

Blindness and Cataract Outcomes Survey in Southern India

Cataract Survey Protocol

By

Lions Aravind Institute of Community Ophthalmology
Aravind Eye Hospital, Madurai, Tamilnadu, India

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Cataract Survey Protocol

1. Background

In 1999 World Health Organisation (WHO) made a global estimate that there are over 45 million persons blind (bilateral blindness) and another 135 million persons with low vision who are at great risk of becoming blind. 90% of them are distributed in the developing countries. It is estimated that there are over 12 million blind (visual acuity in the best eye < 6/60) people in India. . Cataract is the leading cause of blindness. Most of the blinding disorders are either preventable or curable with the available technology.

India has a long history of eye care with a community focus. India was the first country to launch National Programme for the Control of Blindness (NPCB) in 1976. This programme got further importance when it was included as one of the 20 points targeted to influence national development The voluntary and private sector are also very active in eye care delivery and account for nearly two third of the services provided nation-wide.

Indian Council of Medical Research conducted a National level survey in 1971-74 and reported blindness prevalence of 1.38% (VA < 6/60) and over 50% of blindness was due to cataract. It was based on this survey report that Government of India launched the National Programme for Control of Blindness in 1976 with the objective of reducing the blindness prevalence to 3 per 1000 or 0.3%. In 1986-89, GOI /WHO national survey indicated prevalence of blindness to be 1.49% (all ages) and cataract accounting for over 80% of the blindness in India. It is in the background of the mounting backlog of cataract that World Bank Assisted Cataract Control Project financed with an International Development Assistance Credit of US\$ 117.8 million was launched in 1994 in seven major states in India. The key objectives of the project were to:

- Expand services delivery to under served population
- Reduce the backlog of cataract blindness by more than 50% in the seven selected states: Uttar Pradesh, Madhya Pradesh, Andhra Pradesh, Rajasthan, Maharashtra, Tamilnadu & Orissa.

The project strategies include promotion of outreach activities and public awareness through NGO's and community organisations and strengthening key institutions at the central, state and district levels. A major change in the programme management of the NPCB has been the decentralization of blindness control activities and involvement of NGOs and private agencies through the establishment of District Blindness Control Society (DBCS) throughout the country.

With several activities ongoing, it is appropriate that they are evaluated to provide necessary information to further strengthen the programme. Most of the regularly reported data is based on hospital performance and not on the impact on the community. Community based evaluation done on a regular interval will provide data on impact to help planners in deciding on

new effective strategies for blindness control. Rapid Survey (1998) conducted in 7 Project States showed that 70% of the persons with cataract blindness are getting operated. While trying to evaluate the impact on the community, one has to focus not only on the effect on the magnitude

of the problem (prevalence) but also on the clinical outcome of the cataract surgical services and how it has improved the socio-economic life of the people. The information from the studies has helped in redefining the intervention strategies to address the issues of clinical quality and surgical coverage. Since there is a significant thrust towards cataract blindness control, the time is most opportune to carry out such studies in India so that the results can help in refining the interventions.

Since India is a vast country, with over 1 billion people and considerable autonomy to the state governments in providing the health care, there is a need to carry out such surveys in several states so that the findings become relevant to the local state governments. When several surveys are carried out, it is necessary that a standard protocol be followed in order to allow comparisons. This protocol and manual operations has been prepared to meet this need and is based on the experience of doing such studies in Nepal, China and in two pilot districts in India.

2. Objectives

2.1 Over all objective:

To evaluate National Programme on Control of Blindness, particularly cataract blindness control activities, in selected districts of India.

2.2 Specific objectives:

1. To estimate the prevalence of blindness (and that due to cataract) among population of age 50 years in the selected districts.
2. To estimate the cataract surgical coverage rate in the selected districts.
3. To assess the outcome of surgical treatment including visual acuity and complications of surgery of the operated persons.

3. Study organisation and staffing

3.1 Overview including participating agencies:

This study, to evaluate National Programme for Control of Blindness will have a main focus on cataract services. This study is to be carried out by selected organisations identified by Government of India. The protocol has been finalised with technical advice from the National Eye Institute (NEI), National Institutes of Health (NIH), and USA. The fieldwork will be done in collaboration and cooperation from the DBCS of the districts in which the study will be done. DBCS would also provide assistance in arranging local staff, vehicles and logistics. The survey organizations will provide the requisite manpower. The study personnel could be from the survey organisation or hired specifically for this study. In either case the responsibility for mobilizing the necessary manpower rests with the organisation. The cost of the personnel and related expenses would be borne by Govt. of India.

3.2 Technical Advisory Committee:

During the pilot survey in 2 districts, following TAC advised on development of protocol quality assurance in data collection and in the analysis.

Carl Kupfer, MD	-	National Eye Institute, USA.
Leon B. Ellwein, Ph.D	-	National Eye Institute, USA.
G.P.Pokharel, MD	-	Eye Care Himalaya, Nepal
Sergio R Munoz	-	University De La Frontera, Chile

3.3 Monitoring Team:

The Survey will be monitored by various officials of Directorate General Health Services, Ministry of Health & Family Welfare and key faculty involved in pilot surveys who were from Dr. R.P.Centre for Ophthalmic Sciences, New Delhi and LAICO, Madurai. Key members of the monitoring team are:

- Dr. R. Jose, DDG(O), Dte.GHS
- Dr. D.Bachani, ADG(O),''''''''S
- Dr.Srinivas Tata, Deputy Secretary, Ministry of Health & FW
- Dr. A.K.Gupta, (ex-Dean, MAMC ; ex-Director, Guru Nanak Eye Hospital;
- Dr. Rajkumar, Country Director (India), ORBIS International, New Delhi
- Dr. G.V.S.Murthy, Associate Professor, Dr. R.P.Centre for Ophthalmic Sciences, AIIMS.
- Mr. R.D.Thulasiraj, Executive Director, Lions Aravind Institute of Community Ophthalmology, Madurai.

3.4 Study staffing:

At different levels, appropriate staff will be either hired by or deputed from Aravind Eye Hospital and will be provided specific training as required. The staffing at different levels is:

A. Survey Organisation’s Level:

Chief Investigator: is responsible for overseeing the overall conduct of the study and provide necessary direction and guidance as per the protocol.

Survey Manager: will work directly under Chief Investigator and help in preparation of the field protocol. He will be responsible for the recruitment, selection and training of the different category of study staff. Ensure the availability of required equipment and supplies. Develop the schedules for various activities like staff selection, training, pre-pilot/pilot study, organize field work, assist in the collection of data & responsible for the budget in terms of ensuring cash flow, expenses and the accounting.

A. Field Level:

The field staff will be organised as four enumeration teams and two clinical teams. Each clinical team will be supported by 2 enumeration teams. The workflow and detailed logistics are described in Section 6. The enumeration and clinical teams should have adequate female members in order to ensure better response rate from the women, some of who may be unwilling to be examined or interviewed by men. The team composition will be as follows:

Enumeration Team [4 Teams]	Clinical Team [2 Teams]
**Supervisor : 1 (Total 4) Enumerator cum mapper: 2 (Total 8) Helper/Village volunteer : 2 (Total 8) (Locally recruited- two per site, will also assist the clinical team)	Ophthalmologist :1 (Total 2) Ophthalmic Assistant :2 (Total 4) Helper/Village volunteer: 2 (Total 4)

** In Budget, it is provided only for 2 Supervisors totally

3.5 Study co-ordination committee:

In each of the states the study will be confined to one selected representative district. District Blindness Control Society will provide support & assistance during the fieldwork. In order to structure the interaction and support, a co-ordination committee consisting of the following will be formed.

- Chief Investigator
- Survey Manager
- Chief Medical Officer
- District Ophthalmic Surgeon
- Member Secretary of DBCS.

4. Study design

4.1 Introduction of Study area:

The survey will be conducted in 13 districts representing 13 major states of the country. The States of Rajasthan and Tamilnadu have already been covered during 1999. One district has been allotted to each Survey Team. List of Survey Teams & districts allotted to each are given below:

ALLOCATION OF DISTRICTS TO SURVEY TEAMS

Survey Teams	States	Districts
<u>Group A</u>		
Dr. R.P Centre, AIIMS, New Delhi	Uttar Pradesh	Sultanpur
Christian Medica College, Ludiana	Himachal Pradesh	Solan
Indian Institute of Health Management Research, Jaipur	Gujarat	Surendra Nagar
Mahatma Gandhi Institute of Medical Sciences, Wardha	Chhatisgarh	Rahnandgaon
PGIMER, Chandigarh	Punjab	Bhatinda
State Institute of Ophthalmology, Allahabad	Bihar	Vaishali
Regional Institute of Ophthalmology, Ahmedabad	Madhya Pradesh	Dewas
<u>Group B</u>		
Lions Aravind Institute, Madurai	Kerala	Palakkad
Vivekanand Mission Hospital, Haldia	Orissa	Dhenkanal
Regional Institute of Ophthalmology, Bangalore	Maharashtra	Satara
Regional Institute of Ophthalmology, Calcutta	West Bengal	Malda
JIPMER, Pondicherry	Andhra Pradeh	Prakasam
Sarojini Devi Eye Hospital, Hyderabad	Karnataka	Gulbarga

4.2 Sample Size:

Of the objectives outlined, the one considered for the sample size calculation is the estimation of prevalence of cataract blindness in persons of age 50 years and over. The following assumptions are made in order to calculate the sample size.

Estimated prevalence of cataract blindness (VA<6/60): 8% (p=0.08)

Confidence Interval: 95% (Z=1.96)

Error bound (precision): 15% { $\Delta = p(0.08) \times \text{error}(15\%) = 0.012$ }

The sample size formula to estimate prevalence with specified relative precision is

$$N = z^2 (1-p) p^2$$

$$\text{Substituting the values in the formula: } N = \frac{(1.96)^2 (1-0.08) (0.08)}{(0.012)^2} = 1,963$$

In simple random sampling the sample size is scattered across the population. Cluster sampling makes the survey more practical and has the benefit of both reducing the cost of the survey as

well as improving response rate through better rapport in a cluster. It has a cost in terms of sampling inefficiency, which is usually determined by design effect. In cluster sampling, the design effect is an indication of the variation due to clustering. So the sample sizes have to be adjusted for the cluster design effect. It is estimated by the ratio of the variance when cluster sampling is used to the variance when simple random sampling is used. Based on the few surveys conducted so far, we have information on design effects for varying cluster sizes. Considering average village sizes and operational factors a cluster size of 200 is appropriate with an associated design effect of 2.0. Assuming a design effect of 2.0 for clusters of 200 and a response rate of 85%:

Sample needed by cluster sampling is: $1,963 \times 2.0 \div 0.85 = 4,619$ persons of age 50

Rounding off the sample size required is = 5,000

The proportion of the population 50 in India is = 13.03% (1991 census)

Therefore, the total population (all ages) to be surveyed is = 38,000

The number of clusters required are = 25

The cluster population is = 1,500 to 1,600

4.3 Sample population:

The demographic data of 1991 Census will become the frame of sampling design. Tables showing population of each village/ward in the study area will be made available to the Survey Teams.

4.4 Sampling Plan:

The following steps are to be followed in the selection of the study clusters:

- a. Identify target area within the district, which will constitute the sampling frame. The target area should have at least 60,000 persons of age 50 while it is preferable that it is > than 1,00,000. Thus the target area should have a minimum population (all ages) of 500,000. This will constitute the sampling frame.
- b. List the villages and their population based on the census estimates.
- c. Create sampling clusters to yield about 200 (125 to 250) persons 50 years. Thus the total population in the cluster will be between 850 and 1,700. The sampling clusters are to be created by grouping villages with the less than 850 populations and subdividing villages with more than 1,700 populations into segments as A, B, C etc.

For example:

- Two villages of population 800 and 750 will be combined into one cluster for the purpose of sampling.
- A large village of 6,000 will be subdivided into 4 clusters as A, B, C and D.

The actual geographic boundaries of these segments based on local layouts will be defined only for such segments that are chosen. (Each study group will describe the process of actually

defining the cluster in case of it being one amongst the multiple clusters of a large village).

- d. Randomly select 25 clusters using a simple random sampling of clusters. The principle is to ensure that each village resident has an equal chance of being selected regardless of village size.

Cluster Selection: Twenty-five clusters will be selected from the sample frame with equal probability. One approach is to proceed as follows:

- The sample frame is in the same order as the census list. As per the above- described procedure, the larger villages are to be divided and smaller villages are to be combined.
- Select random numbers between one and the total number of clusters until 25 clusters are selected without replacement. Above sample size calculation method is an example and not the generalised one. Sample size will vary according to the estimated prevalence of cataract blindness and population. Statistician is needed to calculate the sample size.

FORMAT FOR BUILDING THE SAMPLE FRAME:

Sl.no:	Village/Ward Name	Population

5. Training and Pilot Study

5.1 Training of Study Staff:

The Survey Manager with support from the Chief Investigator will assign to the study or hire all study staff from the ophthalmologist to the enumerator. Intensive training imparted is on the following:

Purpose of evaluation: The study staff is briefed on the present eye care programs in the State and in the study area. A brief introduction to any previous surveys and the results will be shared with the study team, so that they become aware of the magnitude of the major blinding conditions like, cataract, glaucoma, and trachoma etc. The aim of the program is outlined briefly.

Survey forms: Survey questionnaires are discussed in detail. Why the question is being asked? How it will make difference? All these points are discussed in detail question by question with the individuals who will be responsible for the data collection.

Survey techniques: Sociologist will take class on how to approach people for interview. Different types of customs are discussed. Emphasis is put on behaviour of field staff towards local people.

5.2 Training of Enumeration Team:

The enumeration team is responsible for listing all the individuals 40 years and ensuring that all aged 50 year come to the central examination site for the eye examination. The enumeration gives the denominator, based on which many of the results are computed. Hence accuracy of the survey depends largely on the completeness of the enumeration and following that the examination of those enumerated.

The “mapper” must be trained to map the selected clusters showing the boundaries and all the important landmarks, streets and houses. The map should become the guide to the enumerators to help them cover the entire cluster without missing any household. As part of the training, the mappers will be required to map a given area.

The enumeration team will be the first contact that the individuals will have with the survey process. Thus it is important that the training includes, in addition to enumeration techniques, the process of building rapport and creating the right climate for the survey. As part of the training, the enumerators will enumerate households in the mapped area as part of the training.

The Chief Investigator, the Survey Manager and Ophthalmologists will give this training. The training imparted for one week will include fieldwork to ensure familiarisation with field situations.

5.3 Training of Ophthalmologists and Ophthalmic Assistants:

They are trained at Dr. R.P. Centre, AIIMS, New Delhi or LAICO, Madurai, for one week. The training will include fieldwork to ensure familiarisation with field situation. This will be important especially if they are not exposed to fieldwork. Ophthalmologists and Ophthalmic Assistants will be trained together. The purpose of the study will be discussed. They are required to become familiar with all the details of the fieldwork. Clinical examination form is discussed in detail. To be familiar with the clinical form the ophthalmologist and OA's will be required to fill the Eye Examination Forms on 50 hospital outpatients.

Ophthalmic Assistants will also be taking part in the above discussions and are further trained on vision testing in field conditions. Taking intra-ocular pressures using perkin's refraction and dilating the pupils are practised on outpatients in the Hospital. Additional responsibilities in the field such as care and maintenance of equipment will also be discussed in detail.

5.4 Pre-Pilot Study and Pilot Study:

After training is completed Pre-Pilot Study will be done in a small village with a population of about 500-750. Two days will be allotted for enumeration and two days for examination. This village can be anywhere. It is not necessary that the Pre-Pilot village should be in the study area as the main emphasis is training.

After Pre-Pilot Study is finished, Pilot Study will be done in two clusters –one by each of the clinical teams. This will be done in the study district in two villages, which are not part of 25 study clusters. One of them should be a segment from a large village. Two teams will be dispatched separately to these two sites. Two days will be allotted for enumeration and two days for examination in each site. Quality assurance of the Ophthalmic Assistants and the Ophthalmologists will also be done in the Pilot survey.

All the field staff will participate in the Pre-Pilot Study and Pilot Study. In addition the Chief Investigator and Survey Manager will observe the study to sort out any difficulties and provide directions when necessary.

5.5.1 Purpose of pre-Pilot Study

The main purpose is to test the entire survey procedure and to train the survey team.

1. To test the instruments of measurements - forms & equipment
2. To test all the field procedures, arrangements and logistics involved in enumeration and eye examination.
3. To get a feel for response rates and how it can be improved
4. To observe whether the training to enumerators, ophthalmic assistants, and ophthalmologist is adequate or not.
5. To provide more practice to the field staff
6. To observe inter-observer reliability, agreement of ophthalmic assistants in Visual Acuity screening and ophthalmologists on clinical findings and diagnosis.

5.5.2 Purpose of Pilot Study:

Similar to that of the Pre-pilot study. The Pilot study is done incorporating the lessons learnt in the Pre-pilot study. It also serves as the “dress rehearsal” for the main study and gives one more opportunity to fine-tune the procedures.

The importance of training and standardisation can’t be emphasised enough. It forms the foundation for quality in data collection, efficiency in study implementation and getting the study done on schedule.

6. Summary of Field Procedure

The population-based survey in the selected districts will be carried out in 25 clusters. Each cluster will have approximately 200 persons who are 50 years or older. Data will be collected at Cluster level (village/ward), household level and individual level. Quality assurance data in a prescribed format will be collected at individual level.

A letter of introduction describing activities will be sent to the community and political leaders of Towns and Villages prior to the visit. Necessary permissions from the concerned health authorities will be obtained. A personal meeting between the community leaders and the enumeration supervisor will follow, to describe the proposed survey and seek their co-operation. A central site will be identified (preferably school, village offices, health sub-centre) and permission obtained to use it on the scheduled dates for eye examination of individuals 50 yrs from the selected cluster.

A mapper will be part of the enumeration team whose primary responsibility will be to map the cluster boundaries with details such as schools, temples, health centres, other land marks, streets, houses etc. The map will then be given to the enumeration supervisor who will use this as reference to check the households and ensure that all the houses in the map have been enumerated. For larger villages the segmentation will be done using the map and the segment labels will be assigned randomly. The first randomly selected segment will be called as ‘A’ the second ‘B’ and so on. On completion of mapping, the mapper will join the enumeration team and assist in all their other activities.

At the household level, enumerators will complete the household folder (Form No. (a) & (b). All members in a household will be recorded in form 2(a). Details of all those above the age of 40 years will be recorded in form 2(b). All those 50 years will be requested to come to the central site for examination by the ophthalmologist. Each household is given a ticket with list of persons 50 years and date and time for examination by the clinical team. For each person 50 years, the person's identification data is filled in the Eye Examination Record (Section A of Form-3).

Prior to the arrival of the clinical team, the enumeration teams will prepare the central village site for eye examination. The ophthalmologist and the clinical team arrive on the day as per prior communication. All enumerated persons 50 years are tested for Visual Acuity by the ophthalmic assistant and examined by ophthalmologist as per the protocol and Eye Examination Record (Form No.3) are completed.

People outside the study area presenting with eye problem will also be examined and treated at the end, after finishing the examination of enumerated persons.

At the end, the enumeration supervisor will fill the Summary details in Form-1. All the forms are checked and crosschecked by the other enumerators and the ophthalmologists to ensure that they are complete.

6.1 Field Team Composition:

ENUMERATION TEAM [4Teams]	CLINICAL TEAM [2Teams]
Supervisor : 1 (Total 4)	Ophthalmologist : 1 (Total 2)
Enumerator cum mapper :2 (Total 8)	Ophthalmic Assistant : 2 (Total 4)
Helper/Village volunteer :2 (Total 8)	Helper/Village volunteer : 2 (Total 4)
(Locally recruited- two per site will also assist the clinical team)	

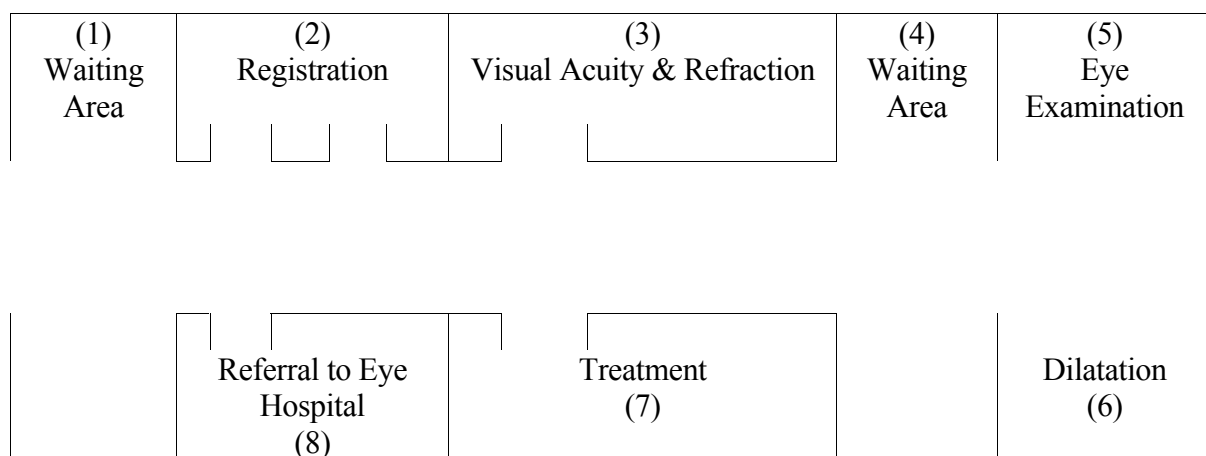
6.2 Eye Examination Site Selections and Examination Procedure:

It is the responsibility of the enumeration team's supervisor to select a suitable site within each village for ophthalmic examination. A location, or locations, must be selected where people can be gathered for examinations preferably within a 15 minute walk of their households. Arrangements must also be made for examination space, waiting space, tables, benches and a place for keeping equipment, forms and medicines. The enumerator will consult with the village/ward leader in deciding the venue. In general, the examination site should include:

- An examination room, which can be made dark (by curtains or by closing doors and windows) for examination and made also bright enough for writing.
- Two doors to facilitate entry and exit (preferable)
- A separate room for ophthalmic assistants to provide ocular treatment as advised by ophthalmologist, for dilation of the eyes, to perform, etc.
- There should be enough space outside for people to wait for examinations and visual acuity testing.
- It is preferable to have electricity; generators should be hired as standby.

The actual arrangement of each examination site will be different depending upon the actual layout of the building number of rooms and furniture available. The sketch below will be taken as a guideline in preparing the site.

These numbers refer to the following nine stations for performing different activities:

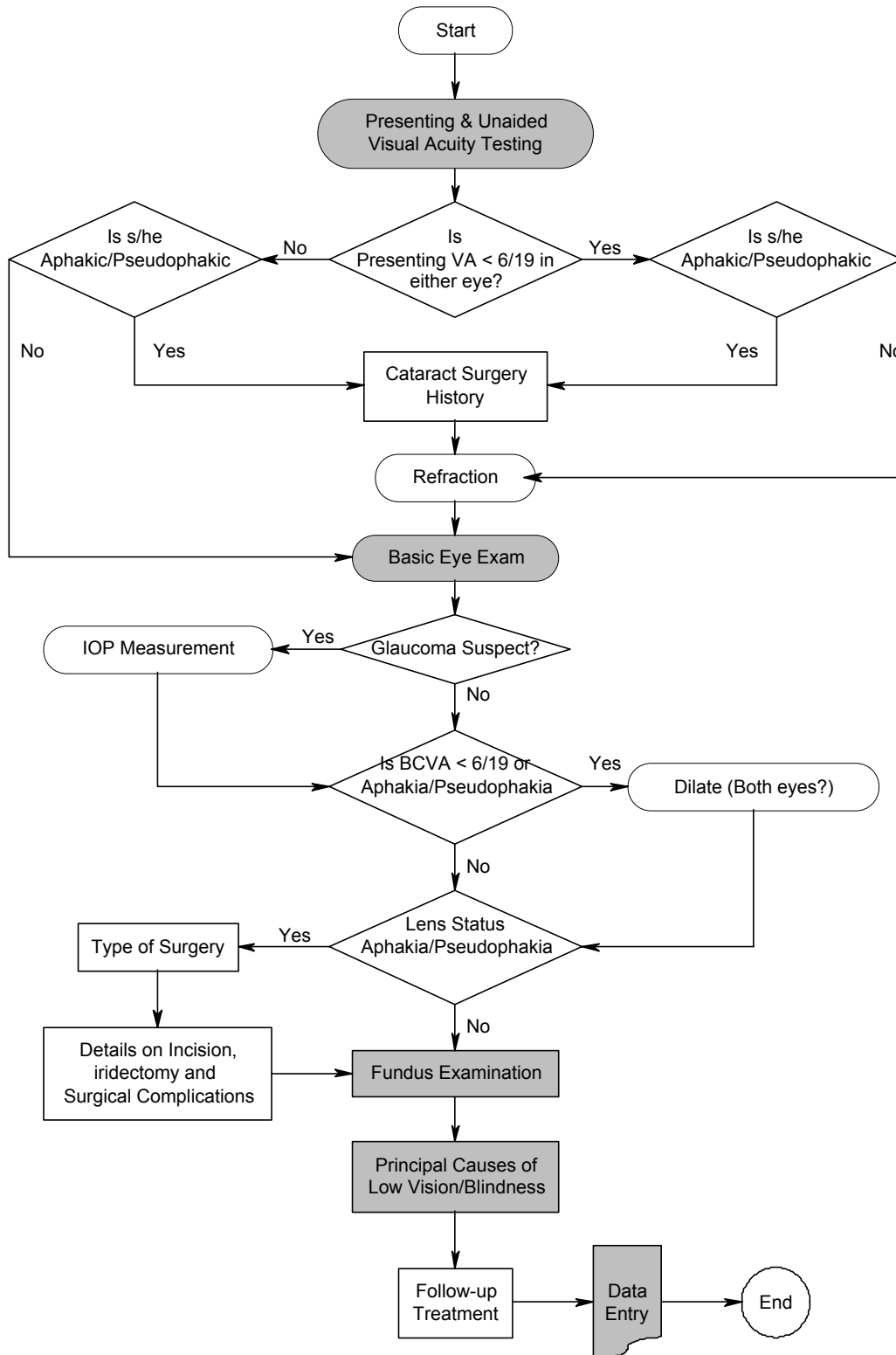


Floor Plan of central examination area in each site

1. The queue for registration for examination.
2. **Registration by enumerators**: Enumerator identifies the person from the referral slip. Identification is then verified by asking the age, name of the head of the household and confirmed. The individual's Eye Examination Record (Form-3) is then handed over to the person who proceeds to visual acuity station. Persons not belonging to the survey cluster will be asked to wait in a separate queue and are examined after all the enumerated persons presenting at the examination site have been examined.
3. **Visual acuity assessment & Refraction**: The first ophthalmic assistant determines the visual acuity by using a back illuminated ETDRS chart at a distance of 4 meters. The details of this are given in Chapter 8 on forms filling. The presenting VA is measured first and if the person wears glasses then the VA is measured again without glasses. After this, the ophthalmic assistant enquires to check if the person has had cataract surgery and examines both eyes by torchlight. Deep anterior chamber, jet-black pupil, presence of IOL (if IOL Surgery), iridoniasis are signs of cataract surgery. If necessary, slit lamp will be used to confirm the cataract surgery. If the person has undergone cataract surgery in either eye, the details as in section-C of the form 3 will be filled.
4. After the visual acuity and examination for cataract surgery, the ophthalmic assistant records these and sends the person for refraction or to the ophthalmologist. All persons with presenting VA $< 6/18$ and those operated for cataract in either eye are sent for refraction and the rest will proceed directly to the ophthalmologist for a detailed eye examination.
5. Refraction is to be done on all patients with presenting VA $< 6/18$ in either eye. Special care is to be taken while refracting aphakics and pseudoaphakics as the visual outcome in this group is of interest. Those **blind due to refractive error** are to be given free glasses (the actual details and modalities of when, where and how the glasses will be given are to be decided by the coordination committee re the DBCS).
6. Queue for eye examination by the ophthalmologist.
7. **Eye Examination by the ophthalmologist**: Basic eye examination with the slit lamp, torchlight and ophthalmoscope is carried out by the ophthalmologist and the form 3 is filled as per the manual.
8. **Dilation**: All study persons who have best corrected vision $< 6/18$ in either eye which is not due to corneal causes, or are suspected to have cataract, open angle glaucoma, retinal or disc abnormalities, will have their pupil dilated for ophthalmoscopy and slit lamp examination. The ophthalmologist will use his / her judgment as to whether to dilate a person or not.
9. Treatment for ocular illnesses, as advised by ophthalmologist, is provided by ophthalmic assistant.
10. Persons who have completed the examination leave the area. Those needing further treatment are provided with an explanation and referral slip for treatment in the nearest eye hospital/dept. Those VA $< 6/60$ due to cataract in either eye will be offered free surgery.

11. All data will be sent to Central Ophthalmology Cell, Directorate General of Health Services, Nirman Bhawan, New Delhi for data entry and analysis

Flowchart: Overall workflow in the eye examination site



6.3 Field Logistics:

The field staffs are divided as four enumeration teams including mappers and two clinical teams. The enumeration team also acts as the advance team and carries out necessary activities like mapping, informing the village elders, enumerating those who have to be screened and preparing a central site for the eye examination. This is immediately followed by eye examination by the clinical team. For each of these activities, two days are provided. Two days are being provided mainly to increase the response rate. During the two days of eye examination, the enumeration team will continue to be in the site with the clinical team to help with registration, ensure orderly flow of patients and in mobilizing the enumerated persons to increase the response rate to the desired level.

Thus for each site the Enumeration team will spend 4 days while the Clinical team will spend two days. Since there are two Enumeration teams, for each clinical team, with proper coordination and necessary arrangements, it should be possible to cover three clusters per week and the entire field work can be completed in about 10 weeks giving allowance of festivals, rains or unforeseen circumstances which can slow down the work. The following table illustrates the movement and activities of the field teams over a two-week period in which six clusters are completed. A lot of attention to logistics planning and scheduling cluster visits taking into account local situation (marriages, festivals, etc.) can ensure that this schedule can be met.

Day	Enumeration Team 1	Enumeration Team 2	Clinical Team																														
1.	Enumeration in cluster 10	Assist Clinical Team in cluster 9 (enumeration already done)	Eye examination in cluster 9																														
2.				3.	Assist Clinical Team in cluster 10	Enumeration in cluster 11	Eye examination in cluster 10	4.	5.	Enumeration in cluster 12	Assist Clinical Team in cluster 11	Eye examination in cluster 11	6.	7.	----- Rest Day -----			8.	Assist Clinical Team in cluster 12	Enumeration in cluster 13	Eye examination in cluster 12	9.	10.	Enumeration in cluster 14	Assist Clinical Team in cluster 13	Eye examination in cluster 13	11.	12.	Assist Clinical Team in cluster 14	Enumeration in cluster 15	Eye examination in cluster 14	13.	14.
3.	Assist Clinical Team in cluster 10	Enumeration in cluster 11	Eye examination in cluster 10																														
4.				5.	Enumeration in cluster 12	Assist Clinical Team in cluster 11	Eye examination in cluster 11	6.	7.	----- Rest Day -----			8.	Assist Clinical Team in cluster 12	Enumeration in cluster 13	Eye examination in cluster 12	9.	10.	Enumeration in cluster 14	Assist Clinical Team in cluster 13	Eye examination in cluster 13	11.	12.	Assist Clinical Team in cluster 14	Enumeration in cluster 15	Eye examination in cluster 14	13.	14.	----- Rest Day -----				
5.	Enumeration in cluster 12	Assist Clinical Team in cluster 11	Eye examination in cluster 11																														
6.				7.	----- Rest Day -----			8.	Assist Clinical Team in cluster 12	Enumeration in cluster 13	Eye examination in cluster 12	9.	10.	Enumeration in cluster 14	Assist Clinical Team in cluster 13	Eye examination in cluster 13	11.	12.	Assist Clinical Team in cluster 14	Enumeration in cluster 15	Eye examination in cluster 14	13.	14.	----- Rest Day -----									
7.	----- Rest Day -----																																
8.	Assist Clinical Team in cluster 12	Enumeration in cluster 13	Eye examination in cluster 12																														
9.				10.	Enumeration in cluster 14	Assist Clinical Team in cluster 13	Eye examination in cluster 13	11.	12.	Assist Clinical Team in cluster 14	Enumeration in cluster 15	Eye examination in cluster 14	13.	14.	----- Rest Day -----																		
10.	Enumeration in cluster 14	Assist Clinical Team in cluster 13	Eye examination in cluster 13																														
11.				12.	Assist Clinical Team in cluster 14	Enumeration in cluster 15	Eye examination in cluster 14	13.	14.	----- Rest Day -----																							
12.	Assist Clinical Team in cluster 14	Enumeration in cluster 15	Eye examination in cluster 14																														
13.				14.	----- Rest Day -----																												
14.	----- Rest Day -----																																

6.4 Time Schedule:

A detailed schedule has been prepared for the survey teams. To ensure that survey is completed as scheduled, timely completion of each activity is important. Following schedule was agreed upon by the participating survey teams:

Months	Period	Activity
<u>Month 1</u>	Procurement of Survey Equipments	DANPCB
	Finalize & dispatch Survey Proformas	NPMC
	Information about population (Census/ NSS)	NPMC
	Identify survey team members	Survey Organisation
	Letters to State Government/ Collectors/ CMOs	NPMC
	Release of 1 st Instalments of Survey Organ.	NPMC
	1 st Visit to District by key Team Members	Key Team Members
<u>Month 2</u>	Recruit Survey Team Members	Survey Teams
	Training of Survey Teams	RP Centre/ Aravind
	Pre-pilot study	Survey Teams
	Preparation of Cluster Framework	Survey Teams
	Cluster Identification	RP Centre/ Aravind
<u>Month 3</u>	Mapping of selected clusters	Enumeration teams
	Enumeration	Enumeration teams
	Pilot survey	Survey teams
<u>Month 4, 5 and 6</u>	Data collection for the survey	Survey teams
	Data entry	NPMC/ DANPCB
<u>Month 7, 8 and 9</u>	Data Analysis & report	NPMC

The actual start date of the study would depend on getting necessary approval and funding. The study schedule will change accordingly, however the duration of the entire study would be about 6 months.

6.5 List of Equipment & Supplies:

Equipments: (to be arranged by Government of India and returned after survey)

Portable Slitlamp (Haag Streit)	-2 ***With Spare bulb
Lensometer	- 2
Parkin's (Perkin's) Tonometer	- 2 (or Tonopen, that is handy)
Torch light	- 2
Loup	- 2
BP Set	- 2
Stethoscope	- 2

Supply: (To be arranged by DBCS)

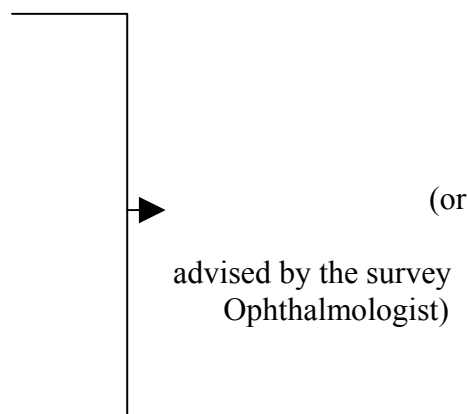
General Items

Power Generator	- 2	
Water Carriers (20 Lit)	- 2	
Thermos	- 2	
Office Items	- 6	
Aphakic glasses (+9 to +12)	- 200	
Hand towels	- 20	
Direct Ophthalmoscope	- 2	With 2 spare bulbs
Indirect ophthalmoscope	- 2	"
StreakRetinoscope	- 2	"
Trial set	- 4	
Stapler	- 6	
Examination site furniture	- 2 sets	

How about prescription of other glasses
Flourescien strips

Medicines per site:

Methyl Cellulose drops (300)
Tropicamide drops (150)
0.3% Gentamycin drops (1000)
Tetracycline eye ointment (3000)
2% Pilocarpine Drops (150)
equivalent/alternative on
2% Fluorescein strips (30 packs of 100 strips each)
Sulphacetamide eye drops (1500)
Homatropine drops (150)
4% Xylocaine (600 vials)
Tab. Accetazolamide (diamox) (1000)



To be arranged by Survey Organisation:

Illuminated ETDRS chart - 4

7. Role & Duties of Field Staff

Chief Investigator: Is responsible for overseeing the overall conduct of the study and provide necessary direction and guidance as per the protocol.

Survey Manager cum Epidemiologist: Will work directly under the Chief Investigator. He / She will be responsible for the recruitment, selection and training of the different categories of study staff, ensure the availability of required equipment and supplies, develop the schedule for the various activities like staff selection, training, pre-pilot, pilot, field work and collection of data. Responsible for the budget in terms of ensuring cash flow, expenses and the accounting.

7.1 Role & responsibilities of the Ophthalmologist:

The ophthalmologist for this study will be a fully qualified ophthalmologist with 3-5 years clinical experience in ophthalmology. Ophthalmologists with experience of surveys or community outreach work will be preferred. Duties will include collecting information in rural areas on clinical signs of eye diseases and on the epidemiology of blindness in the survey area. The ophthalmologist will ultimately be responsible for carrying out all activities described earlier in Field Procedure.

The duties and responsibilities of the ophthalmologist will include the following:

- Conducting clinical ophthalmic examinations according to the survey protocol (basic eye examination and more detailed examinations where necessary).
- Supervising measurement of visual acuity, refraction and carrying out prescribed treatment to those presenting with eye diseases.
- Supervision of the activities of a team of six to eight persons.
- General responsibility for the reviewing and quality control of all survey forms and data collected at the sample site.

As an examiner, the ophthalmologist has overall responsibility for completing all examinations in a cluster.

The ophthalmologist must actually assume many roles in the survey: examiner, physician, supervisor, and team leader. These are not distinct roles to be assumed at specific times, but they serve to summarise conveniently the many activities that an ophthalmologist must carry out as part of the survey of a cluster.

When a person presents for examination, checks are made to ensure that the person has been enumerated. The examination begins with the visual acuity measurement by the ophthalmic assistant and following this basic eye examination is conducted. An evaluation is made to determine whether detailed examination and assessment for cause of reduced visual acuity are necessary. Detailed examination is conducted on persons with pinhole visual acuity $< 6/18$ and as specified in the manual. The detailed examination includes examination of the cornea, measurement of intra ocular pressure, dilation of pupils (when necessary) for examination of the lens, retina and optic nerve and evaluation of the cause of visual impairment. Appropriate treatment of any other presenting complaints should be handled in a similar manner. Those who

can be readily treated at examination cluster will be attended to and others requiring further treatment or investigations will be referred to the base hospital.

Another role for the ophthalmologist is as a supervisor of activities of the other team members. Periodically during the day's work, the ophthalmologist will make spot checks of OAs, and enumerators and supervisors activities. A short visit to observe their work will increase morale and improve the quality of work being conducted. At the end of the day, all completed forms will be reviewed by the ophthalmologist to check the completeness and accuracy of the data collected. Errors should be brought to the attention of the enumerators or other responsible team members and corrected.

A final role of the ophthalmologist is to serve as the team leader. Decisions about schedules of activities in the cluster, personnel problems, physical or health difficulties, transportation, and the completion of assignments is the responsibility of the ophthalmologist. If there are questions about the conduct of the survey in a particular cluster, the ophthalmologist should address them to the central office. Team meetings at the end of each day will be conducted under the direction of the ophthalmologist to resolve questions and review the forms completed during the day.

The "ophthalmologist" is the recognised head of the team. As such, he is ultimately responsible for the smooth performance of the team in a site, as well as for the overall quality of the results collected by the team. He must assume more than the role of an examiner of eyes. Supervision, and hence knowledge of the activities of each team member representing the projects, and general direction of the teams activities will also be the responsibility of the ophthalmologist. The impression people have about the programme will reflect perhaps more than anything else on the perceptions they have of the ophthalmologists leading the teams.

It is useful to note that a head of the team, the ophthalmologist will have a direct and indirect impact on the health of the people in the segments visited. The direct provision of health care for presenting ailments will have a beneficial, if short-lived, effect on the health of the survey communities. The long term benefits of a well-planned blindness control programme are far more important to the health of the community and the country. Complete and accurate data on every household, every person, and every cataract patient will provide a good base on which to plan improvement in the blindness prevention program. Although the immediate problems, logistics as well as personnel, encountered in the field may appear overwhelming, the ophthalmologist must also focus on the long-term implications of the survey.

7.2 Role & responsibilities of the Ophthalmic Assistants:

The ophthalmic assistant for the Study will be a trained, certified person who has worked for more than 2 years in an eye hospital under the supervision of an Ophthalmologist. He will travel with the Eye Examination Team. The job in the field shall consist of using the back illuminated ETDRS Chart to assess visual acuity and perform refraction in accordance with the descriptions provided. He shall be expected to help out in the general work of the team, whenever necessary.

Ophthalmic Assistants will also help the ophthalmologist during the examination: dilating eyes, checking intra ocular pressure, refraction and presbyopic correction. Ophthalmic assistant is responsible for all instruments and equipment necessary for the eye examination and ensure that these are available and in working condition. This includes periodic recharging of batteries of equipment like ophthalmoscope, retinoscope, tonometer and torchlight. The ophthalmic Assistant (OA) determines the visual acuity with the ETDRS chart as explained in Chapter 8. The Ophthalmic Assistant will perform refraction on all persons with presenting vision < 6/19 in

either eye and pay special attention to those who have been operated for cataract (Aphakics & Pseudophakics). This is done because the study is particularly interested to find out the visual outcome after surgery.

7.3 Role & responsibilities of the Enumeration team:

The enumeration team will consist of 1 mappers and 2 enumerators (total number of 4 mappers and 8 enumerator team) with prior field survey experience. Since several surveys are being carried out throughout the country, recruiting such personnel will be quite feasible. Of the eight enumerators, four will also function as the supervisor for the enumeration activity. In segmented villages, cluster numbering should begin from north of the village.

Sample surveys are used to study a wide range of problems and suggest solutions. A survey involves collecting data through interviews or examination of a sample of people, selected to represent some layer of population of interest. Every person in the survey is asked the same basic set of questions, and the responses or results are later studied and conclusions drawn from them.

The enumerator's job throughout this survey is to accurately list the persons resident in the sampled clusters (villages or wards).

The principal aim of this survey is to estimate the prevalence of low vision and blindness from examination of persons aged 50 years and above belonging to the sampled villages. The prevalence of blindness consists of a numerator and a denominator:

$$\text{Prevalence of blindness} = \frac{\text{Number of blind persons in the community}}{\text{Total number of persons in that same community}}$$

The ophthalmic assistants who will be recording the visual acuity are responsible for accurately identifying all the persons whose vision is less than 6/60 – the definition of blindness. They will thus be contributing to the "numerator".

As census enumerators, their responsibility will be to provide the "denominator", by identifying as exactly as possible the persons (and only those persons) who make up the community selected for the purposes of the survey. This will obviously include all those determined as blind as described above.

Any bias or error that may creep into the collection of these data will affect the prevalence rate, pushing it above or below its true level. Let us imagine, for instance, that we include in the survey some persons who do not live in the area under consideration but wish to be examined. If these persons do not present any blinding condition, their inclusion in the "census population" will excessively inflate the denominator used in the calculation of the rate but contribute nothing to the numerator. If such a bias is created in recruitment to the survey, the rate of blindness will be estimated below its true level in the country.

If blind people from outside the community are wrongly included in the sample in order to get them relevant medical opinion, their inclusion will modify both the numerator and the denominator. This will result in over estimation of blindness by raising the number of blind people in the numerator.

If the persons who are "absent" on the day of the survey are not included in the census, and actively "tracked down (making every possible effort to find and examine them), the resident population and the "population examined", will not accurately reflect demographic reality, and rates of prevalence based on such data will not be of much significance.

There are many possible distortions that may follow from errors made in the course of census taking and registration. Thus it is not our role to indiscriminately register every person who comes to you. On the contrary, we will keep up a permanent dialogue with local leaders, and with the heads of every household, in order to obtain an accurate picture of the demographic reality of the community that they make up. For every person that we register, we will first have to decide whether that person is a "usual resident", an "absent resident" or a non-resident. Any person who has resided in the cluster for more than 6 months will be documented as "Usual Resident". Persons who have been residing for more than 6 months but absent on that day will be documented as "absent". Persons who reside for less than 6 months will be documented as "non resident." Any mistake in classification / diagnosis at this level will have repercussions on the accuracy of the rates that are being investigated. We are fully aware that the precision and value of the survey results will depend closely on the quality of our contribution.

7.3.1 Job description and duties

Mappers: The prime responsibility of the mappers will be to prepare a detailed map of the selected clusters prior to enumeration. They will outline the boundaries of the clusters and mark important landmarks such as temples, schools, health centres, streets, and all households in the village / urban ward. On completion of mapping, he will hand over the map to the enumeration supervisors of the respective cluster. He will also assist the enumeration team in all their activities.

Enumeration team: The first duty after the arrival of the team at the cluster is for the supervisor to meet with the village leader. He will inquire about the letter previously sent to the village chairman. If the letter has not been received, he will provide a copy of the letter and introduce himself, the enumerators and the project activities to the village leader. An informed discussion about the activities of the survey is held with the village leaders and their co-operation is requested. The supervisor, after meeting with the village leader, will confirm the cluster and its boundaries based on the map done earlier by the mapper. All persons in the household are enumerated by a door to door visit, and those aged 50 or above in each household will be referred to come to the central site for eye examination as per the study protocol. The following format is to be used for referring those aged 50 or above to the central site:

Cluster:		Cluster No:		HH No:	
In order to examine your eyes thoroughly for the purposes of this study and to provide necessary treatment, a medical team consisting of an eye doctor and para-medical staff will be coming to this village on _____. They will be available from _____ am till _____ pm. It is very important that you attend this examination.					
Signature					
Per.No	Name	Age	Sex		
1.					
2.					
3.					
4.					

Hiring of local assistance: The supervisor will request the help of a local volunteer to assist in the enumeration and other activities in the cluster. Their help will be extremely useful especially in ensuring a high response rate. Reasonable remuneration for their services will be made.

Duties of the supervisor and enumerators during the examination period

- 1.To ensure that the site selected for eye examination and facilities available are adequate.
- 2.To announce the verbal consent to the persons to be examined and get their agreement for examination. The verbal consent is as follows:

<p>Verbal Consent Form</p> <p>You are invited to participate in an eye survey. You will undergo an eye examination, which may require the application of eye drops. You may also be required to answer some questions. You will receive complete medical attention if any problems arise during the examination process, and you will also be offered free treatment recommended by the doctor. After eye examination, if you feel eye pain and/or headache, please contact the team immediately.</p> <p>Do you agree to participate?</p>
--

- 3.Orderly flow in the examination centre, maintaining the queue and ensuring that there is no exchange of clinical forms in between individuals.
4. Assistance to Ophthalmic Assistants in the Visual Acuity taking and to the ophthalmologist in the detailed eye examination
- 5.To call the reluctant individuals enumerated but not examined.

6. Supervisor should check the list of unexamined persons and efforts will be made to bring the person by at least making three attempts. No one will be forced for examination against his or her will to be examined. Those who fail to appear even after three such attempts will have their forms marked "refused examination".

7.3.2 Some difficult situations & solutions:

Often - perhaps more often than not/ respondents in the sample clusters will be suspicious of your work or refuse to co-operate. The following are some typical questions and problems and some suggested ways to handle them. Several replies and suggestions are given in each instance - use those appropriate to your situation.

Who is doing this survey and why is it being done?

"This survey is being conducted by (name of the hospital), the State Government of _____ and the Government of India. We are trying to find out how many blind persons there are in your zone and some of the reasons they become blind. We need to ask questions at people's homes and to examine blind as well as sighted people to find out what kinds of things cause blindness and in order to help us determine ways to prevent blindness. We are also trying to find out why some people use available eye care services whether it is an eye hospital or an eye camp and why some don't?"

Tell me more about the survey. How do I know you are not a tax collector or someone else?

"I am a professional Enumerator. I have spoken with the village chairman and brought a letter of introduction from our hospital. Would you like to talk with him or with my supervisor?"

Why are you examining/asking me these questions? I am not a blind, can't you examine someone_or ask someone else?

"It is important for us to talk to and examine people who are not blind. We also need to examine the eyes of everyone in the selected households to see what kinds of problems they have with their eyes. Some of these problems may lead to blindness later. You and your family were selected by chance according to methods worked out at my office. You will represent several other families in our sample of families in this zone. Your answers to these questions and the examination of your eyes are important - talking to, and examining someone else will not be good enough."

I do not have time to do this , I am not interested.

"Our questions will not take too long. You can continue with your work here and I will ask these questions as you are working. The examination will take only a few minutes as well. All you need to do is go down to the examination centre with me. The doctor will look at your eyes quickly and you can come back."

I just dont have the time now I am really not interested.

"I can come back later. What would be a good time, when you are not so busy?"

I don't know enough to give you good answers

"You may not think your answers are very good, but they will be helpful to us. What you say can be useful for planning the program for control of blindness in your area."

What will be done with this information?

“The answers you give will be added to provide us with a national view of these problems. No individual's data will ever be used alone - we will always be combining answers for many people to look at trends and patterns. Your answers and the results of your eye examination will be kept confidential (secret).”

Why do you want to know that?

“The physicians working on the project want to know about these things so that they will know more about blindness in this area. Many other persons will be asked these questions. We want all the people selected to answer these questions.”

I don't want to answer that question.

“You don't have to answer any question that you don't want to, of course. We need your answer to make the survey more accurate and help us plan a better program.”

If the respondent still refuses, go on to next question; mark the item "REFUSED".

In addition there may be a number of unexpressed reasons the informant does not give but nonetheless lead to a refusal:

- Informant feels threatened or embarrassed because he or she does not think they know enough to answer the questions.
- Informant thinks you have some other reason besides conducting an interview for being there.
- Informant doesn't understand clearly the purpose of the study or why you need him or her to participate.

In order to overcome refusals or reluctant informants, it is important for us to evaluate both the expressed and the unexpressed reasons for refusing. We may be able to devise an appropriate way to convince the informant to allow the interview. In any case, do not attempt to force an informant to an interview when they absolutely refuse. Once again, be polite and firm in your approach.

Best of all, leave the way open for a later visit for another attempt to get an interview. It may be a bad time because of an illness in the family or an argument with a spouse or some other problem bothering the informant and totally unrelated to the survey. Make an appointment if one is suggested, but remember that if the informant truly does not want to be interviewed, he or she will find a way to miss the appointment.

7.4 General Guidelines for Conduct of Field Staff:

For most people in the sample clusters, we may be the first person they will meet. The impressions they form about us will reflect on the survey team they meet later. They will communicate those impressions to friends and relatives, especially those who have eye problems or are blind. The success of the survey depends partly on the impression we make on the people we meet in the sample clusters.

There are certain qualities that we expect every field staff to have. They are not often easily measured nor evaluated for an enumerator, but they can and must be used as a way to measure and evaluate their performance.

Complete honesty is expected from every enumerator and other field staff. Items in the forms must be completed during the course of an interview. If an item is incomplete and you are unable to return to the person to complete the item, leave it blank and write an explanation. Giving incorrect or false answers to an item or for an entire form is sufficient ground for dismissal.

Reliability: We must be able to depend on you to do the work assigned and to do it well. If you are assigned the task of enumerating a group of households, every household must be identified and enumerated. We are depending on you to be reliable and do the work in such a way that we can make good, quality estimates of the number of blind and other visually impaired people for the district. This is a responsibility that you as an enumerator must assume - the responsibility for collecting accurate and complete information in the sample clusters for the survey.

Understanding: Few, if any, of the people you meet as a representative of the survey will have ever been interviewed, let alone examined by an ophthalmologist. They may be suspicious of your motives and activities and they may even be a little hostile. They may have superstitions that make their co-operation difficult. As enumerator you must understand the people you interview. An interest in people and their different points of view is essential in this understanding

Personal Appearance: It is important how you look since you are a professional survey enumerator and interviewer. You are expected to be neatly, if inconspicuously, dressed. We also expect you to maintain attitudes about your work and the places you work in. These attitudes may be very difficult to maintain in some situations, especially toward the end of the survey when you are tired and perhaps a little bored with the work. But we want you to keep them in mind, nevertheless.

Responsibility: Finally, we cannot train you to be able to handle every problem and every alternative you will encounter in the field. You are going to have to assume responsibility for many decisions in the field. If a supervisor or ophthalmologist is present and you are not sure what to do, ask them, but if no one else is around, you must make the decision and do the best that you can. Do not violate the procedures in this manual, but do try to do what is necessary to keep the survey activities moving.

Remember that the quality of information collected in this survey depends on you and how well you do your job. Your job is to collect and record the information accurately and completely. In other words, we want you to conduct your activities for the survey in a careful and scientific way. We consider your role in the survey to be very important in obtaining quality information.

8. Guidelines for filling the forms

8.1 Guidelines to fill Site Summary Form 1 (a)

(Enumeration team Supervisor)

Collection of information /data by the Survey Team starts with filling of Form no. 1(a) which is a District Level Form. Form 1(a) provides an overall picture of the Survey District with reference to the following –

- ☛ Total number of Ophthalmologists in various sectors- government, private, voluntary etc. in the district;
- ☛ Total number of eye hospitals in the district;
- ☛ Total number of eye beds in all sectors within the district;
- ☛ Total number of Ophthalmologists and Paramedical Ophthalmic Assistants in various government facilities; and
- ☛ Number of CHC/PHCs in the selected district.

These particulars from serial no.1-20 in form 1(a) are to be filled in the respective boxes by the Enumeration Supervisor prior to proceeding for the household survey.

Whom to contact ?

The above information can be gathered by contacting the Chief Medical Officer of the district and the data once collected, is to be counterchecked by the Survey Ophthalmologist as it is primarily related to his/her field of specialisation.

8.2 Guidelines to fill Site Summary Form 1 (b) (Enumeration team Supervisor)

This form is in two sections. The first section relates to the village details while the second section gives the survey summary. The Enumerator supervisor will fill the village details, by asking the village chairman or any other well informed person. The Enumeration Supervisor will also fill the survey summary section, which will be checked by the Ophthalmologist of the clinical team.

Village Details:

Cluster Name & No: Fill the cluster name and number given to the cluster (survey unit) by copying it from the list of the clusters.

1. *Number of households in the village:* Enter the most reliable estimate after doing necessary cross checks
2. *Total population:* From the census book or from the village head.
3. *Nearest motorable road where public transport is available:* This information can be quite easily ascertained. Give the distance in Kilometres. If public transport is available at the village itself, then mark the distance in Kms.
4. *Health Facility:* If available mark the "yes" box, if not the "No" box.
 - 4a. *Define the type of Health Facility:*
 - 1 = Primary Health Centre
 - 2 = Health Sub-Centre

3 = Community Health Centre

4 = Private health facility - Doctor, clinic, hospital, nursing home, etc.

4. If answer to item 4 is "no" specify the type of nearest Health facility using the codes as in 4a.

5a. Distance of the nearest Health facility in KM.

5. Name of the nearest Eye Hospital/Clinic

6a. Give the distance in KM. If one is available in the cluster itself mark the distance in KMs.

7. *Eye Camp details:* If any eye camp has been conducted within one year mark the "Yes" box (7) and give the distance in KM (7a) and the place where the eye camp was held (7b).

SURVEY SUMMARY:

1. Cluster Summary:

Total Households: The actual number of households enumerated in the cluster. The households where there are no persons aged 50 years will not be included.

No. of persons enumerated: The actual number of the persons aged 50 years and above in the cluster. Persons living or working away from this cluster for more than six months will not be included. Persons staying for < 6 months will not be enumerated

Nos. available on site for examination: The total number of persons who are present in the village at the time of examination and could have been examined.

Nos. examined: The actual number of persons who underwent the eye examination.

Response Rate: (Nos. examined x 100) □ (No of persons enumerated)

Start Date: Date on which the enumeration in the cluster started

Finish Date: Date on which the eye examination was completed

2. Nos. of Forms:

Count the actual number of forms and put the total number against each category

3. Service Provided:

Consult the individual Eye Examination Records (Form-3) and consolidate the service provided under different categories.

8.3 Guidelines to fill Household Forms 2(a) & 2(b) (Enumerators)

Contact at the household:

There are two stages to the introduction of the survey to the household, although you may find that they blend into a single stage. The first stage occurs at the doorstep and is somewhat

more formal and courteous than the other. The second stage is in the household after you have established your identity and your reason for being there.

In the first stage, the person whom you talk to will probably be curious about you and the survey. Establish your identity with your identification card to alleviate any anxiety that you are a stranger whom they do not wish to speak to. Make the notebook you carry prominent as another symbol of your legitimacy.

The doorstep is not usually a convenient or a comfortable place to conduct an interview, although it may be in some communities. Try to make the doorstep interview brief and move inside. You will be able to convince the members of the household about the importance of their co-operation from inside the household. Do not ask permission to enter since they may refuse quickly. Instead, state that you want to move inside as "I would like to come in and talk with you more about the survey." Assume that the household members have time to be interviewed, but if they really do not have the time, arrange for another time when you can return to collect the interview. Be firm, but polite during these introductory conversations. Do not press too hard since we want their co-operation later.

Once inside the household, most people will be quite willing to be interviewed and only need a brief explanation of what the survey is about and what they need to do. Although it may be a new experience for them, their curiosity generally leads them to be receptive to answering the survey questions. Do not be too specific about the nature of the questions, to avoid introducing bias into their answers. General remarks such as "we are interested in finding out about the eye health of people who live here" will be sufficient.

Some people may be uncooperative or have some reasonable concerns about the survey. You must respond in a positive and confident manner to their questions, always maintaining a courteous manner. Remember that you are a stranger to them, probably of a different caste or tribe. Their concerns and questions are legitimate and require your careful attention.

Household information is to be collected in two steps. The first step is the listing of households in every cluster-(Form 2(a)) and detailed information/data about each household in the respective clusters –(Household Folder form 2(b)).

The following are the instructions for filling up the household forms 2(a) & 2(b)-

The very first step for enumerators would be to start moving in a clockwise direction in each cluster and keep listing one by one, every household falling in that particular cluster. As the enumerator will proceed from one household to the next, he/she will have to keep numbering each household and after establishing contact with members of a household, collect information about the name of head of the household as well as the number of male/female members in various age groups.

Age distribution of all Household members:

Four columns for age groups 0-14 years, 15-39 years, 40-49 years & 50+ years are provided which are to be properly filled against each household in order to get a correct estimate of the 50+ population in each cluster. Each column is divided by gender (M-Male, F-Female).

Columns for recording total number of male/female members is also provided & is to be filled in accurately for each HHNo. in Form 2(a).

Instruction for filing the household folder form 2:

Cluster Name and No: Copy from the list of clusters.

Enumerators: Fill in the name and ID number of the enumerator.

Household No: Copy from the number written on the wall or door, which had been previously painted by Enumerator Supervisor. A household unit will consist of a family who shares food cooked in one kitchen. If the head of the household gives consent for interview go ahead and complete the interview. If he refuses terminate the interview. With proper introduction and permission of village elders, we expect that this will happen very rarely.

Visit Date: Record the date, month and year at each visit to the household.

Time: Record the time of each visit.

Name: Fill in the name of all persons 50 years in the household.

Age: Enter completed years of age. If you have any suspicion regarding age of the person list his name but further enquiries should be made. In such cases local event calendar would be useful. E.g.: 1947 Year of Independence. You can ascertain if the person was born before or after independence. All persons born before independence will be 50 years of age and this is the age group of interest to us.

Other columns: For other information such as relationship of head of household, sex, literacy, type of resident, education and occupation, details to be filled in as per the table given below in Form 2.

Wearing glasses: At the time of filling the household form, enumerator observes whether the person is wearing glasses or not, and enters the information in the corresponding column. If the person is not present, they will enquire from the respondent if the person normally wears glasses.

DETAILS OF RESPONDENT:

A. Respondent: Name, age and sex of the respondent to be filled in.

B. **Relationship to the Head of Household:** The relationship of the respondent is to be filled by entering in the box the alphabet corresponding to wife, household member, neighbour and others.

8.4 Guidelines to fill Eye Examination Form 3

(Ophthalmologist & Ophthalmic Assistant)

All subjects are tested at the examination site. The Eye Examination Record comprises of twelve sections as listed below:

- A. Demographic (Name, ID and personal information)
- B. Vision & details of cataract surgery if any
- C. Cataract Surgery History
- D. Refraction with Retinoscopy
- E. Basic Eye Examination
- F. Intra ocular Pressure

- G. Anterior Chamber
- H. Pupils dilatation
- I. Lens Status
- J. Cataract Surgery Details
- K. Funds
- L. Causes for Low vision or blindness.
- M. Current Action needed
- N. Remarks

Section A - Demographic information

Enumerators fill section-A at the time of enumeration for all person's 50 years of age.

- Name:** The name of the person to be examined
- Cluster:** The serial number of the survey cluster, expressed in two digits. If the serial number is "5", it should be filled as "05" in the box and not as "5".
- HH:** The number of the household expressed in three digits with leading zeroes when the number is less than 100. If the serial number of the household is " 5 ", "005" should be filled in the box. Start with "001 " for each cluster
- Pers.No:** The serial number of the person as listed in the household Form-2.
- QA** This box has a number already filled in –1 for the first examination and 2 for the second examination if performed for the purpose of quality assurance.
- Age:** The age of the person to be examined to be expressed in number of years.
- Sex:** Gender of the person
1 = Male 2 = Female.
- Mon** The month of clinical examination
- Date** The date of clinical examination
- Year** All the digits of the year for eg: 2000 will be entered as 2000.

Section B - Vision - This section is to be filled in by Ophthalmic Assistants.

Ophthalmic Assistant ID: All the ophthalmic assistants will be given a separate identification number and the OA who will test the vision and will enter his/her ID code and vision in the respective boxes.

Presenting vision: The ophthalmic assistant determines the visual acuity by using a back illuminated ETDRS chart at a distance of 4 metres. Visual acuity is tested separately for each eye (one eye at a time) using the person's usual distance correction glasses, if any. Visual acuity is recorded as the smallest line read with one or fewer errors. Persons unable to read the largest line of the chart at 4 metres will be asked to read the chart at 2 metres and this will correspond to a VA of 3/60. If the person is unable to read the largest letters in the chart even at 2 metres, then finger counting is done at 2 (2/60), down to meter for hand movements and light perception. Care will be taken to ensure that the unexamined eye is adequately covered with the palm or cloth and not pressed. For details of measuring VA using the ETDRS chart, refer to Annexe - A.

Wearing glass: Record 1 or 2 depending on whether the person is wearing glasses or not. If person is wearing glasses the unaided vision is recorded.

Whether the person can be tested: In a dumb/deaf or mentally retarded person, it may not be possible to record visual acuity. Hence record in box a value of 1 or 2.

1 = The visual acuity can't be tested; 2 = The visual acuity can be tested

Cannot be tested: In conditions where vision cannot be tested the ophthalmic assistant will mark on the boxes "Cannot be tested". In such cases the ophthalmologist has to make a subjective determination of visual acuity which can be done at the end of examination, and record one of the three possible values listed below:

1 =Believed blind; 2=Believed not blind; 3=Undetermined

Section C - Cataract Surgery History:

Did you have cataract surgery: For each eye record 1 or 2 in the box based on whether the person has had cataract surgery or not.

1 = No (did not have cataract surgery); 2 = Yes (had cataract surgery)

If Yes: For each eye record the month and the year in the space provided. Use only numerals. E.g.: Jan 2000 should be recorded as 1/2000 and record the place of surgery as given below:

1 = Govt. Hospital; 2 = Private & NGO hospital, 3 = Private Practitioner (operating in a clinic or Nursing Home), 4 = Eye camp

Name of Hospital/Camp: For each eye, record the name of the hospital or the place of eye camp, in the space provided.

Section D - Refraction with Retinoscopy

The ophthalmic assistant should record their ID number in the box provided prior to refraction. All persons whose presenting vision in either eye is $< 6/18$ and those with aphakia or psuedoaphakia in either eye will undergo refraction. Special care is taken to refract aphakics and Pseudophakics using a retinoscope if necessary. Best corrected VA and the corresponding refraction values for each eye is noted down. Refraction with dilation is not done at this moment. Presbyopic and those with vision 6/60 or better will be given glass prescription if they request.

Section E - Basic Eye Examination:

From this section onwards all the examination are to be carried out by Ophthalmologist, while ophthalmic assistants could do IOP measurement and dilation. The ophthalmologist should enter his ID number in the space provided before conducting the examination. The basic eye examination consists of examination of eyelid, globe and papillary reflex using torchlight slit lamp and ophthalmoscope. The examination includes the determination of type of cataract surgery and any obvious surgical complications. In the sections under "Eye lid & Globe" mark all the boxes that apply. The findings will be marked as 1,2 or 9 as the case may be, where 1 indicates the finding is not present, 2 indicates present and 9 indicates undetermined cases

Eye Lid:

Defective Closure: When a person is asked to close the eyes the upper and lower lid should come in contact and globe is not visible But in cases of lagophthalmos, ectropion, loss of lid margin, etc, the lid may not come into apposition. In such conditions eye boxes adjacent to "Defective closure" is to be marked.

Inturned margin/trichiasis: Look at the lid margin by torchlight and note whether lashes are touching the globe or not. If even one lash is touching the globe, then mark the box adjacent to inturned margin/trichiasis. Evidence of recent removal of lashes will also be coded as trichiasis.

Globe:

Conjunctiva, cornea and eyeball are examined externally with the help of a torchlight and slit lamp.

Phthisical/disorganised/absent: Include staphyloma as a type of disorganised globe.

Conjunctivitis: Red eye & discharge

Central Corneal Opacity: Only if it is within the pupillary area or obstructs vision.

Corneal ulcer: Mark if active ulcer is present. If corneal ulcer is suspected the ulcer is stained with fluorescein and examined with blue light.

Pterygium: If pterygium has progressed onto cornea, pterygium is marked. If not, the box is marked as 1.

Other (specify): If there is any other findings mark the box and describe in the space provided. All corneal oedema / bullous keratopathy should be marked in the cataract surgical complications. If the eye is not operated, then include in this section.

Pupillary reflex: Assess Pupillary Reflex and Mark 1, 2, 3 or 9 where 1 is reactive pupil. 2 is sluggish pupil, 3 is non reactive pupil and 9 is undetermined.

Section F - Intra ocular pressure

IOP measurement will be conducted by Ophthalmologist on persons who are suspected to have Glaucoma or in those patients where the anterior chamber is shallow. Drops of 4% Xylocaine will be instilled in both eyes and after five minutes, IOP will be measured using a Tonometer. If IOP is not done mark 1 in the box and if done mark 2 in the box. Three measurements will be taken and the average will be recorded within the boxes provided for each eye.

Section G – Anterior Chamber

AC Depth: The depth of anterior chamber can be estimated both with oblique illumination and if in doubt from the slitlamp appearance of the anterior chamber. In the technique described by Van Herrick, et al, a thin slit beam is focussed on the cornea and anterior chamber, at and perpendicular to the temporal limbus and the optical section is viewed at a 60° angle. The AC depth is to be graded against the corneal thickness as “normal, shallow, deep and undetermined”.

The findings are categorised as 1,2,3 and 9, where 1 is normal depth, 2 is shallow depth, 3 is deep chamber and 9 is undetermined.

Any person who is suspected to have glaucoma will be referred to the hospital for further examination.

Section H - Pupil dilation

Protocol for pupil dilatation for detail examination: Those whose vision does not improve to 6/18 or better with refraction in either eye, and all aphakics and psuedoaphakics will have a detailed examination of media and fundus after dilating the pupil. Also if the ophthalmologist suspects that individuals whose vision 6/18 to have open angle glaucoma, retinal or disc abnormalities, their pupils are also to be dilated. Intra Ocular Pressure is measured using Tonometer wherever possible. Based on the results of the Intra ocular Pressure and after assessing the AC Depth, the individual is judged by the ophthalmologist to see if the pupil can be dilated for further examination. In cases where obvious cataract (white, brown) can be confirmed by oblique light examination (with no red reflex) and slitlamp, and anterior chamber is shallow, there may not be a need for dilation and this could also prevent possible angle closure glaucoma.

Pupils are dilated using 1%. Tropicamide until a minimal pupillary diameter of 6 mm is achieved. In a semi dark condition distant direct ophthalmoscopy is performed to examine the

red reflex. After pupil dilation, media (aqueous, lens, vitreous) and fundus are examined with the slit lamp and direct ophthalmoscope.

If pupil was not dilated, record 1 in the box provided and if dilated record 2. Also record whether the dilation was 6 mm. If no, mark 1 and if yes mark 2.

Section I - Lens Status Lens:

There are nine possibilities. Ophthalmologist determines the right one for each eye and enters the corresponding code (1 to 9) in the appropriate box. The lens status is determined by distant direct Ophthalmoscopy and Slit lamp. In case dilated examination is required, follow the protocol for dilation as detailed under Section H. In a semi dark condition distant direct ophthalmoscopy is performed to examine the red reflex. Ophthalmoscope is held at 50 cms from the person who is asked not to look directly at the examiner (usually asked to look at distance slightly to the left or right) and red glow on the pupillary area is examined. If the glow is bright, the lens is clear and cataract has not developed. If the red reflex is present but reduced, early cataractous changes/posterior sub-capsular cataract may be present. If there is no red reflex, one of the causes is cataract. In such cases, there is low vision or blindness for which slit lamp examination and fundus examination by ophthalmoscope will be carried out to rule out posterior segment pathology like vitreous haemorrhage or retinal detachment.

Section J - Cataract surgery details

Type of Cataract Surgery: The type of cataract surgery is to be identified by the ophthalmologist as one of the following and the code number against it has to entered in the appropriate box.

- | | |
|----------------------|---|
| 1 = ICCE | Intra Capsular Cataract Extraction |
| 2 = ICCE with AC IOL | Intra Capsular Cataract Extraction with Anterior Chamber Intra-Ocular Lens Implant. |
| 3 = ECCE - no IOL | Extra Capsular Cataract Extraction |
| 4 = Phaco/SISCS-IOL | |
| 5 = ECCE- PC IOL | Extra Capsular Cataract Extraction with Posterior-Chamber Intra Ocular Lens implant |
| 6 = Others (specify) | |
| 9= Undetermined | |

Incision: The type of incision will be determined by the ophthalmologist as one of the following, and the code number against it will be entered in the appropriate box.

- | | |
|--------------------------|---|
| 1 = Corneal | : Obvious corneal scar is present anterior to limbus. |
| 2 = Corneoscleral/limbus | : Scar is seen at limbus or posterior to limbus. |
| 9 = Undetermined | : Cannot be distinguished. |

Iridectomy: The type of Iridectomy is to be determined by the ophthalmologist as one of the following and the code number against it will be entered in the appropriate box.

- | | | |
|----------------|---|--|
| 1 = Peripheral | : | Opening is visible peripherally. |
| 2 = Sectoral | : | Sectoral/complete Iridectomy is visible. |
| 3 = None | : | No Iridectomy is visible. |

9 = Undetermined

Complication: If any of the following complications are found in the operated eye, the ophthalmologist will mark, 1 not present, 2 if present and 9 undetermined as the case may be.

<i>Iris prolapse:</i>	Iris is seen bulging or captured in the wound.
<i>Vitreous in AC/Wound:</i>	Many times in ICCE, even in uncomplicated cases vitreous herniates through the pupil. If the vitreous is touching cornea or captured in the wound then only it will be marked as complication.
<i>Corneal decompensation:</i>	Cornea is oedematous, or bullae are seen on the surface and it is hazy. If late, deep vascularization might have occurred.
<i>Pupillary capture by IOL:</i>	Pupil is distorted physically by IOL AC or PC
<i>Subluxated IOL:</i>	IOL is not in place but part of it is still visible through undilated pupil.
<i>Dislocated IOL:</i>	IOL is not visible through undilated pupil.
<i>CME</i>	Cystoid Macular Oedema due to intra operative/postoperative reasons.
<i>Post-operative Glaucoma</i>	Increased intraocular pressure due to intra-operative/post-operative reasons.
<i>Uveitis:</i>	Signs of uveitis: redness, keratic precipitates, cells, flare, hypopyon. One or all may be present.
<i>Other (specify):</i>	In this case specify any other complication, which has not been listed

If the eye cannot be examined for complications the reason must be given.

Section K - Fundus

The fundus examination is done using direct ophthalmoscope by the ophthalmologist in a dim room. In cases of very dense cataracts, or if more detailed examination is necessary, the person will be referred to the base hospital where indirect ophthalmoscopy can be performed. The fundus examination is marked as 1 if the lesion is not present, 2 if it is present, and 9 if undetermined for either eye.

Normally in community screening, if the vision is 6/18 or better in the particular eye no further examination is necessary. But as we are examining older population and we are collecting data for a survey, the optic disc has to be examined by direct ophthalmoscope in all cases. If best corrected VA is < 6/18 in either eye, a dilated examination is to be performed if indicated by the ophthalmologist. Refer to Section H for guidelines relating to pupil dilation.

Section L - Principal Cause for Low Vision or Blindness

Low vision is defined, as walking around vision is less than 6/18. Using the best judgement, the Ophthalmologist will determine one cause for each eye thought to be the principal cause. The code against this will be entered in the box provided. While diagnosing cataract, the lens opacity should commensurate with the loss of vision.

Examples:

- 1.If a person presents with glasses and his vision is 6/18 or better, no diagnoses should be marked. His vision may be 6/60 without glasses

2. Red glow is diminished, but his vision is 6/18 or better no cause to be marked.
3. Red glow is diminished, presenting vision is 6/24, 6/60 or 3/60, but vision improves to 6/18 with pinhole or refraction. Principal cause in such case is *Refractive Error* even if cataract is present.
4. *Glaucomatous cupping with cataract*: If the lens opacity does not explain visual loss, then mark Glaucoma. Same is the case in presence of maculopathy.

Only one condition has to be marked as the principal cause of low vision/blindness in either eye.

If there any other contributory causes, record 1 and if yes, record 2 in the box provided. If yes, the two main causes may be marked in the appropriate order as per the list given under principal causes.

Section M - Current Action Needed

This section relates mainly to the intervention necessary for the individual and its provision will be co-ordinated by the DBCS. If no action is needed, record 1 in the box provided. If action is needed, record 2 and also tick the appropriate boxes. Those who are < 6/60 because of high refractive error in either eye and others upon request are to be given prescription and glasses will be provided by the DBCS.

If YES,

Cataract surgery: Refer to the hospital by providing a referral slip. It is presumed that cataract surgery is marked only if there is satisfactory light perception, accurate projection of light and pupillary reflex. All patients with visual acuity less than 6/60 in either eye and diagnosed with cataract will be referred for cataract extraction surgery.

Eyelid surgery: Refer to hospital

Glaucoma surgery: Refer to hospital

Referral to Hospital: If further investigations or treatment are indicated which have to be done only in the hospital

For Posterior Capsule Opacification in Aphakes/Pseudoaphakes: Refer to hospital for YAG laser.

For uncorrected Aphakia: Provide the most suitable aphakic glasses.

Others: Specify under remarks.

Section N – Remarks

Make diagrams of conditions not listed that you want to illustrate and write down description or comments.

Ophthalmic Assistant Quality Assurance: Form No. 4

This form is to be filled for monitoring inter-observer agreement as part of quality control. This form will be filled as per the guidelines given under section A, B, and D in Form

3. The pre-printed value of 2 in the box labelled QA in section-A indicates that this person needs to be examined by the second ophthalmic assistant.

9. Information Management

9.1 Data Collection:

As per the study design and the data requirements, all the data will be collected in the field itself. There are 3 different forms in total for data collection. Data for Form-1 will be collected and filled by supervisor/enumerator at the end of the data collection in a cluster. The enumerator will fill the Form-2. After finishing the enumeration the clinical team will visit to the central site to examine all the enumerated persons 50 years and the findings will be recorded in Form-3 (Eye Examination Record). The ophthalmic assistants will fill vision, intra ocular pressure and refraction data in Form-3, while the rest will be filled by the ophthalmologist. In addition to the above three forms, there is a form 4 which is for inter observer agreement between ophthalmic assistants as part of the quality assurance and will be administered only in five randomly selected clusters.

In summary the following table shows the data collection system:

Form No:	Form Description	Respondent	Person responsible
Form No: 1	Cluster level form	Based on secondary data and summary of individual forms	Supervisor/ Enumerator
Form No: 2	Household form	All the households from the sampled cluster	Enumerator
Form No: 3	Eye Examination record	All individuals from the sampled cluster with age 50 yrs	Ophthalmologist & Ophthalmic Assistant
Form No: 4	Quality assurance	Individuals as per the protocol from the 5 randomly selected clusters for ophthalmic assistant quality assurance	Ophthalmic assistants

9.2 Data Forms management:

During the enumeration process, as each household is completed, the supervisor will do a quick check to see that all data is collected and is accurate. Similarly during the eye examination at the central site also as each person completes the eye exam, one of the enumeration staff assigned will check to ensure that all-relevant data has been collected. Missing data and mistakes are rectified after consultation with the concerned person.

When the data collection at a survey cluster has been completed, the forms will be arranged for each cluster by household number and person number. These will be well packed in the same sequence in a water proofed plastic bag for transportation to the central office. In central office the forms will be unpacked and checked to ensure that all forms have been received as in the cluster summary form (Form-I) and will be signed by the Survey Manager.

9.3 Data Editing:

Before sending forms for data entry in the field, the forms will be edited and cross-checked for completeness and consistency. If the forms are not filled completely, the concerned person will be consulted to fill in the missing data or clarify an inconsistent data. It is recognised that this process is done with minimum time delay. Most of the variables have the codes mentioned in the forms itself. However some of the fields (with descriptive data) may require coding and this will be done in the Central Office after the entire data collection and entry is completed. All changes and coding made either in the field or in the central office will be made in ink by crossing out the original data and recording the new data beside it. It will be signed and dated by

the person making the changes. Over writing shall be avoided.

9.4 Data Entry & Analysis

Data entry and analysis will be done by the Central Ophthalmic Cell and Directorate General of Health Service.

10 Quality Assurance

10.1 Inter & Intra observer agreement:

Assessing the consistency and inter-observer agreements of measurements is a central part of quality assurance. While it may not be necessary or practical to do this on each and every variable it should be done on all critical variables. In clinical examination, the critical variables are:

Ophthalmic Assistants:	Visual acuity and refraction
Ophthalmologists:	Diagnosis of lens status
	Diagnosis of Cause of low vision/blindness

As part of the training and standardisation the study ophthalmologists and a senior ophthalmologist considered the ‘gold standard’ will independently examine about hundred persons (fifty persons have visual acuity 6/18, other fifty persons have visual acuity is < 6/18). One ophthalmologist does not know what other ophthalmologist has diagnosed. The clinical forms will be then matched and analysed using the Kappa statistic to see the inter observer agreement. Similarly the two ophthalmic assistants will independently examine the visual acuity in about hundred persons (fifty persons have visual acuity 6/18, other fifty persons have visual acuity < 6/18). The inter-examiners repeatability will be analysed, again using the Kappa statistic. These can be patients from the hospital itself and those in the pilot studies.

In order to assess both inter and intra-observer variation data will be collected during training, pre pilot and pilot studies. The data will be analysed and presented for review to the Technical Advisory Committee.

As part of quality assurance for the main study, five out of the 25 clusters selected for the main study, will be randomly selected for inter observer agreement between ophthalmic assistants for visual acuity and refraction. This data will be recorded in Form- 4. This data should be analysed for each of the variables and presented as shown in the eg. below with the Kappa statistic.

AGREEMENT BETWEEN OPHTHALMIC ASSISTANTS ON VISUAL ACUITY ASSESSMENT.

	2 nd Examiner				
	6/19	6/60- <6/19	3/60- <6/60	<3/60	Total
6/19					
6/60 - <6/19					
3/60 - <6/60					
<3/60					



Total					
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10.2 Quality Assurance in the field:

While training and constant monitoring can achieve the desired quality in the study staff, a similar approach has to be taken in the case of equipments used in the study. These will be of standard quality and regularly maintained and calibrated.

1. **Visual Acuity:** In order to obtain consistent Visual Acuity, back illuminated ETDRS chart boxes will be used. The distance between the chart and the person being examined must be measured by a tape and marked for each site.
2. **Measuring Intra-Ocular Pressures:** A Perkin's tonometer will be used for this study.
3. **Slit lamp & Ophthalmoscope:** Standard equipment with good optics and illumination will be used. These will be checked and cleaned each day, as they will be used in rough conditions in the field.

10.3 Response rate:

The second aspect of quality in a field survey is the response rate. Higher the response rates more valid the study becomes. This is a challenge when you recognise that a vast majority of the persons who are required to come for examination will have normal vision. Results from studies with low response rates are subject to a lot of speculation. Thus getting a high response rate of around 95% should be the aim. Some of the strategies and steps to achieve this are:

- Getting good co-operation from the village elders. Hence the time spent to describe the study and enlist the support is very important and should be done well taking into account the local leadership dynamics and other factors.
- The location of the central examination site and the examination timings must suit the villagers
- At the examination site closely monitor who has come and who hasn't. This can be done by checking the name in the household folder as a person comes along. All the names not checked indicate non-attendance. In addition to the enumerator and the village volunteer making frequent visits to bring in the patients, and we will also elicit the help of neighbours who have come to the examination site. In quality assurance clusters, all eyes <6/18 and 10% of normals (vision 6/18), will have duplicate visual acuity assessment. Duplicate retinoscopy will be done in 10% of eyes < 6/18.

10.4 Pilot Study:

Another aspect of quality is adherence to the protocol. A lot of preparation is required to be able to adhere to the protocol. This can be felt once the study enters the field where there are many uncertainties and situations not under our control. If one goes to the field directly, then the first few sites will become the learning ground and in most instances either the data collected will be unreliable or a lot of logistical difficulties would have been encountered. In order to avoid it, a Pilot study is necessary. Following this time must be taken to formally review the data and the field procedures. In addition to this daily review meeting in the early stage also helps in the smooth implementation of the study.

11. Service delivery & Ethical Considerations

This is a research study & it is important to meet the ethical considerations. When we come across a blind person during the survey, it is important that necessary service is provided. Thus during the survey, all persons who are blind (VA < 6/60) in either eye should be thoroughly evaluated and appropriate action should be taken or arranged. The following may be the causes and the corresponding action is indicated:

Cause of blindness (VA < 6/60) Action

In either eye

Cataract	Refer to hospital and provide free surgery
Refractive error	Provide spectacles free
Incurably blind in both eyes	Refer to rehabilitation services
Other reasons	Refer to hospital for more detailed examination and further management

Extra efforts will need to be taken in the case of bi-laterally blind, by follow-up visits if necessary, to ensure that they receive the required services. The following formats will be used for referring patients to the hospital and for monitoring the service delivery.

For ethical considerations, the protocol was reviewed and approved by the "The Institutional Review Board" of R.P.Centre, AIIMS, New Delhi and by ICMR.

11.1 Form for referring patients to an eye hospital for further management:

Dear Dr.		I am referring the following	
patient to you for further management.		Referred to:	
Patient Name:		Age:	Sex:
Cluster Name:		Cluster No:	Household No:
	Right Eye	Left Eye	
Vision			
Diagnosis			
Notes on further action required:			
Signature & Date			

11.2 Format for monitoring service delivery - Cataract surgery:

Fill in details of those who are blind due to cataract (VA < 6/60) in either eye.

Sl.	Name	Cluster	HH	Blind eyes		Date Referred	Status
				One	Both		
1.							
2.							
3.							
4.							

Under "Blind eyes" tick the column under "one" if unilaterally blind and the column "both" if bilaterally blind.

11.3 Format for monitoring service delivery - Provision of free Spectacles

Applies to only those who are blind in either eye due to refractive errors.

Sl.	Name	Cluster	HH	Date prescribed	Date Delivered	Signature of Patient
1						
2						
3						
4						

11.4 Service Delivery budget:

In most institutions, free services are provided to the poor patients. DBCS will coordinate services to those who are detected with visual impairment or any other ophthalmic problems.

Annexe - A (Using ETDRS Chart)

The ETDRS (Early Treatment for Diabetic Retinopathy Study) E chart will be used to measure the VA. This chart is made of non-reflective white polystyrene material and is installed in light box illuminated by fluorescent tube lights. The chart is retro illuminated luminescence of 150 cd/m² or greater.

This chart is placed at a distance of 4 meters from the measuring eye of the person. There are 5 letters (E) in each row of the chart. The person undergoing the test must correctly recognize at least 4 letters in order to get the score for the line. There are 14 (rows) lines in the chart but only the top 11 lines are used for testing. Being able to read the 11th row from the top is considered as a normal VA. of 6/6. This line represents the minimum angle of resolution that a normal eye should have. When there is a need to test a person from 1 meter only the top 6 lines are shown for the test and recorded in different fractions such as 1/60, 2/60, HM, FC, PL and NPL.

Room illumination: Ideally, the standard ambient room illumination for the VA screening room is 100 lux.

Distance: In ETDRS, the VA is measured at 4 meters and 1-meter distances. Hence in each examination site, marking must be made on the floor indicating the position of the chart, 1 meter and 4 meters from the chart position. A chair is positioned from the person so that it is in perfect line with the center of the chart.

Person: Seat the person comfortably in the seat and explain the procedure. Measure the VA in one eye at a time with the other eye covered. Start with the Right Eye. The other should be covered gently but not pressed as it can affect the VA measurement of that eye. Please make sure that the person is not squeezing the eye into a slit as it can produce a pinhole or slit effect.

Procedure: VA measurement is started from the top line (6/60) of the chart in order to familiarize the person with the chart. If the person can see all the letters of the top line, then jump to the middle line (6/30). If this line is also recognized correctly, then go to line 6/15 down to 6/6. One letter misread in the line will be considered complete. If more than one letter is misread, then go up one line, if it happens again. If a person is unable to read the top line at 4 meters, then move the person close to the 1-meter position and repeat the test.

Recording the Visual Acuity: Against each line in the ETDRS chart, the visual acuity in different systems is shown. Since the study is being done in India, following the local convention, “meter equivalent values” will be used in the study. When measuring the vision from 4 meters, directly record the VA corresponding to the last line read correctly (minimum of 4 out of 5 letters). If the measurement is done at 1 meter, use only the top six lines, and depending on the last line read correctly, record the values as 1/60, 1/48, 1/38, 1/30, 1/24 or 1/19 where 1/60 corresponds to the top line and 1/19 corresponds for the 6th line. If a person is unable to read the first line at 1 meter, perform tests like Finger Counting, Hand Movements, and Perception of Light and record the findings as FC, HM, PL or NPL.