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RAAB7 Protocol Template for RAAB surveys

Sept 2023 V1.2

FULL RESEARCH PROPOSAL

# Project title

Rapid Assessment of Avoidable Blindness in <*survey district name>*

## Personnel

This research proposal has been prepared by:

* <*Implementing Partner*>
* <*Collaborator(s)*>
* The International Centre for Eye Health (ICEH), at the London School of Hygiene & Tropical Medicine (LSHTM)

Principal investigator

<*name and contact details of PI*>

Survey coordinator

<*name and contact details of Survey Coordinator*>

Administrator

<*name and contact details of Administrator*>

Research advisors

*<Delete as appropriate>*

Dr Islay Mactaggart, International Centre for Eye Health, London School of Hygiene & Tropical Medicine, London, UK

Mr Ian McCormick, International Centre for Eye Health, London School of Hygiene & Tropical Medicine, London, UK

## Conflicts of interest

<*add if relevant*>

​

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# Overview

RAAB provides representative, population-based estimates of the prevalence and causes of blindness and vision impairment and collects data on existing eye care service indicators. These are vital to ensure evidence-based eye care planning meets the eye health needs of the community in <*survey district name>*.

RAAB is a standardised survey methodology that is widely used in the global eye care sector to determine the magnitude of blindness and vision impairment for the purposes of planning and advocacy for eye care services. It focuses on vision impairment in the population 50 years and older as the higher prevalence in this age group allows for a smaller sample size than if the all-age population were surveyed. A smaller sample size, along with a simplified exam protocol, means the survey can be completed relatively quickly, and consequently with less expense, compared to a comprehensive survey. RAAB is a complete system and includes provision for training, data collection and analysis.

The most recent version of the methodology – RAAB7 – integrates mobile data collection with a cloud-based server via automatic data upload, and allows administrators to set up and review survey progress via a web-based platform. New inputs have been built into the platform, including uncorrected visual acuity (UCVA) measurement and new survey monitoring data. Written informed consent has replaced verbal consent as standard.

Three or four survey teams, equipped with basic eye care equipment are needed to conduct the survey. They will visit households door-to-door in selected areas, assessing and interviewing inhabitants 50 years and older to obtain information about blindness and vision impairment in this age group. In addition to calculating the age-specific prevalence of blindness and vision impairment, the analysis will provide evidence of the main causes of vision impairment, cataract surgical coverage and effective cataract surgical coverage and barriers to cataract surgery.  These all provide important information for planning and implementing effective eye care service in the district health system.

The training week for this RAAB is scheduled to commence on <*date*> with fieldwork begin directly afterwards. The duration of the fieldwork is estimated to be 4 to 6 weeks, depending on the availability of human resources. Provisional survey results should be available within 2 weeks of completion of data collection, with an official report available 4 to 6 weeks later.

*<Insert statement about following relevant health authority COVID-19 guidance>*

# Background

## Vision Impairment: Global and regional situation

In 2020, it was estimated that 43 million people were blind and 295 million people were moderately or severely vision impaired. In total, 596 million people were living with distance vision impairment.(1) According to the International Agency for the Prevention of Blindness’s (IAPB) Vision Atlas,(2) 90% of vision loss is avoidable, and the major global causes of blindness amongst all ages in 2020 were:

1. Un-operated cataract (17 million)
2. Uncorrected refractive error (4 million)
3. Glaucoma (4 million)

The major causes of moderate to severe vision impairment amongst all ages in 2020 were:

1. Uncorrected refractive errors (160 million)
2. Un-operated cataract (83 million)
3. Age-related macular degeneration (6 million)
4. Glaucoma (4 million)
5. Diabetic retinopathy (1 million)

Around 90% of vision impairment globally is avoidable, meaning that public health interventions to control avoidable sight loss are a priority. It is estimated that 55% of blind and moderately or severely vision impaired people were female and the vast majority (86%) were aged 50 years and older. The vast majority of people affected by vision impairment (90%) live in low- and middle-income countries.(3)

*<Insert regional & national content>*

RAAB provides representative, population-based estimates of the prevalence and causes of blindness and vision impairment and collects data on existing eye care service indicators. These are vital to ensure evidence-based eye care planning meets the eye health needs of the community in <*survey district name>*. To date, there has been no population-based data on vision impairment and its causes in the <*survey district name, update as appropriate>*. The <*implementing partner*> have secured funding from <*sponsor or funder*> to carry out such a survey in *<year>*.

## RAAB

RAAB is a standardised survey methodology that is widely used in the global eye care sector to determine the burden of blindness and vision impairment for the purpose of planning of and advocacy for eye care services.(4) It focuses on blindness and vision impairment in the population 50 years and older as the higher prevalence in this age group allows for a smaller sample size than if the all-age population were surveyed. Causes of blindness in this age group can be considered representative of the all-age situation in a population.(5) A smaller sample size, along with a simplified exam protocol, means the survey can be completed relatively quickly, and consequently with less expense, compared to a conventional survey. RAAB is an ‘end-to-end’ methodology, supported by bespoke software, which provides standardised sample size calculation, cluster selection and automated analysis and report generation.

The newest version of the RAAB methodology – RAAB7 – uses paperless mobile data entry connected to a cloud-hosted, web-based system available via web browser. It has been developed by ICEH and Peek Vision1 with support from several funders. Users do not need to install software or maintain databases. Dashboard views of surveys in progress allow for real-time overview of survey progress and completeness and permit frequent review of inconsistencies in data entry.(6)

RAAB7 includes uncorrected visual acuity (UCVA) measurement for the first time, alongside corrected visual acuity where distance correction is worn. Presenting visual acuity (the basis of WHO vision impairment categories) is derived from these two measures. This update is in line with WHO recommendations, and will allow the calculation of met need for refractive error correction and effective refractive error coverage (eREC),(7) a candidate WHO universal health coverage service coverage tracer indicator.

## Aim & Objectives

The aim of this project is to conduct a RAAB7 survey amongst people aged 50 and above in <*survey district name>* in order to estimate the magnitude and causes of blindness and vision impairment to provide information that will be used to design efficient services.

The objectives of the study are:

1. To report the prevalence of blindness and vision impairment in people aged 50+
2. To report the main causes of blindness and vision impairment in people aged 50+
3. To report the effective coverage and visual acuity outcomes of cataract surgical services in people aged 50+
4. To report the effective coverage of refractive error services in people aged 50+
5. To report barriers to cataract surgical services in people aged 50+

# Methodology

RAAB is a standardised, population-based cross-sectional survey.

## COVID-19:

The population of interest for RAAB is adults aged 50 years and above, who are at risk of more severe outcomes following COVID-19 infections, requiring careful and conservative risk mitigation.

*<Insert content on COVID-19 guidance received from relevant national and/ or local health authority here>*

COVID-19-related adjustments to the standard RAAB survey protocol are included in Appendix 5.

## Study Population:

The population of interest for this study is all residents (male and female) of <*survey district name>* aged 50 years and older. <*Sampling frame data e.g. Census 2018*> will be used to generate a sampling frame of census enumeration areas, determine the representativeness of the study sample relative to the population make up and produce age and sex adjusted estimates where required.

## Sampling Methodology:

RAAB uses a multistage cluster sampling methodology. The first stage is to select at random as many population units as there are clusters from a list that includes all population units in the survey area (the sampling frame). The number of clusters is determined by the sample size and the cluster size (which, in this instance, will be 50 people *<amend as necessary if completing RAAB DR>*). The sampling frame for *survey district name*> will be <*Sampling frame data e.g. Census 2018*>. Enumeration areas will be automatically selected with probability proportionate to their size using RAAB custom software.

The second stage is to randomly select 50 eligible people in each cluster via compact segment sampling. Each cluster is visited two to five days before the survey by a local fieldworker to inform them of the survey. <*Provider of EA maps, usually Bureau of Statistics*> will be asked to provide a map showing major landmarks and the approximate distribution of neighbourhoods and households in a selected enumeration area. From <*sampling frame data*>, the proportion of the population that is aged 50+ will be estimated. For example, if an enumeration area has 2100 people, and 12% of the population is aged 50+, we require five segments of 420 all-age people in order to find 50 people aged 50+ in any one of them.

On the day of the survey the enumeration area is divided into segments of approximately equal population size and with well-demarcated boundaries (using the map), so that each segment includes the desired cluster size of 50 people aged 50+. It should be clear to which segment each house in the village belongs. Each segment is given a number, and these numbers are written on a piece of paper. The pieces of paper are folded, shaken, and one is selected at random by a community leader where possible. All households in the selected segment are visited door-to-door, until the correct number of people aged 50+ are identified. If there are fewer than the necessary number of people of age 50+ in this segment then a second segment is chosen at random and sampling continues until person number 50 has been enrolled.

If the population unit is too small to provide 50 people aged 50+ then all households in the unit should be enrolled first and the remaining participants should be enrolled from the next nearest population unit.

## Sample Size Calculation:

The exact prevalence of a condition (e.g. blindness) can only be measured by examining all persons in the entire survey area. This is not feasible and therefore we examine only certain people or groups of people from the entire population (a sample), assuming that the results from the sample are representative for the entire survey area. This gives us an estimate of the prevalence of the condition in the sample. The precision of this estimate depends on the number of people examined, the distribution of the condition in the population of the area under survey and the procedure followed in the selection of subjects for examination. This precision is expressed by the sampling error (SE) and the 95% Confidence Interval around the estimate. The Design effect (DEFF) is the correction factor with which the sample size for simple random sampling has to be multiplied to compensate for the Cluster Sampling methodology we have used.

The sampling error for cluster sampling (SEcrs) is usually larger than the sampling error for simple random sampling (SEsrs).

The formula used for the calculation of the sample size for simple random sampling is the same as in the StatCalc module of Epi Info2 (version 6.04d):

**S**infinite population = Z\*Z(P(1-P))/D\*D

**S**finite population = Sinf./(1+(Sinf./population))

where

S = sample size

P = expected prevalence of the condition

D = half the width of the desired sample confidence interval

Z = percentile of the standard normal distribution, determined by the specified confidence level (1.96 for 95% CI; 1.65 for 90% CI and 1.28 for 80% CI)

The sample size for cluster sampling is then calculated by multiplying the selected sample size for simple random sampling by the Design Effect. The design effect can only be calculated from the actual data of a study, which means only after completion of that study. From earlier studies on cataract blindness, it was calculated that the design effect for cataract blindness was 1.4 for cluster size 40, 1.5 for cluster size 50, 1.6 for cluster size 60. When the cluster size is higher than 60, the design effect, and therefore the sample size, increases to around 2.0. These estimates for the design effect are confirmed in recent RAAB surveys.

RAAB software calculates the sample size automatically using the following parameters for the population of interest:

* Expected prevalence of blindness in age 50+: <*x%>*
* Required (relative) precision of estimate: <*x%>*
* Confidence Level: 95%
* Cluster size: <*select 35, 50, 60*>
* Design Effect (to account for clustering): <*select 1.4, 1.5, 1.6*>
* Non-response: 10%
* Population size 50+: <total number in sampling area>

Based on these parameters, the required sample size is <sample size>. This equates to <*number of clusters*> clusters of 50 people 50+.

## Participant Inclusion and exclusion criteria:

In each household, all persons aged 50 years and older, residing there for six months or more over the past year, are eligible to participate. ‘Residing in the household’ must be defined clearly for the entire survey area (e.g., sharing meals from the same kitchen with the other members of the household). Visitors are not eligible for the study.Participants will be identified from the general population by door-to-door enrolment and not by state of health. The study does not involve any special populations or people in institutions. Random selection of segments allows all people an equal chance of selection, including those from marginalised groups.

Where necessary, examination should include a COVID-19 case status, exposure and symptom screen for enumerated participants. At each household, the screen should be completed for all eligible participants 50+ residing in the household during enumeration.Suspected or confirmed cases or contacts of cases, and household members, should be excluded from the study.

## Recording Examination Status:

For each of the eligible people aged 50+ identified, a RAAB examination form is initiated on a mobile data collection device. If there are eligible subjects who are not available for other reasons, an exam is initiated, saved to a ‘mop-up’ list and the survey team arranges to revisit at an appropriate time. If a house is locked, survey teams check with neighbours whether any people aged 50+ live there for at least six months in the year. If so, a RAAB exam is initiated for each unavailable person and saved to ‘mop-up’ and the house is revisited at a later date. The survey continues with a systematic route until all the houses in that area have been visited or until 50 people aged 50+ have been included.

People not examined: may be away (not available), may refuse to be examined or unable to communicate (e.g. deaf, dementia or psychiatric illness). Any eligible people too ill to participate will be enrolled as non-responders and not examined. Absenteeism and refusals of eligible subjects should ideally be less than 10% to avoid bias. Return visits to clusters with low response rates should be undertaken.

## Standard Examination Protocol:

Examination consists of the following components:

* Participant information (age, sex, spectacle use history)
* Measurement of uncorrected, corrected and pinhole (where applicable) visual acuity (VA) using Peek Acuity, a validated mobile visual acuity test application
* Assessment of lens status in each eye with distant direct ophthalmoscopy
* If presenting VA<6/12 and not due to cataract, corneal scar or refractive error, dilatation of pupil and examination with direct ophthalmoscope and/or slit-lamp
* Assessment of main cause of presenting VA<6/12 in each eye and for the person
* If poor vision due to cataract, determination of the reason(s) for not having had surgery
* If previously operated for cataract, details of surgery: age at the time of surgery, the place where surgery was conducted, type of surgery, cost of surgery, cause of borderline or poor visual outcome (if VA<6/12)

*<Optional sociodemographic data collection>:*

*<Insert a description of the subjective SEP and/ or one or two editable optional variables included in the survey if relevant>*

*<Optional GPS data collection>:*

*<Insert a paragraph explaining why GPS coordinates per examination are to be recorded if relevant. Include a data analysis plan, i.e., how will (rounded) GPS data be analysed along with the RAAB survey data.>*

The data collection form (Appendix 3: RAAB7 data collection form) has been directly translated to a series of data entry screens for RAAB7 data collection on mobile devices in order to record the above. Logic skips determine which screens (and options within screens) are presented based on previously entered data.

## Method for VA testing:

Teams will first record whether or not the participant habitually wears distance correction and how long they have had their current correction for. All eyes will first be tested uncorrected, in line with new WHO recommendations for the calculation of effective refractive error coverage (eREC). If participants habitually wear distance correction, they will then be retested with this. Blindness and vision impairment are categorised using bilateral presenting visual acuity (PVA). Presenting visual acuity will be derived from these two measures – PVA will equal UCVA if a participant has no correction, or equal corrected VA if VA is also measured with habitual correction. The classification of distance vision impairment used in RAAB is in accordance with the International Classification of Diseases (ICD-11), i.e., according to the better eye:

* Visual acuity of 6/12 or better is considered as normal vision
* ‘Mild vision impairment’ refers to visual acuity less than 6/12 but at least 6/18.
* ‘Moderate vision impairment’ refers to visual acuity less than 6/18 but at least 6/60.
* ‘Severe vision impairment’ refers to visual acuity less than 6/60 but at least 3/60.
* ‘Blind’ refers to visual acuity less than 3/60.

An eye with a presenting VA of 6/12 does not need to be re-tested with pinhole. Any eye with a presenting VA less than 6/12 is tested for acuity with a pinhole as well. If the person wears spectacles, the pinhole is placed in front of the spectacles (available correction) as in some cases the available correction is not the optimal correction.

## Method for Lens Examination:

Lens examination is carried out on all participants irrespective of VA. Lens status will be assessed by distant direct ophthalmoscopy and/or portable slit-lamp without dilatation of the pupil. The lens is examined in each eye and marked as: normal lens or minimal lens opacity; obvious lens opacity present, lens absent (aphakia), IOL implanted without posterior capsule opacification or IOL implanted and posterior capsule opacification present. If the lens cannot be seen because of, e.g., corneal scarring, mark ‘No view of lens’.

## Determining cause of VA less than 6/12:

For RAAB, there is a standardised list of causes of VA <6/12. The main cause of presenting VA <6/12 must be determined for each eye, or recorded as “not examined, can see 6/12”. If there are two diagnoses in one eye, the primary cause responsible for VA loss is selected. If this cannot be determined, select the most easily corrected or prevented. The principal cause in the person is then determined based on the findings in each eye. For different diagnoses between eyes the cause more easily treated to move the person from VI to normal vision is selected.

Where an eye does not improve to 6/12 with pinhole and there is no corneal opacity or obvious cataract, it should be dilated to facilitate easier diagnosis of the cause.

## Optional RAAB modules:

In addition to the standard RAAB examination protocol, optional data collection modules for diabetic retinopathy and disability are available (See Appendix 1 for further details).

*<Describe if either, one or both optional modules are included in the study>*

# Ethical considerations & data security

Written informed consent will be sought from all participants prior to their enrollment in the survey. The English language and <insert local language(s)> participant information and written informed consent sheet are included in Appendix 4. The RAAB survey trainer and Principal Investigator will agree a shared and common translation of the PIS and informed consent sheet into any local languages as required.

On arrival at the household, the information sheet will either be read out or given to study participants to read. A copy will be left with the participant.

Participants will not receive any compensation for participation. They will be visited at home and not be asked to assume any out-of-pocket costs for participating in the survey. RAAB is not a case-finding exercise, however, any participants with referable eye disease will be given instructions to attend local eye care services <*add detail of advice on cost to participants*>, with the appropriate level of urgency for their condition.

Encrypted, six-digit PIN-protected mobile devices are used to collect data. Participants’ age and sex are recorded during data collection. Eligible participants’ names are only recorded when they need to be revisited at mop up (either because they are unavailable or are not able to complete the examination in one visit). Names are held on the local device only, i.e., not synced to the Peek RAAB7 server (see below), and deleted when an exam is completed or finalised as incomplete. Any unresolved mop-up data will be purged from local devices on completion of the data collection.

All other data are uploaded directly from devices to the Peek Vision encrypted server. Peek solutions has been developed specifically as a cloud-based system. RAAB7 is hosted on a dedicated Amazon Web Serices (AWS) Virtual Private Cloud. The server utilised is located in AWS’s availability zone in Frankfurt, Germany (European Union) providing data protection assurance as governed under the General Data Protection Regulation (GDPR).

Peek is an ISO 27001 certified company and is subject to independent audit to demonstrate adherence to strict information security controls and standards. In addition, Peek follow the GDPR guidelines that stipulate tight controls over ownership, processing and control of personal data. Using AWS allows Peek to leverage Amazon’s more than fifteen years of experience delivering large-scale, global infrastructure in a reliable, secure fashion. The AWS cloud provides levels of scale, security, reliability, and privacy serving hundreds of thousands of customers worldwide across multiple industries that include finance, the public sector and health.

Survey data access is strictly controlled and only accessible to personnel with approved administrative privileges for the RAAB7 server, database and web console including the study PI, co-PI, survey coordinator, RAAB trainer and limited Peek technical staff. On completion of the survey, a copy of the final dataset is forwarded to a secure server at LSHTM for safe-keeping.

*<If applying to collect household level GPS coordinates, include section here on GPS data analysis plan/ justification for use. Note that a separate Agreement is required to collect GPS data as this is personally identifiable. Please request this from enquiries@raab.world>*

Survey metadata is collated on the RAAB Repository ([https://www.raab.world](https://www.raab.world/)) to support global eye health research. Additional levels of optional open data sharing via the repository are specified in the RAAB7 Partner Agreement (see Appendix 2).

# Terms of Use

Prior to conducting a RAAB Survey, RAAB Agreements need to be signed between the RAAB Partner conducting the Survey, LSHTM and Peek Vision Ltd. They detail responsibilities of each party and aspects such as use of software, data ownership and liability. The RAAB Support Team will provide these to you when your Survey planning has progressed.

# Training of Survey Teams

A 5-day training programme has been developed by ICEH. This includes:

* Survey design and planning, selection of clusters
* Mobile device data entry and protocol for examinations
* Inter-Observer Variation (IOV) assessment
* Field Practice

For the IOV assessment, the results of visual acuity, pinhole acuity, lens status and cause of vision impairment of each examiner will be compared with the findings of the most experienced examiner, the so-called ‘Gold Standard’. It is assumed that the findings of the Gold Standard are correct. RAAB7 automatically calculates an agreement statistic (Kappa) for each examiner compared with the Gold Standard. Only examiners with good agreement (Kappa ≥0.60) will be allowed to conduct eye examinations in the survey. If agreement is poor, they will undergo additional training until their Kappa is higher than 0.60.

# Study Personnel

|  |  |  |
| --- | --- | --- |
| Role | Name & email address | Responsibilities |
| Principal investigator | <*name & details*> | Ethical and operational conduct of the study, as stipulated by the approved version of the research proposal.  Includes overseeing all the study-related activities, procedures, staff and study participant matters |
| Principal Co-investigator (Optional) | <*name & details*> | Support to principal investigator in all aspects of their role |
| Survey Coordinator | <*name & details*> | Administration and Logistics: responsible for organising the administrative and financial matters related to the study, including the support of the training and fieldwork logistics |
| RAAB trainers/facilitators | <*name & details*> | Generate sample size, select survey clusters, provide training in the RAAB7 methodology, oversee the generation of good quality data and reporting |
| Additional country roles | <*add where relevant*> |  |

Survey Teams:

*<Insert number of teams>* teams will collect the RAAB data. Each team will be composed of:

* 1 ophthalmologist to examine the anterior segment of all study participants using portable slit lamp, to examine the retina using direct and indirect ophthalmoscope
* 1 ophthalmic nurse/assistant *<delete as required>* to undertake visual acuity examination
* 1 local fieldworker to facilitate fieldwork by informing each selected enumeration area of the survey before the survey
* 1 driver

# Equipment

Per field team:

* Android mobile device with RAAB7 app installed
* Battery pack for mobile device
* Occluder with pinhole, preferably with multiple holes
* Shoulder bag
* Pen torch
* Direct ophthalmoscope
* Portable slit lamp (optional)
* Spare batteries
* Mydriatic drops
* Identity cards

# Ethical Approval

Ethical approval for the study is sought from <*add local ethics committee approval*>.

# Dissemination of Results

Results of the survey will be disseminated to stakeholders of the <*survey district*> eye care programme and provided in report form to the Ministry of Health.  Survey metadata will be forwarded to the RAAB repository ([https://www.raab.world](https://www.raab.world/)) and additional data shared via the repository after an 18-month embargo period, according to the level of open data sharing described in the RAAB7 Partner Agreement. The RAAB repository is a vital resource for eye health and hosts results and data for the collective benefit of the global eye health community. The survey results may also be published as papers in peer-reviewed journals and presented at conferences to add to the body of knowledge about the global magnitude of avoidable blindness. Due processes requesting authorisation will be followed.

# Timetable

*<complete as relevant>*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| starting -> | **Month 1** | **Month 2** | **Month 3** | **Month 4** | **Month 5** | **Month 6** | **Month 7** | **Month 8** |
| **Preparation of protocol** |  |  |  |  |  |  |  |  |
| **Scheduling of activities** |  |  |  |  |  |  |  |  |
| **Procurement of supplies** |  |  |  |  |  |  |  |  |
| **Organising logistics** |  |  |  |  |  |  |  |  |
| **Training of field teams** |  |  |  |  |  |  |  |  |
| **Data collection and analysis** |  |  |  |  |  |  |  |  |
| **Draft / Final report** |  |  |  |  |  |  |  |  |
| **Close of project** |  |  |  |  |  |  |  |  |

# Budget

<*Add*>

# References

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# Appendix 1: Optional RAAB modules

## Diabetic Retinopathy (DR) Module

* Cluster size for RAAB+DR should be either 35 (1 team) or 60 (2 teams). Note that Cluster size 60 has higher DEFF and therefore effects sample size
* Sample size for RAAB+DR should be based on expected prevalence of blindness or DR – whichever is lower
* One additional day for training and DR IOV should be included in the training week schedule for RAAB+DR
* RAAB7 includes mobile data entry for the DR module. It does not include fundus imaging

The module includes two additional components: 1) Assessment of the diabetes status of all eligible survey participants at their household, and 2) Assessment of DR among eligible survey participants identified as having diabetes at the household. In our study we will examine the retina of all patients.

***Diabetes Assessment Methods****:* Participants are first asked whether they have previously been told by health professional that they have diabetes, sugar in urine or high blood sugar. Survey participants then undergo a random blood glucose (RBG) test using finger prick blood sample. This is carried out for all participants regardless of whether or not they have had a previous diagnosis of diabetes.

***Diabetic Retinopathy Assessment Methods****:* All known diabetics (reporting “yes” to having been told by health professional that they have diabetes, sugar in urine or high blood sugar) and newly diagnosed diabetics (RGB level of 200+ mg/dl) will undergo retinal examination. using direct and indirect ophthalmoscope. Retinopathy and maculopathy are grading according to the Scottish Diabetic Retinopathy Grading Scheme criteria (see Table 1).

**Table 1.** Scottish Diabetic Retinopathy Grading Scheme

|  |  |
| --- | --- |
| **RETINOPATHY** | **Description** |
| **R0** (no visible retinopathy) | **No diabetic retinopathy anywhere** |
| **R1** (mild) | **Background retinopathy BDR – mild**  The presence of at least any of the following:   * dot haemorrhages * micro-aneurysms * hard exudates * cotton wool spots * blot haemorrhages * superficial or flame-shaped haemorrhages |
| **R2** (observable background) | **Background diabetic retinopathy BDR - observable**  Four or more blot haemorrhages in one hemi-field only (inferior and superior hemi-fields delineated by a line passing through the centre of the fovea and optic disc) |
| **R3** (referable background) | **Background diabetic retinopathy BDR – referable**  Any of the following features:   * four or more blot haemorrhages in both inferior and superior hemi-fields * venous beading * IRMA |
| **R4** (proliferative) | **Proliferative diabetic retinopathy PDR**  Any of the following features:   * active new vessels * vitreous haemorrhage |
| **R6** (inadequate) | **Not adequately visualised**:  Retina not sufficiently visible for assessment |

|  |  |
| --- | --- |
| **MACULOPATHY** | **Description** |
| **M0** (No maculopathy) | No features in ≤2 disc diameters from the centre of the fovea sufficient to qualify for M1 or M2 as defined below. |
| **M1** (Observable) | Lesions as specified below within a radius of > 1 but ≤2 disc diameters the centre of the fovea.   * Any hard exudates |
| **M2**(Referable) | Lesions as specified below within a radius of ≤ 1 disc diameter of the centre of the fovea.   * Any hard exudates |
| **M6** (inadequate) | Not adequately visualised:  Macula not sufficiently visible for assessment |

Additional Equipment:

***For diabetes assessment:***

* Digital glucometer (one per team)
* Test strips (designed for use with glucose meter, one per participant)
* Lancets (single use disposable e.g. Accu-chek Safe-T-Pro Lancet, one per participant)
* Disposable gloves (one pair per participant)
* Sharps disposal box (one per team)
* Alcohol swabs (one per participant)

***For DR assessment:***

* Direct and indirect ophthalmoscope
* Slit lamp (optional)

Informed consent:

Additional participant information should be available in <*local Language*> explaining:

* the purpose of the DR module
* the procedures involved for the participant in the study
* the risks and benefits of taking part
* that participation is voluntary
* that all information collected will be kept confidential to the survey team

Participants will be informed of their RBG level and results of the DR examination. All participants with elevated RBG levels (whether known or newly diagnosed diabetes) and signs of DR will be referred to the appropriate health facility. All participants with RBG levels below 200mg/dl should still be advised to attend the appropriate health facility for diabetes check-ups. Similarly, participants with diabetes and no retinopathy should be advised of the need for regular eye examinations and where they should attend for this.

## Disability Module

The Washington Group Questions were developed by the Washington Group3, who were set up by the United Nations Statistical Division. They do NOT ask people whether they think they have a disability. Disability is strongly stigmatised in many settings, so instead they ask about difficulties in functioning, in line with the World Health Organisation International Classification of Functioning, Disability and Health (ICF), and the United Nations Convention on the Rights of People with Disabilities.

Self-reported functioning in RAAB is assessed using the Washington Group Short Set (WG-SS) of questions, alongside the Washington Group questions on anxiety and depression:

1. Do you have difficulty seeing, even when wearing your glasses?
2. Do you have difficulty hearing, even if using a hearing aid?
3. Do you have difficulty walking or climbing steps?
4. Do you have difficulty remembering or concentrating?
5. Do you have difficulty (with self-care such as) washing all over or dressing?
6. Using your usual (customary) language, do you have difficulty communicating, for example understanding or being understood?

The response options for each question above are:

1. No, no difficulty
2. Yes, some difficulty
3. Yes, a lot of difficulty
4. Cannot do at all

Anxiety and Depression questions:

1. How often do you feel worried, nervous or anxious?
2. Daily
3. Weekly
4. Monthly
5. A few times a year
6. Never
7. Thinking about the last time you felt worried, nervous or anxious, how would you describe the level of these feelings?
8. A little
9. A lot
10. Somewhere in between a little and a lot
11. How often do you feel depressed?
    1. Daily
    2. Weekly
    3. Monthly
    4. A few times a year
    5. Never
12. Thinking about the last time you felt depressed, how would you describe the level of these feelings?
    1. A little
    2. A lot
    3. Somewhere in between a little and a lot

Participants who respond with “Yes, a lot of difficulty” or “Cannot do at all” in Questions 1 to 6, and/or reporting at least “daily” feelings of anxiety or depression “a lot” of the time are categorised in analysis as having a disability in that domain.

Referral mapping will be completed in advance of data collection to identify onward services for people with disabilities identified to have unmet need.

# Appendix 2: Data Use Permissions for RAAB PIs

DATA USE PERMISSIONS

 I understand that metadata (location, year and implementing organisation) from this survey will be made available to the RAAB Repository once the survey is closed. Then, following the 18 month embargo period, I give the following permission:

Please select one of the following:

|  |  |
| --- | --- |
| Selection | Signature |
| No further permissions |  |
| I give permission for the main survey outputs only to be shared on the Repository |  |
| I give permission for the main survey outputs1 and survey reports to be shared on the Repository |  |
| I give permission for the main survey outputs1, survey reports and survey data to be shared on the Repository |  |

1Prevalence of vision impairment and blindness, main causes of vision impairment and blindness, cataract surgical coverage, effective cataract surgical coverage, effective refractive error coverage (total, male, female)

|  |  |
| --- | --- |
| Selection | Signature |
| If giving permission for survey data to be shared on the Repository:  I would like to be included in the International RAAB Studies Authorship Group |  |

# Appendix 3: RAAB7 data collection form

|  |  |  |  |
| --- | --- | --- | --- |
| **Enumeration and Demographics** | | | |
| 1. Participant Number | ? 2 digit number 01 – 50 (autoincremented) |  | |
| 2. Current Location - Description | ? text |  | |
| 3. Current Location - GPS (optional) | Auto-Recorded | **Latitude** | **Longitude** |
| 4. Age | ? maximum 3 digit number 50-120 |  | |
| 5. Gender | x Select one | **☐** Male  **☐** Female | |
| 6. Examination Status | x Select one | **☐** Now  **☐** Not Available  **☐** Refused  **☐** Not able to communicate | |
| Note: If form saved incomplete, participant first and last name captured and stored on local device for mop up until form is finalised | | | |
| 7. Subjective Socioeconomic Position (optional)  7a. Household Food Adequacy      7b. Household Income Sufficiency | x Select one      x Select one | **☐** Less than adequate  **☐** Just adequate  **☐** More than adequate    **☐** Not enough, must borrow  **☐** Not enough, use savings  **☐** Just enough  **☐** Enough, save a little  **☐** Enough, build savings | |
| 8. Additional editable optional questions (1 or 2 possible) e.g., ethnicity, urban/rural location | x Select one | **☐** A  **☐** B  **☐** C  **☐** D | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Distance Visual Acuity** | | | | |
| 1. Distance Spectacles | x Select one | **☐** Yes  **☐** No | |  |
| 2. Age of Current Distance Spectacles | x Select one | **☐** Less than 2 years  **☐** 2 to 5 years  **☐** More than 5 years | |  |
| 3. Near Spectacles | x Select one | **☐** Yes  **☐** No | |  |
| 4. Acuity Test Method | x Select one | **☐** Peek Acuity  **☐** E Chart | |  |
| 5. Uncorrected visual acuity | Auto-Recorded LogMAR result or radio button by threshold | **R** | **L** | |
| 6. Corrected visual acuity | Auto-Recorded LogMAR result or radio button by threshold, if distance glasses used | **R** | **L** | |
| 7. Pinhole visual acuity | Auto-Recorded LogMAR result or radio button by threshold, if presenting\* VA <6/12 | **R** | **L** | |

\*Presenting VA recorded as composite variable: UCVA if no correction worn, or CVA if correction worn. Pinhole only collected if presenting VA<6/12

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Lens Examination and Cause of VA <6/12** | | | | |
| 1. Lens Status | : Examine with torch or direct ophthalmoscope  x Select one | **R**  ☐   Normal/ minimal lens opacity  ☐   Obvious lens opacity  ☐   Lens absent (surgical aphakia, including couching)   ☐   Lens absent (non-surgical aphakia)  ☐   Pseudophakia without PCO  ☐   Pseudophakia with PCO  ☐   No view of lens | | **L**  ☐   Normal/ minimal lens opacity  ☐   Obvious lens opacity  ☐   Lens absent (surgical aphakia, including couching)   ☐   Lens absent (non-surgical aphakia)  ☐   Pseudophakia without PCO  ☐   Pseudophakia with PCO  ☐   No view of lens |
| 2.  Main cause of presenting vision <6/12 | : Examine with torch or direct ophthalmoscope  x Select one | **R**  ☐ Not examined: can see 6/12  ☐ Refractive error  ☐ Aphakia, uncorrected  ☐ Cataract, untreated  ☐ Cataract surgical Complications  ☐ Trachoma corneal opacity  ☐ Other corneal opacity  ☐ Phthisis  ☐ Onchocerciasis  ☐ Glaucoma  ☐ Diabetic retinopathy  ☐ ARMD  ☐ Other posterior segment  ☐ All globe/CNS abnormalities  Optional causes:  ☐ Myopic degeneration  ☐ Pterygium  ☐ Other surgical complication  ☐ Anterior uveitis | | **L**  ☐ Not examined: can see 6/12  ☐ Refractive error  ☐ Aphakia, uncorrected  ☐ Cataract, untreated  ☐ Cataract surgical Complications  ☐ Trachoma corneal opacity  ☐ Other corneal opacity  ☐ Phthisis  ☐ Onchocerciasis  ☐ Glaucoma  ☐ Diabetic retinopathy  ☐ ARMD  ☐ Other posterior segment  ☐ All globe/CNS abnormalities  Optional causes:  ☐ Myopic degeneration  ☐ Pterygium  ☐ Other surgical complication  ☐ Anterior uveitis |
| 3. Principal cause of presenting vision <6/12 in person | : Examine with torch or direct ophthalmoscope only  x Select one | | ☐ Not examined: can see 6/12  ☐ Refractive error  ☐ Aphakia, uncorrected  ☐ Cataract, untreated  ☐ Cataract surgical Complications  ☐ Trachoma corneal opacity  ☐ Other corneal opacity  ☐ Phthisis  ☐ Onchocerciasis  ☐ Glaucoma  ☐ Diabetic retinopathy  ☐ ARMD  ☐ Other posterior segment  ☐ All globe/CNS abnormalities  Optional causes:  ☐ Myopic degeneration  ☐ Pterygium  ☐ Other surgical complication  ☐ Anterior uveitis | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Details about cataract operation (if previously operated)** | | | |
| 1. Age at Operation | ? maximum 3 digit number 50-120 | **R** | **L** |
| 2. Place of Operation | x Select one | **R**  ☐ Govt hospital  ☐ Voluntary/charitable hospital  ☐ Private hospital  ☐ Eye camp/improvised setting  ☐ Traditional setting | **L**  ☐ Govt hospital  ☐ Voluntary/charitable hospital  ☐ Private hospital  ☐ Eye camp/improvised setting  ☐ Traditional setting |
| 3. Type of Surgery | x Select one | **R**  ☐ No IOL  ☐ IOL Implant  ☐ Couching  ☐ No view of lens | **L**  ☐ No IOL  ☐ IOL Implant  ☐ Couching  ☐ No view of lens |
| 4. Cause of VA<6/12 after cataract surgery (if the case) | x Select one | **R**  ☐ Ocular comorbidity (Selection)  ☐ Operative complications (Surgery)  ☐ Refractive error (Spectacles)  ☐ Long-term complications (Sequelae)  ☐ Does not apply, vision acceptable | **L**  ☐ Ocular comorbidity (Selection)  ☐ Operative complications (Surgery)  ☐ Refractive error (Spectacles)  ☐ Long-term complications (Sequelae)  ☐ Does not apply, vision acceptable |

|  |  |  |
| --- | --- | --- |
| **Barriers to cataract surgery** | | |
| 1. Barriers to cataract surgery | x Select up to two if unoperated cataract present in either eye | ☐ Need not felt  ☐ Fear of surgery or poor result  ☐ Cannot afford operation  ☐ Treatment denied by provider  ☐ Unaware that treatment is possible  ☐ No access to treatment  ☐ Other |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **The Washington Group Short Set questions (optional)** | | | | | |
|  | | No, no difficulty | Yes, some difficulty | Yes, a lot of difficulty | Cannot do at all |
| 1. Do you have difficulty seeing, even when wearing your glasses | x Select one | □ | □ | □ | □ |
| 1. Do you have difficulty hearing, even if using a hearing aid? | x Select one | □ | □ | □ | □ |
| 1. Do you have difficulty walking or climbing steps? | x Select one | □ | □ | □ | □ |
| 1. Do you have difficulty remembering or concentrating? | x Select one | □ | □ | □ | □ |
| 1. Do you have difficulty (with self-care such as) washing all over or dressing? | x Select one | □ | □ | □ | □ |
| 1. Using your usual (customary) language, do you have difficulty communicating, for example understanding or being understood? | x Select one | □ | □ | □ | □ |

|  |  |  |
| --- | --- | --- |
| **Diabetic Retinopathy (optional)** | | |
| 1. Have you ever been told that you have diabetes, sugar in your urine or high blood sugar? | x Select one | **☐** Yes  **☐** No |
| 1. Does the participant consent to a blood test? | x Select one | **☐** Yes  **☐** No |

|  |  |  |
| --- | --- | --- |
| **Questions for known diabetics** | | |
| 1. What age were you when you were told you had diabetes? | ? enter age in years |  |
| 1. Are you currently receiving treatment for diabetes | x Select one | **☐** No treatment  **☐** Diet only  **☐** Tablets  **☐** Insulin  **☐** Tablets and Insulin  **☐** Other |
| 1. Before today, when was the last time you had your eyes examined because of your diabetes, e.g. drops were put in your eyes before the examination or a photograph was taken of the back of your eye? | x Select one | **☐** Not examined  **☐** 0-12 months ago  **☐** 13-24 months ago  **☐** >24 months ago |

|  |  |  |  |
| --- | --- | --- | --- |
| **Diabetic retinopathy assessment (for all people with known/ newly diagnosed diabetes)** | | | |
| 1. DR Examination method | x Select one | ☐ Dilatation and fundoscopy  ☐ Fundus camera  ☐ Refused dilatation and/or fundus photograph | |
| 2.  Retinopathy grade | : Examine with indirect ophthalmoscope or slit lamp    x Select one | **R**  ☐ R0 – No visible retinopathy  ☐ R1 – Mild  ☐ R2 – Observable background  ☐ R3 – Referable  ☐ R4 – Proliferative  ☐ R6 – Not adequately visualised | **L**  ☐ R0 – No visible retinopathy  ☐ R1 – Mild  ☐ R2 – Observable background  ☐ R3 – Referable  ☐ R4 – Proliferative  ☐ R6 – Not adequately visualised |
| 3.  Maculopathy grade | : Examine with indirect ophthalmoscope or slit lamp    x Select one | **R**  ☐ M0 – No maculopathy  ☐ M1 – Observable  ☐ M2 – Referable  ☐ M6 – Not adequately visualised | **L**  ☐ M0 – No maculopathy  ☐ M1 – Observable  ☐ M2 – Referable  ☐ M6 – Not adequately visualised |
| 4. Laser photocoagulation scars | : Examine with indirect ophthalmoscope or slit lamp    x Select one | **R**  ☐ Laser scars absent  ☐ Scars present – pan retinal laser  ☐ Scars present – macular laser  ☐ Scars present – pan retinal and macular laser  ☐ Not adequately visualised | **L**  ☐ Laser scars absent  ☐ Scars present – pan retinal laser  ☐ Scars present – macular laser  ☐ Scars present – pan retinal and macular laser  ☐ Not adequately visualised |

# 

# Appendix 4: Participant information and written informed consent

**Project Title:** Rapid Assessment of Avoidable Blindness (RAAB) in <*survey district name>*

**Sponsor & Funder:**  <*name of implementer/ funder>*

**RAAB project team:** International Centre for Eye Health at the London School of Hygiene & Tropical Medicine and Peek Vision (email: [enquiries@raab.world](mailto:enquiries@raab.world))

**Study Principal Investigator:**<*name of PI>*

**Phone number(s):** <*phone number>*

You are invited to take part in a research study. The study is organised by <Insert names and description of organisations involved in RAAB>.

If you decide to join the study, you will need to sign or thumbprint a consent form saying you agree to be in the study. You will receive a copy of the consent form.

**Why is this study being done?**

We are doing a study to understand how many adults aged 50 years and older have eye diseases and difficulties seeing in <*survey district name>*.  This will help us plan services to support the health of people in <*survey district name>*.

**Why have I been chosen?**

We have randomly selected <*number of clusters>* areas in <*survey district name>* and are inviting all people aged 50 years and older in these areas to take part in the study. You have been chosen because your household is in one of these areas.

**What will the study involve?**

*<[Insert info on COVID-19 screening if relevant]>*

You will be examined by an eye doctor and will be asked to give information about your vision and eye health <*and diabetes/ and general functioning [delete or select as appropriate]*>. We will measure how well you see and briefly examine your eyes. These checks are no different from the procedures somebody would undergo to obtain routine eye health care in a health facility. You will not be subject to any experimentation. The duration of the examination will be approximately fifteen to thirty minutes. If you have an eye condition that requires treatment *<or suspected diabetes or unmet need for disability>* you will be given a referral to the nearest health facility.

**What is the Rapid Assessment of Avoidable Blindness project?**

The RAAB project is a well-established vision and eye health survey that has been conducted in 80 countries worldwide over more than 20 years. It is supported by the International Centre for Eye Health (ICEH), a research and education group at the London School of Hygiene & Tropical Medicine (LSHTM), a globally renowned research institution; and Peek Vision, a social enterprise which helps eye health organisations improve their services. Along with <*insert local partner name*>, ICEH and Peek Vision are jointly responsible for securely collecting your information.

**How will my data be stored and used?**

Your data will be stored on a secure computer, located in the United Kingdom, European Union or India. Your personal information will only be seen by the study team members, and if necessary, the Research Ethics Committee and relevant Government authorities. If we collect any personal information (e.g your name and location) our use of it is limited to only what is required for the purpose of completing the survey and it will be deleted as soon as the survey is complete without leaving the country. Your data will then be used anonymously (meaning that you cannot be identified in any way) to estimate how common difficulties seeing, and diseases that cause difficulties seeing, are. This information will be used to plan services in <*survey district name*>. In addition, your anonymised data will be added to a scientific database managed by ICEH at LSHTM and may be made available (via the internet) to support other researchers around the world to conduct future studies of eye health. Data will be kept in this database for a long time. We will not be able to share specific outputs with you, but you will be able to view the database online at [www.raab.world](http://www.raab.world/). As your data is anonymous, it cannot be re-identified or removed once added to the database.

**What harm or discomfort can I expect in the study?**

There are no risks of physical harm associated with this survey. As part of the study, we may need to use eye-drops to help us look at your eyes. These can cause short term stinging, burning or blurring of vision that can be uncomfortable and will mean you cannot read or drive for a short time. However, these will not cause any long-term physical harm.

*<Insert if relevant: If you consent, we will do a finger prick blood test to see whether you might have diabetes.>*

**What benefits can I expect in the study?**

There is no payment for participation. If the survey team finds that you have unmet eye health needs <or a need for disability-related services, if using disability module>, you will be informed of this and referred to the relevant service. In addition, the information collected in this survey will help to improve eye care services for all people in <*survey district name*>.

**What happens if I refuse to participate in the study or change my mind later?**

You are free to decide to join the study or not, and you are free to stop being in the study any time without giving a reason. You will still get normal medical care.

**Who should I contact if I have questions?**

If you have any questions or are worried you can contact <*PI and/or Coordinator name and contact details*>. You can also email [enquiries@raab.world](mailto:enquiries@raab.world) for further information about the RAAB project. Please feel free to ask any question you might have about the study.

**Who has reviewed this study?**

This study has been checked by scientists at the <*Local Ethics Committee*>. The study has also been checked and approved by LSHTM in the UK. The Ethics Committees protect your rights and wellbeing and have given permission for this study to take place.

**CONSENT FORM**

Participant Identification Number: |\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|\_\_|

(Printed name of participant)

I have read the written information **OR**

I have had the information explained to me by study personnel in a language that I understand,

and I:

* confirm that my choice to participate is entirely voluntarily,
* confirm that I have had the opportunity to ask questions about this study and I am happy with the answers that have been provided,
* had enough time to think about whether I want to take part in this study,
* understand that my personal information may be collected for this study as described in the information sheet,
* understand that an anonymous version of my information will be stored by the International Centre for Eye Health at the London School of Hygiene & Tropical Medicine and may be made available to other eye health researchers,
* agree to take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Participant’s signature/  thumbprint\* |  |  |  |  |
|  |  |  | Date (dd/mm/yyyy)                 Time (24hr) | |
|  |  |  |  | |
| Printed name of witness\* |  | | | |
| Printed name of person obtaining consent |  | | | |
| **I attest that I have explained the study information accurately in** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\_\_ to, and was understood to the best of my knowledge by, the participant. He/she has freely given consent to participate *\**in the presence of the above-named witness (where applicable).** | | | | |
| Signature of person obtaining consent |  |  |  | |
|  |  |  | Date (dd/mm/yyyy)                 Time (24hr) | |
| *\* Only required if the participant is unable to read or write.* | | | | |

# Appendix 5: COVID-19 adjustments to RAAB survey protocol

*<Insert relevant content>*