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To cite this version:

Lisa O'Donoghue, Kathryn J Saunders, Julie F Mcclelland, Nicola S Logan, Alicja R Rudnicka, et al.. Sampling and measurement methods for a study of childhood refractive error in a United Kingdom population. British Journal of Ophthalmology, 2010, 94 (9), pp.1150. 10.1136/bjo.2009.167965 . hal-00557332

HAL Id: hal-00557332

https://hal.science/hal-00557332v1

Submitted on 19 Jan 2011

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Title: Sampling and measurement methods for a study of childhood refractive error in a United Kingdom population

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Keywords
Myopia, refractive error, epidemiology, methods

Word count 2763

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Competing Interest: None declared

ABSTRACT

Background

There is a paucity of data describing the prevalence of childhood refractive error in the United Kingdom. The Northern Ireland Childhood Errors of Refraction study, along with its sister study the Aston Eye Study, are the first population-based surveys of children using both random cluster sampling and cycloplegic autorefraction to quantify levels of refractive error in the United Kingdom.

Methods

Children aged 6-7 years and 12-13 years were recruited from a stratified random sample of primary and post-primary schools, representative of the population of Northern Ireland as a whole. Measurements included assessment of visual acuity, oculomotor balance, ocular biometry and cycloplegic binocular open-field autorefraction. Questionnaires were used to identify putative risk factors for refractive error.

Results

399 (57%) of 6-7 years and 669 (60%) of 12-13 years participated. School participation rates did not vary statistically significantly with the size of the school, whether the school is urban or rural, or whether it is in a deprived/non-deprived area. The gender balance, ethnicity and type of schooling of participants are reflective of the Northern Ireland population.

Conclusions

The study design, sample size and methodology will ensure accurate measures of the prevalence of refractive errors in the target population and will facilitate comparisons with other population-based refractive data.

INTRODUCTION

Although refractive errors are common in children,[1] their importance as a public health issue has often been underestimated. However the financial costs can be considerable. In Australia, the provision of spectacles, contact lenses and refractive surgery for myopia runs into hundreds of millions of dollars.[2] The management of associated ocular morbidity such as the increased risk of amblyopia and strabismus associated with hyperopia[3] and the pathological complications associated with myopia[4] also have significant cost implications.

Uncorrected refractive error is the most common cause of visual impairment in school-aged children in both industrialised and developing countries[5] and can dramatically affect the learning capability and educational potential of children.[1] Vision 2020, a World Health Organisation initiative to eliminate avoidable causes of blindness by 2020, has estimated that there are 153 million people worldwide with visual impairment (presenting acuity <6/18) due to uncorrected refractive errors (www.v2020.org).

Numerous epidemiological studies have described an increase in the prevalence of myopia in young adolescent eyes,[6] especially in Asia.[7] However the evidence for changing myopia prevalence in white populations is equivocal.[2] The prevalence of myopia also varies between countries even when subjects of similar ethnicity are compared,[8,9] suggesting that prevalence rates may be population specific.

The few studies that have published on childhood refractive error in the United Kingdom have examined selective populations such as children attending community eye clinics[10] or optometric practice[11] or have estimated the prevalence of refractive error on the basis of vision screening data.[12] Sorsby's description of the distribution of ocular refraction was carried out on a non-random sample of school-children and the participation rate was low (30-40%).[13] More recently the Avon Longitudinal Study of Parents and Children used non-cycloplegic closed-field autorefraction to estimate the prevalence of refractive error.[14,15] Due to the effects of active accommodation, use of habitual refractive status in children can substantially overestimate the prevalence of myopia and underestimate the prevalence of hyperopia.[16] Cycloplegic refraction is considered essential in childhood epidemiological surveys of refractive error, with cyclopentolate hydrochloride frequently being utilised.[1,17,18] In some such studies participation rates of over 90%[19,20] have been reported, confirming that its use is not a major barrier to participation.

The Northern Ireland Childhood Errors of Refraction (NICER) study examines the burden of refractive error in school children in Northern Ireland (NI) where the population is mainly white. It aims to be representative of NI as a whole, with an appropriate mix of children from urban/rural areas and deprived/non-deprived areas. Associations with age, gender, socio-demographic and lifestyle determinants, especially the effect of urbanisation, are determined. The NICER study is a sister study to the Aston Eye Study (AES) which

examines refractive error in multi-ethnic urban school children in Birmingham, England.[21,22] The current report describes the methodology employed by the NICER study and presents data on the participation rates and characteristics of participants.

MATERIALS AND METHODS

Ethics

Approval for the study was obtained from the University of Ulster's Research Ethics Committee. The research adhered to the principles of the Declaration of Helsinki.

Study area, sample identification and sample size

The two age-groups (6-7-years and 12-13-years) were selected to facilitate comparisons with other studies of childhood refractive error.[18, 23] School-based testing was employed as compulsory education for children in NI from 4-16 years of age ensures the present study captured children representative of the NI population.

Sample size calculations were based on 3% prevalence of myopia with 1% standard error for 6-7 year olds and 10% prevalence with 1.5% standard error for 12-13 years olds. A modest inflation of the sample size was made to allow for clustering within school (30%) and an assumed a response rate of 65% at both ages. Therefore, a minimum of 585 6-7 year olds and 800 12-13 year old children were required.

Data on population density and deprivation (Multiple Deprivation Measure) available from government databases (www.nisra.gov.uk) were used to broadly classify the schools into four strata of urban/rural and deprived/ not deprived. Stratified random sampling of schools was performed in order to obtain representation of schools and children across these four strata from four Local Government Districts (Derry, Limavady, Coleraine and Ballymena). We aimed to recruit 4 primary schools and 4 post-primary schools from each stratum. All 6-7 year olds in a primary-school and two or more classes of 12-13 year old children in post-primary schools were invited to participate and this resulted in slightly higher numbers overall of children being invited and examined. A randomization list was prepared in advance, and if a school was unable or refused to participate it was replaced by the next school on the list from the same stratum.

Recruitment

Initially the school principal was sent a letter outlining the study, followed up several days later by telephone when arrangements were made to visit the school to explain the study in detail and to identify a suitable time in the school calendar for data collection to take place. Children who were invited to participate in the study attended an information session in the school which explained the rationale behind the study and the study procedures in detail. Children were given a detailed information pack for their parents/guardians and written informed consent was obtained from a parent or other responsible adult prior to the child's participation in the study.

Study personnel
All personnel involved in data collection were checked by the Criminal Records Bureau and were trained in the exact protocols and procedures required. In line with similar large-scale studies [1,18] multiple examiners were used. The study co-ordinator (LOD), a qualified registered optometrist, carried out all initial contact with the schools and was present at all times during data collection.

Examination procedures
The children were tested within school premises during the school day. Verbal assent was obtained from the children aged 6-7 years, and written consent from the 12-13-year-old children. The following protocol was employed:

- focimetry of any current spectacles.
- assessment of ethnicity by the study co-ordinator.
- monocular distance visual acuities (unaided and presenting) were measured at a distance of at least three metres, using the logMAR chart on the Test Chart 2000, a windows-based computerised test chart (http://www.thomson-software-solutions.com/html/test_chart_2000.html) and the by-letter scoring system.
- assessment of heterophoria/tropia at distance (at least three metres, using the smallest letter on the logMAR chart that could be seen clearly with each eye) and near (33cm, using an appropriately sized fixation target on the Budgie Stick) using the cover/uncover test both unaided and with spectacles if worn.
- completion of a child questionnaire by the 12-13-year-old children to identify risk factors for myopia, including amount of time spent on near work and level of physical activity. Support for the questionnaire completion was available from the study personnel if required.
- cycloplegia of both eyes using one drop of cyclopentolate hydrochloride 1% (Minims® single dose, Chauvin Pharmaceuticals) following instillation of one drop of proxymetacaine hydrochloride 0.5% (Minims® single dose, Chauvin Pharmaceuticals).
- height (in centimetres) using the Leicester Height Measure.
- weight (in kilograms) using Tanita digital scales (Model HD-327).
- digital photography of the optic disc of both eyes using the Nidek NM200 Fundus Camera.
- ocular biometry. One examiner (LOD) used the Zeiss IOLMaster to measure axial length, anterior chamber depth (ACD) and corneal curvature.[23,24] At least three measurements of axial length, five simultaneous ACD measurements and three corneal curvature readings were taken. Only axial length measurements with a signal to noise ratio (SNR) greater than two were considered valid for subsequent analysis.
- distance autorefraction, with the subject fixating the centre of a Maltese Cross, was carried out using the binocular open-field

autorefractor, the Shin-Nippon SRW-5000,[25] at least 20 minutes after the instillation of the eye drops. The presence of dilated pupils which were non-responsive to light and an amplitude of accommodation of less than two dioptres were used to confirm that cycloplegia had been achieved prior to autorefractor measurement. The representative value as determined by the instrument was used in subsequent analyses.

- adult questionnaires. After examination had been completed the child was given an information pack for their parents/guardians. This pack included a thank-you letter, drug information sheet and a detailed questionnaire designed to elicit risk factors for myopia, including child's birth history, family history, and lifestyle questions . The parents/guardians were asked to complete the questionnaire and to return it directly to the study co-ordinator in the Freepost envelope provided.

Definitions

In line with recommendations from the World Health Organization, 'uncorrected visual acuity' is used to refer to unaided vision and 'presenting visual acuity' is the visual acuity with distance spectacles if worn [26].

The spherical equivalent refractive error (SER: sphere + ½ cylinder) of the right eye was used to classify participants as myopic, hyperopic or emmetropic. To facilitate comparisons with previously published studies myopia prevalence was described as ≤-0.50DS. SER was classified as hyperopic when greater than or equal to +0.50DS, with moderate hyperopia defined as a SER ≥+2.00DS and emmetropia defined as a SER >-0.50DS and <+0.50DS.[1,18]

Follow up

Subsequent to the examination, if there were any concerns about the eye health of a participant, the parents/guardians were contacted directly advising them of the necessity for the child to have a full eye examination. No major adverse reactions to the eye drops were reported.

Parents/guardians who failed to return the questionnaire were sent a second copy, together with a Freepost envelope in which to return it.

Data entry, analysis and statistics

Initial data entry was carried out using Excel 2003. The data was anonymised by using an individual code for each participant. A separate password-protected file was created to store the names of the participants, together with their unique identity code. The data were then transferred to the statistical package (Intercooled Stata 9.2 software), where error checking was carried out prior to analysis. t-tests were used to compare parental consent rates between deprived/non-deprived schools and urban/rural schools, with linear regression used to describe the association between parental consent rate and school size.

RESULTS

Response rates and characteristics of participants
Data collection took place between May 2006 and April 2008. Of the 16 primary schools originally identified, 15 participated in the study (94%). 13 out of the 15 post-primary schools originally identified participated in the study (87%). Suitable replacement schools were identified and participated in the study.

Table 1 describes the consent and participation rates for each age-group. Consent was not established for 14% of primary school children and 20% of post-primary school children due to non-return of the forms. 24% of primary school children returned the consent form with consent actively declined compared with 14% of post-primary school children.

Of the children for whom parental consent was received 93% of the 12-13-year-old children and 92% of the 6-7-year-old children participated in the study. The difference between the consent rate and the actual participation rate was due to non-attendance on the day of testing (3.7% primary, 4.6% post-primary) or the child refusing to consent to the instillation of eyedrops (4.6% primary, 2.5% post-primary).

One child in each age-group was excluded from analysis due to the presence of Down syndrome. Refractive and biometric data collection was complete for 99.8% of 12-13-year-old children and 98.7% of 6-7-year-old children.

There was no statistically significant difference between the parental consent rate in schools in deprived versus non-deprived areas ($t=0.96$, $p=0.35$) or between schools in urban versus rural areas ($t=0.21$, $p=0.84$). There was also no statistically significant relationship between the size of schools and their consent rate ($F=0.08$, $p=0.77$).

In NI academic selection at 10-11 years of age is used to determine entrance to post-primary schools, with grammar schools selecting the higher performing children. Parental consent rates were similar between grammar and non-grammar schools: 63% (range 46-80%) in grammar schools and 66.5% (range 47-89%) in non-grammar schools. 43.4% of post-primary school participants attend grammar school.

Table 2 summarises the characteristics of the participants.

DISCUSSION

The participation rate in the NICER study compares favourably with the Collaborative Longitudinal Evaluation of Ethnicity and Refractive Error study, a multi-centre study of refractive error in childhood in the United States of America where consent rates ranged from 30-50%.[17] However, despite using similar procedures and protocols the parental consent rate was lower for the NICER study than the Sydney Myopia Study (75% in 12-year-olds, 79% in six-year-olds),[27,28] a large-scale epidemiological survey of refractive error in Australian school-children.

Due to ethical constraints it is difficult to establish reasons for lack of parental consent in the NICER study. Differing cultural attitudes to research may help explain the variation in participation rates between similar studies in other countries. Lack of consent due to non-return of the forms was greater in post-primary school children, possibly because it was easier for primary school teachers to monitor and encourage return of the forms. The variation in parental consent rate between schools reflected the variation in enthusiasm between teaching staff within the schools involved, with schools where one or more members of staff took an active interest in the study having the highest participation rates. A greater proportion of parents of primary school children actively declined consent; this may have been due to concerns about the use of eye drops.

Although it is not possible to establish if the consent rate affected the validity of the results, the schools' participation rates were not statistically significantly affected by the size of the school or the deprivation or population density of the area in which the school resides (Figure 1 and Figure 2). The ethnicity, gender distribution and type of schooling of participants are also comparable with those of the target population, supporting the assumption that the results are applicable to the general population. The proportion of post-primary school children in the sample that attend a grammar school is similar to the figure for NI as a whole (43% versus 42% respectively) (www.deni.gov.uk/). The gender of the participants closely matches that of the NI population (49% male in NI) (www.nisra.gov.uk/). Ethnicity was assessed by the study co-ordinator and confirmed by the response given in the parental questionnaire; this confirmation could not be carried out in cases of non-return of the questionnaire. Where the appropriate data are available, the ethnicity as identified by the study co-ordinator agreed with the parental identification of ethnicity in all cases, confirming the validity of assessing ethnicity in this manner in this study group. 98.8% of school children in NI are from a white ethnic group (www.nisra.gov.uk/), this figure closely matching the ethnicity of the participants.

Data from the NICER study will allow us to describe the prevalence of refractive error and to explore issues such as how lifestyle, refractive status and biometry measures influence refractive outcome. The influence of familial factors such as socio-economic status, parental education and birth order on visual development during childhood will also be investigated.

The data will also enable us to quantify the extent to which uncorrected refractive error is a problem in this United Kingdom population and will provide evidence of the effectiveness of the NI vision screening program in identifying uncorrected refractive error and reduced vision in childhood.

Future plans include the use of the sampling frame to examine trends and patterns in the prevalence and development of refractive status in childhood. Participants in the current study are currently being re-examined three years after they originally participated in the NICER study, providing useful longitudinal data on refractive error and its correlates.

Data from this population will provide a valuable database on refractive error distribution in a white population. Comparisons with data from white participants in the multi-ethnic Aston Eye Study will establish the generalisability of the findings to the UK population as a whole. The outcomes of these sister studies will be used to examine the influence of ethnicity on childhood refractive error in the UK.

CONCLUSIONS

This report describes the protocol employed by the NICER study. The use of cycloplegic autorefraction, considered the gold standard for epidemiological studies of refractive error will facilitate comparisons with other such studies, including the Sydney Myopia Study [18] and the Refractive Error Study in Children (RESC).[1]

With participation rates of 57% (6-7-year-old children) and 60% (12-13-year-old children) the required sample size was achieved for both age-groups. The majority of subjects in both age-groups participated fully with data collection. The gender distribution and ethnicity of participants closely matches the Northern Irish child population, supporting the robustness of the data. Future papers will describe the prevalence of myopia, hyperopia and astigmatism within this population. Collaborative reports from the NICER study and the Aston Eye Study will compare the distribution of SER and ocular biometric parameters in school-children in NI with those of their multi-racial peers in England.

WHAT IS ALREADY KNOWN ABOUT THIS TOPIC

Numerous studies have described the prevalence of refractive error world-wide. However these studies suggest that refractive-error prevalence is population specific and they cannot be used to predict prevalence in the UK, where little reliable data exist. The few studies that have published on childhood refractive error in the UK have examined selective populations or have not used cycloplegia, now considered essential in epidemiological studies of childhood refractive error.

WHAT THIS STUDY ADDS

The NICER study is the first population-based survey of childhood refractive error in the United Kingdom to use both random-cluster sampling and cycloplegic autorefraction. The current paper describes the methodology and participant characteristics of this study which, due to the paucity of up-to-date refractive error data for UK children, is likely to be heavily cited by our future publications and others. Future publications from the NICER study will provide evidence of the effectiveness of the vision screening program in identifying uncorrected refractive error and reduced vision in childhood and will help inform service providers. Examining how exposures in early life, including body size (at birth and later in childhood), early nutrition, life-style behaviours and familial factors affect early visual development will also be the topic of future work.

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ACKNOWLEDGEMENTS
The authors are grateful to the College of Optometrists who provided a research scholarship to Lisa O'Donoghue, to the Northern Ireland Optometric Society who provided funding for the portable digital fundus camera and to Prof Peter Whincup for support in the design of the questionnaires.

LEGENDS FOR FIGURES AND TABLES

Table 1: Parental consent and participation rates
IQR: interquartile range

Table 2: Characteristics of participants
Data from white participants only

Figure 1: Bar chart illustrating the consent rate from primary schools in deprived versus non-deprived areas and rural versus urban areas.
'Deprived' Multiple Deprivation Measure (MDM) ≥20; 'Non-deprived' MDM <20
'Urban' population density ≥10 persons per hectare; 'rural' population density <10 persons per hectare

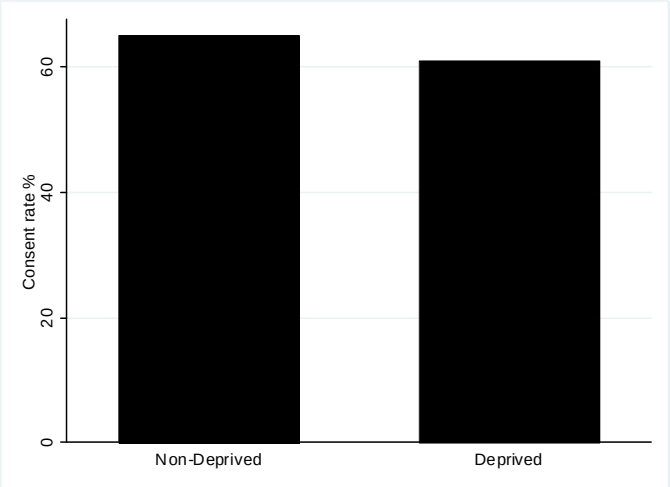
Figure 2: Bar chart illustrating the consent rate from post-primary schools in deprived versus non-deprived areas and rural versus urban areas.
'Deprived' Multiple Deprivation Measure (MDM) ≥20; 'Non-deprived' MDM <20
'Urban' population density ≥10 persons per hectare; 'rural' population density <10 persons per hectare

Age-group (years)	Number invited	Parental Consent % (median)	IQR parental consent % individual schools	Participation % (median)	IQR participation % Individual schools	Number of participants examined
6-7	700	62 (62)	58-72	57 (57)	52-69	399
12-13	1115	65 (71)	59-78	60 (67)	53-77	669

Table 3: Parental consent and participation rates
IQR: interquartile range

	Age Group	
	6-7-year olds	12-13-year olds
% White	98.5	98.8
% Male#	49.5	50.5
Age range (years) #	6.33-7.83	12.08-14.08
Mean age (± SD) #	7.07 (±0.38)	13.1 (±0.38)

Table 4: Characteristics of participants
Data from white participants only


Consent rate %
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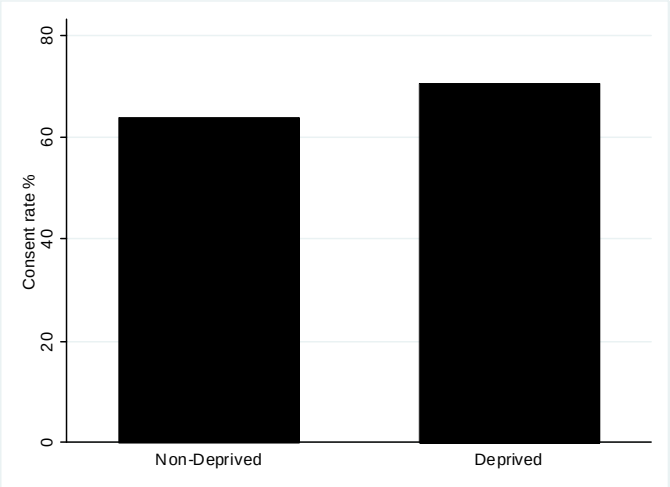
60
Non-Deprived
Deprived


Consent rate %
0
20
40
60
80
Non-Deprived
Deprived