, telephone number)*

**Certificate of consent**

My child has been invited to take part in the research on vision impairment of children. I have read the foregoing information, or it has been read to me. I have had opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child's participation as a subject in this study and understand that my child has right to withdraw from the study at any time without any way affecting his medical care.

Name:_____________________________ Signature: ___________________________
Date:____________________________

If illiterate:
Name of independent literate witness:
_____________________________ Signature:____________________________
Date:___________________________

(If possible, the witness should be selected by the illiterate participant and have no connection to the research team)

Name of Researcher:________________ Signature:___________________________
Date:___________________________
ANNEX III

RESC EYE EXAMINATION FORM
RESC EYE EXAMINATION

Examination Station

School Name: ____________________________
Exam Date _____/_____/_____

SECTION A: CHILD IDENTIFICATION

Child Name: __________________________________

Child ID: [ ] School [ ] Grade [ ] Class [ ] Child

Age [ ] Sex (1: Male; 2: Female) [ ]

SECTION B: VISION ASSESSMENT

VA Examiner ID [ ]

B1. Child is wearing corrective lenses? [ ]
0: NO; Go to B3  1: YES

B2. Visual Acuity with corrective lenses:

<table>
<thead>
<tr>
<th>VA</th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>

Visual Acuity cannot be determined (reason):
________________________________________

B3. Uncorrected Visual Acuity (UCVA):

<table>
<thead>
<tr>
<th>UCVA</th>
<th>OD</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>
Visual Acuity cannot be determined (reason):

____________________________

SECTION C: BINOCULAR MOTOR FUNCTION

Examiner ID

C1. Tropia at 0.5 meter fixation:  
0: None   1: Esotropia   2: Exotropia   
3: Vertical   9: Undetermined

   If tropia, degrees?  
   1: 1 to 15;   2: 16 to 30;   3: 30+

C2. Tropia at 4 meter fixation:  
0: None   1: Esotropia   2: Exotropia   
3: Vertical   9: Undetermined

   If tropia, degrees?  
   1: 1 to 15;   2: 16 to 30;   3: 30+

SECTION D: EXTERNAL/ANTERIOR SEGMENT EXAMINATION

Examiner ID

0: Normal   1: Abnormal   9: Undetermined

D1. Eyelids?
OD          If abnormal: ______________
OS          If abnormal: ______________

D2. Conjunctiva?
OD          If abnormal: ______________
OS          If abnormal: ______________

D3. Cornea?
OD          If abnormal: ______________
OS          If abnormal: ______________
D4. Pupil?
OD □ If abnormal: ________________
OS □ If abnormal: ________________

D5. Other anterior segment?
OD □ If abnormal: ________________
OS □ If abnormal: ________________

SECTION E: REFRACTION WITH CYCLOPEGIA

E0. Is Uncorrected VA $\geq 20/32$ in both eyes? □
   0: NO; continue             1: YES; Go to G
   9: Undetermined; continue

E1. Pupil dilated $\geq 6$mm AND light reflex absent?
   0: NO; Go to E5             1: YES; continue
   2: Light reflex absent, but $< 6$ mm; continue
   8: $\geq 6$mm, but light reflex present; Go to E5
   9: Undetermined; Go to E5

OD □ If 0 or 9, comment: ________________
OS □ If 0 or 9, comment: ________________

E3. Autorefraction (staple printout & record results)
   or Retinoscopy
   Examiner ID □

<table>
<thead>
<tr>
<th>Sphere</th>
<th>Cyl.</th>
<th>Axis</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Cannot be examined (reason)_____________________

E5. Subjective refraction (with BCVA)
   Examiner ID □
<table>
<thead>
<tr>
<th>Sphere</th>
<th>Cyl.</th>
<th>Axis</th>
<th>BCVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
<td></td>
<td></td>
<td>/</td>
</tr>
<tr>
<td>OS</td>
<td></td>
<td></td>
<td>/</td>
</tr>
</tbody>
</table>

Cannot be examined (reason) ________________

**E6. Is BCVA ≥ 20/32 in both eyes?**

0: NO; continue   1: YES; Go to F   
9: Undetermined; continue

**E7 Pinhole BCVA (optional)**

<table>
<thead>
<tr>
<th>Pinhole BCVA</th>
</tr>
</thead>
<tbody>
<tr>
<td>OD</td>
</tr>
<tr>
<td>OS</td>
</tr>
</tbody>
</table>

Cannot be examined (reason) ________________

**SECTION F: LENS, VITREOUS AND FUNDUS**

Examiner ID

0: Normal   1: Abnormal   9: Undetermined

**F1: Lens?**

OD If abnormal ________________
OS If abnormal ________________

**F2: Vitreous?**

OD If abnormal ________________
OS If abnormal ________________

**F3: Fundus?**

OD If abnormal ________________
OS If abnormal ________________
SECTION G: IMPAIRMENT CAUSE

Examiner ID [ ]

0: No impairment (UCVA ≥ 20/32)
1: Refractive Error (UCVA ≤ 20/40 and
   BCVA/Pinhole BCVA ≥ 20/32)
2: Amblyopia (only if BCVA & Pinhole ≤ 20/40)
3: Corneal opacity/scar
4: Cataract
5: Retinal disorder
6: Other cause
7: Undetermined cause
8: Missing UCVA, or UCVA ≤ 20/40
   & missing BCVA

OD [ ] If other, specify: ____________________________
OS [ ] If other, specify: ____________________________

SECTION H: ACTION TAKEN

0: None indicated
1: Glasses prescribed & to be provided
2: Glasses prescribed only
3: On-site medical treatment given
4: Prescribed medical treatment
5: Referred to Eye Center
6: Other/Multiple actions

[ ] If other/multiple actions, specify: ____________________________
ANNEX IV

EQUIPMENT (per clinical team)

- Retro illuminated LogMAR Vision Charts (2)
- Magnifying loupe (1)
- Torch Lights (2)
- Hand held Auto refractor--optional (1)
- Streak Retinoscope (1)
- Trial frame (paediatric and adult size) and trial lens set (1)
- Hand held Slit Lamp (1)
- Direct ophthalmoscope (1)
- Indirect ophthalmoscope -- optional (1)
- Computer and software (STATA and epinfo)

MEDICAL SUPPLIES

- Cyclopentolate 1% eye drop (1 ml per child)
- Other medications - antibiotics drops, anti-inflammatory drops, anaesthetic drops
ANNEX V

REFERENCES


