



# Guidelines for the Management of Cataract in India

Revised in August 2020

A VISION 2020: The Right to Sight INDIA Publication

Cover photo -

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Under the aegis of Knowledge Hub initiative of  
VISION 2020: The Right to Sight-INDIA

Developed by

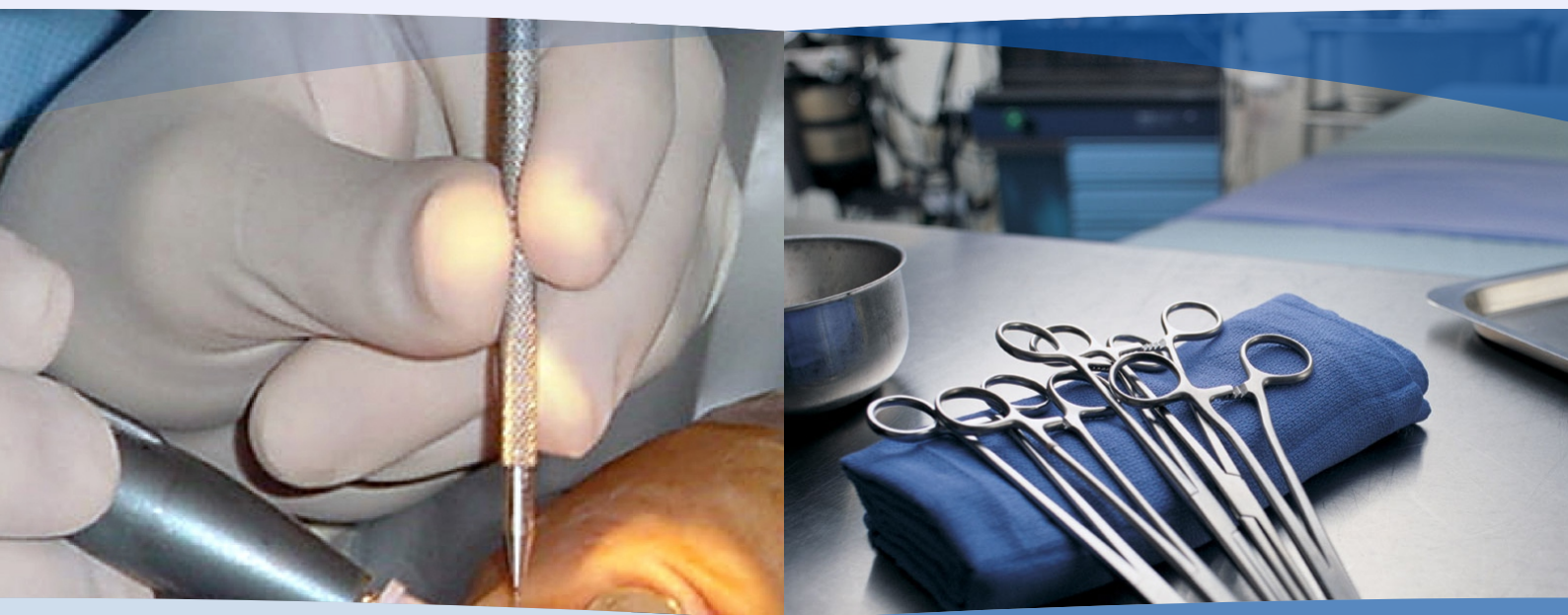
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August 2020 All illustrations and graphic designs by Indus D'Sign

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# Guidelines for the Management of Cataract in India



A VISION 2020: The Right to Sight INDIA Publication



First Edition: October 2011

Conceived and developed with support from





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## **FOREWARD**

Our Country has been able to bring down the prevalence of Blindness to 0.36% (RAAB Survey 2015-2019), since the launch of the National Programme for Control of Blindness more than 4 decades ago, when the prevalence of Blindness was 1.34% in India. However, Cataract still remains the largest cause of visual impairment and avoidable blindness (66.2%) in India. The focus today is on quality surgery with maximum postoperative visual gain. To substantially reduce the national backlog of cataract without compromising on quality, it is imperative to stick to certain minimum quality standards. Hence a manual on guidelines for Cataract Surgery was published by Vision 2020: Right to Sight, India in 2011.

There has been a vast change in the techniques of cataract surgery and Ophthalmic equipment used for management of cataract cases in this last decade. I congratulate Vision 2020: Right to Sight, India on bringing out this updated issue of the guidelines for management of cataract in India. They are quite comprehensive and incorporate the pros & cons of the various techniques and equipment being used in cataract case management. They will be a valuable tool for Managers, Ophthalmologists and Paramedics in reducing the burden of cataract blindness.

Let us all join hands in our endeavor to set India free from avoidable blindness.

  
(Dr. Promila Gupta)





## FOREWORD

Cataract is the commonest cause of blindness and the second common cause of moderate to severe visual impairment in the world. Cataract blindness is avoidable and surgical intervention can effectively restore visual impairment. It is the first major intraocular surgery taught in ophthalmology residency training. Often times the efficiency of eye care programs is measured by three parameters, all connected to cataract surgery and outcome—the Cataract Surgical Rate, the Cataract Surgical Coverage, and Effective Cataract Surgical Coverage. The indicators of effective coverage of cataract surgery have been included in the World Health Organisation Universal Health Coverage index. Two deterrents to an increase in CSC are unaffordable cost and suboptimal quality.

Quality in health care is a broad compass. The elements include effectiveness, safety, people-centred service, timeliness, equity, integration with systemic care and efficiency. In order to address these seven elements one needs evidence-based guidelines applicable to the entire range of health workers. The new cataract surgery guidelines prepared by VISION 2020: The Right to Sight- India is a sincere effort to meeting these goals. All guidelines need periodic revision in league with the change in technology and techniques, and new evidences for safe practices. The current guidelines are the revision of the one made a decade ago. This is very comprehensive, and covers the entire range from pre- to postoperative care for cataract surgery including many new areas in clinical care and hygiene. The new edition would be valuable guide to all health personnel in eye care in India.

A handwritten signature in black ink that reads "Taraprasad Das".

Dr. Taraprasad Das  
President, VISION 2020- India  
Regional Chair, IAPB South East Asia  
Vice Chairman, L V Prasad Eye Institute

May 23, 2020







# All India Ophthalmological Society

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Prof. S. Natarajan

## **Foreword from All India Ophthalmological Society**

Cataract is the leading cause of blindness in people above 50 years, according to the National Blindness and Visual Impairment Survey India 2015-19. In the year 2018-2019, 669083 cataract surgeries were performed in the country. Thus in volume interventions done, this towers over all other interventions in Ophthalmology.

This sheer scale makes certain aspects of cataract treatment particularly important. These aspects are Quality, Replicability and Consistency. A direct tangible outcome of achieving these is more predictable outcomes, which translates into greater advancement towards blindness removal. In my experience a large part of making these things work is actually standardisation following well tested and feasible protocols. The various facets of cataract treatment right from diagnosis, surgery to follow-up benefits immensely from widespread dissemination and adoption of standard best practices. This is where this current document fits in so well.

This revised manual came in after 9 years of the first manual and the efforts of VISION 2020 are commendable in completing this herculean task. In last 9 years, ophthalmology has undergone revolutionary changes, and there have been paradigm shift in the management of Cataract Surgery with new techniques and technologies coming in. This comprehensive manual on Cataract Surgery is an useful resource for the whole ophthalmic community and can be widely used at the all level of ophthalmic care including vision centres, primary health care centres and the apex institutes as well. With the addition of operation theatre sterilisation in the same volume, VISION 2020 has addressed a major point.

In summary, this volume on Cataract Surgery protocols and OT sterilisation is a much needed compilation of key protocols that will hopefully make these more widely available to the entire body of organisations and individuals engaged in cataract treatment. This manual will serve as a companion to all to serve their patients effectively and efficiently.

I congratulate VISION 2020 on this august endeavour and express faith that practitioners will find this beneficial.

Sincerely

**Prof. Namrata Sharma**  
Hony. General Secretary

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26/05/2020

On behalf of ISMSICS, we are very happy that VISION 2020 is publishing revised the guidelines for cataract surgery. All the aspects in Cataract Surgery have been attended to with meticulous details. This guideline should be a good source of information for every cataract surgeon. ISMSICS endorses very much these guidelines.

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# Acknowledgments

## (Second Edition)

The development of the Guidelines for the Management of Cataract in India edition 2 was initiated by the Knowledge Hub of VISION 2020: The Right to Sight – INDIA (VISION2020INDIA) as an update to the Cataract Manual brought out in 2011.

The manual was made possible by the collective effort of the designated technical team who dedicated their quality time for this project. We were fortunate to gain from the team's rich individual professional experiences in making the revised guidelines a comprehensive and useful current reference.

VISION 2020: The Right to Sight-INDIA extends its deepest appreciation and a sense of gratitude to the technical team that worked on revision of the Guidelines for the Management of Cataract in India. The technical team put - in a well-coordinated effort and efficiently brought out the revised version during 2019-2020.

The technical team comprised of **Dr. Uday R. Gajiwala**, Superintendent, Tejas Eye Hospital, Mandvi, Gujarat; **Dr. Asim Sil**, Medical Director, Vivekananda Mission Asram Netra Niramay Niketan (VMANN), Haldia, West Bengal; **Dr. Noopur Gupta**, Assistant Professor of Ophthalmology, Cornea, Cataract & Refractive Surgery Services, Dr. R P Centre, New Delhi; and **Dr Mahesha S**, Medical Director, Sankara Eye Foundation, Shimoga, Karnataka.

VISION 2020 INDIA would like to especially thank Dr. Uday Gajiwala for leading this initiative. His valuable wholesome perspective, technical expertise, referring to other existing guidelines, and laborious task of compilation of various inputs at different points in time, are highly appreciated.

VISION 2020 INDIA sincerely expresses its gratitude to Dr Noopur Gupta, Dr Mahesha and Dr Asim Sil for their invaluable time, technical expertise, constant cooperation, ideas, complete document review and final edit of the guidelines. Their meticulous review of the guidelines specifically on issues with references finds a special mention. A special thanks to Dr Noopur Gupta for developing an extract from “Ophthalmic Practice Guidelines in the Current Context of COVID-19” developed by AIOS for this guidelines.

VISION 2020 INDIA acknowledges All India Ophthalmic Society's contribution by permitting us to include the extract from its guidelines on Ophthalmic Practice Guidelines in the Current Context of COVID-19 for this cataract guideline.

We thank Orbis India for supporting the printing of this guidelines.

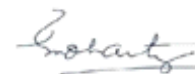
With deep appreciation



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# Acknowledgments

## (First Edition)

The development of these guidelines was initiated by Sightsavers and is the culmination of consultations with partners, experts and Sightsavers staff to look at best practices for the management of cataract.

It would not have been possible to develop it without the support and generous time provided by several individuals. We are very thankful to Dr Uday Gajiwala of SEWA Rural and Ms Tanuja Joshi of Venu Eye Institute and Research Centre for developing this document with their teams. Their wisdom and knowledge have contributed to a learning that has tremendous implications on the scope and quality of cataract services.

We are grateful to Dr R Ravindran, Chairman of Aravind Eye Care System, Dr Taraprasad Das, Director of LV Prasad Eye Institute, Bhubaneswar and Dr Sara Varughese, Programme Manager (Disability and Rehabilitation) of World Health Organisation for their technical expertise in reviewing and finalizing this document.

We appreciate the leadership and encouragement of Ms Sujaya Krishnan, Joint Secretary and Dr NK Agarwal, Deputy Director General (Ophthalmology), Ministry of Health and Family Welfare, Government of India in our efforts to eradicate avoidable blindness from India.

We very much value the participation of various hospitals in India, many of them VISION 2020 INDIA members, in developing these guidelines, and are thankful to them for their generosity in sharing their experiences and learning.

We appreciate the valuable inputs from Sightsavers, especially Ms Elizabeth Kurian, Regional Director India and Mr Pankaj Vishwakarma, Head of Programme Development, in the conceptualization and development of this document that is a useful reference guide for the management of cataract.

Dr. Col. M. Deshpande VSM  
President  
VISION 2020: The Right to Sight - INDIA  
October 2011



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| Standardisation

Every organisation strives for value and volume growth. These are primarily driven by better quality of service and products, higher volumes of satisfied clients and sales. Safety and sustainability play a major role in creating high value and volume. These goals can be achieved by standardisation of all processes and procedures.

### **How does standardisation help?**

It helps through six important factors:

1. Enhanced efficiency
2. Improved monitoring
3. Reduced complications
4. Cost effectiveness
5. Replication
6. Costing and budgeting

### **Standardisation enhances efficiency.**

As all members of a team are trained and aware of standard protocols, they are able to identify deviations as soon as they occur and rectify. In absence of the team leader, the team can continue to work efficiently by adhering to the standard protocols. Any and all members of the team can participate in training and orientation of the newcomers.

### **Standardisation helps monitoring.**

Regular monitoring of results helps quality enhancement, as early detection of complications and their causes can help in timely and relevant interventions.

### **Standardisation helps reducing complications.**

On most occasions, complications occur due to deviation from protocols. When protocols and procedures are standardised and implemented, even minor deviations can be identified and steps for rectification introduced. Timely identification and immediate management of complications can help in reducing morbidity.

### **Standardisation increases cost effectiveness.**

Institution of standard procedures leads to adoption of standard instruments, equipment and consumables. This way, not only can the inventory be controlled more efficiently, bulk purchases of these items and spares can be negotiated for competitive rates, thereby helping in cost containment.

### **Standardisation helps replication.**

Once the procedures and protocols have been standardised, they can be easily documented and effectively implemented. The major advantage being standardised application and implementation anywhere, either in the same organisation at different locations or in an external organisation involved in similar work.

### **Standardisation helps costing and budgeting.**

Standardisation of procedures and a controlled inventory helps in assessing the cost of services at various levels. This helps at the time of planning for new projects, as the costs and budgets can be worked out more effectively.

### **Standardisation: Limitations**

Standardisation of procedures means a uniform adherence by all staff working in an organisation, leaving no room for personal preferences or choice. Standardisation of course leaves little room for innovation. Hence standards and protocols should be periodically reviewed and upgraded when required.

### **What all can be standardised?**

In a service oriented organization, the following can be standardised.

1. Documentation
2. Reporting
3. Monitoring/Audit
4. Instruments and equipments
  - a. Inventory
  - b. Purchase procedures and schedules
  - c. Maintenance schedules
5. Consumables
6. Procedures and protocols
7. Training programs

# | Cataract Surgery Modules



1. Case selection for cataract surgery
2. Pre-operative protocol for assessment for cataract surgery
3. Pre-operative protocol for management of systemic disease
4. Biometry
5. Surgical protocol for cataract surgery
6. Post-operative protocol for management of uncomplicated cases

# 1

## Case Selection for Cataract Surgery

### 1.1 Decision making

Cataract is a common condition of the elderly causing visual impairment. However, the key for deciding towards a cataract surgery is to determine whether the cataract is responsible for functional disability for an individual or not. Careful history taking is important for assessing the decrease in quality of vision and quantity of the visual impairment exclusively due to cataract. Occupational and functional needs of the patients should be taken into consideration before planning for surgical intervention. Before selecting an individual for cataract surgery, symptoms like reduced visual acuity, glare, photophobia, diplopia/polyopia, frequent change of spectacles (usually index myopia in progressive nuclear sclerosis) should be explainable by the changes in the lens. It is important to conclusively correlate the amount of visual loss and the symptoms narrated by the patient to the grade of cataract.

History should also include medications currently being used, other risk factors and ocular comorbidity like glaucoma and retinal disease that can affect the surgical plan or outcome of surgery. Medical history about systemic diseases is important. Patients should be asked about any allergy to any food or medicine.

### 1.2 Indications for surgery

Blurred vision, the letters in the vision chart not seen clearly by the patient are the most frequent indications for a cataract surgery.

#### **Primary indication**

An individual unable to carry out his desired activities due to dimness of vision for which cataract surgery is likely to restore the visual function.



### **Secondary indications**

1. Clinically significant anisometropia in the presence of a cataract where cataract surgery is likely to facilitate binocularity
2. The lens opacity is dense enough to interfere with evaluation and management of posterior segment conditions like diabetic retinopathy, age related macular degeneration
3. Lens induced ocular inflammation or raised IOP corneal decompensation

### **1.3 Contra-indications for surgery**

1. Patient not convinced about surgery
2. Patient has satisfactory functional vision with refractive correction
3. Cataract surgery is unlikely to improve vision
4. Concomitant Nasolacrimal duct blockage with infection
5. Any other local or systemic infection
6. Patient is medically unfit

### **1.4 Timing for surgery**

1. Cataract surgery within a month- in cases of bilateral cataract and fellow eye vision  $> 6/60$
2. Cataract surgery within a week- in cases of bilateral cataract and fellow eye vision is  $< 6/60$
3. Cataract surgery immediately – in cases of affected eye vision is Finger Counting Close to Face (FCCF) and cataract is advanced
4. If surgery is needed in both eyes, it is better to keep a gap of one month between the two. Sometimes early surgery is needed because of hyper mature cataract.



## Summary

While it is true that cataract is only an aging process and today's technological advances enable safe surgery with good outcomes at any stage of cataract, both subjective and objective criteria should be considered before advising surgery. Involvement of the patient and the family in the decision-making process is important.



# 2

## Pre-operative Cataract Surgery Protocol

### 2.1 Examination of vision function

**Presenting visual acuity** with present correction (if glass is available, the power of the present correction should be recorded) or without glass at distance and when appropriate at near. In advanced and mature cataract, **perception of light and projection of rays** should be tested in all the four quadrants to rule out gross retinal problems. Pupillary reaction should be noted. **Two point discrimination test** and **colour perception** helps in assessing the macular function.

**Measurement of best-corrected visual acuity (with refraction, at least with pin-hole) should be done.**

Refraction of the other eye is mandatory to decide biometric power. Biometry of both eyes should be done and any difference between the two should raise a concern.

### 2.2 External Examination

**External examination** (lids, lashes, lacrimal apparatus, orbit). Pressure should be applied over the sac to look for any regurgitation. If regurgitation is positive or dacryocystitis is suspected, syringing of naso-lacrimal duct should be carried out. Syringing may not be required in the presence of purulent regurgitation - DCR/DCT may be done. Syringing in case of post DCT/DCR status. Pooling, matting if patient complains of watering / discharge.

If duct is not free, and has mucus or purulent discharge, DCT or DCR is advised and cataract surgery to be scheduled after one month of successful DCR. If surgery is planned within 24 hours of initial examination of the patient, ROPLAS should be sufficient. It is better to avoid syringing as it may cause undue trauma and dislodge microorganisms which were otherwise dormant. In case of hyper mature cataract, surgery may be performed a week after successful DCR/DCT with appropriate antibiotic prophylaxis.

**Examination of ocular alignment, fixation pattern and motility. This is important for prognostication.**

### **Assessment of pupillary reaction, shape and size**

**Measurement of intraocular pressure** (preferably Applanation, else non-contact tonometer can be used, if not available at least by Shiotz Tonometer). Any contact procedure should better be avoided on the day of surgery.

**Slit-lamp biomicroscopy** of the anterior segment. Special emphasis should be made to assess the corneal thickness, endothelium for any guttata, anterior chamber inflammation, pupil for pseudo exfoliation and the lens for any preoperative compromises on stability. i.e. any evidence of subluxation.



**Gonioscopy** if anterior chamber appears shallow, IOP is raised, presence of any sign that can be related to secondary glaucoma (e.g. pseudo exfoliation), known cases of glaucoma.

**Dilated Examination** of the lens opacity may reveal the extent of visual impairment. For example, opacity in the visual axis may cause more functional visual deficit than a cortical cataract and the posterior sub-capsular opacity may cause more symptoms of glare than a nuclear cataract. It helps in grading nuclear sclerosis, reveals any subluxation. Measuring the amount of maximal dilation helps in planning the surgery, especially in cases of non-dilating pupil. Dilated examination of the optic disc, macula and vitreous is facilitated. If

clarity of media allows, peripheral retina should be examined. Indirect ophthalmoscopy is indicated for known myopes, diabetics, eyes with past history of trauma, eye with uveitis, RD in the other eye. Dilatation of the pupil should be recorded in mm.

**Specular Microscopy** is optional. It is recommended in the following conditions.

1. Corneal thickness appears more than usual
2. Corneal endothelial changes (guttae) and pigment dispersion noted on slit lamp examination
3. Pre-existing corneal opacity
4. Bullous keratopathy/corneal decompensation in the other eye
5. If phacoemulsification is planned in nuclear sclerosis more than grade III (hard cataract).
6. Age more than 80 years and phacoemulsification is planned
7. Secondary IOL implantation/IOL exchange

**OCT** is not a mandatory routine procedure before a cataract surgery to investigate the status of macula. If there is obvious maculopathy clinically, OCT helps in decision making and counseling. Usually not recommended.

**USG** – B scan Ultra Sonogram of the posterior segment is indicated in all cataracts where fundus cannot be visualized and PR is defective, in traumatic cataracts, complicated cataracts and unilateral mature cataracts. For a routine senile mature cataract, a thorough clinical examination and explaining prognosis to the patient is sufficient.

Assessment of relevant aspects of the patient's **mental and physical status is essential.**

Following basic tests are mandatory before a cataract surgery

1. Blood pressure – 140 / 90 mm of Hg
2. Blood sugar – In case of non-diabetic patients, RBS < 200 mg / dl. In the case of diabetic patients, fasting <140 mg/dL. HbA1C is advisable/ Below 7 % is non diabetic
3. Biometry
4. Patency of NLD – preferably ROPLAS, where not possible, syringing. In case of matting of eyelashes / discharge or pooling of tears with a history of discharge from the eye, syringing is recommended
5. Physician's opinion if systemic condition demands

## 2.3 Additional investigations for LA

ECG for adults (known cardiac patients, and those with history suggestive of cardiac ailments), very old patient (>70 years)

## 2.4 Additional investigations: for GA cases

1. Blood count, Hb%
2. Serum electrolytes (In high risk cases)
3. ECG, chest x-ray for adults
4. Pre-operative evaluation by anaesthetist.

### **Conjunctival culture is required in the following cases**

- a) One- eyed patients with any doubt about infection of conjunctiva or lid
- b) Prior Dacryocystectomy (DCT) residual signs of infection (discharge, matting of lashes etc.)
- c) History of chronic infection e.g. blepharitis, moderate to severe meibomitis
- d) Recently healed corneal ulcer

All patients should be preferably seen by the operating surgeon. If not feasible, the surgeon then must examine all one-eyed patients, especially those with associated complications requiring deviation from regular surgical technique and those posted for re-surgery.

Note down the surgical plan and any other important relevant clinical points for other members of the team. Use alert stickers for common safety issues.

## 2.5 Pre-operative counselling

Prognosis of surgery should be clearly explained to the patient in a language understood by him/ her and documented. The explanation should include details about anaesthesia and surgical procedure, the level of pain/suffocation they may experience during surgery specifically after draping the patient, possible conversion to routine ECCE/SICS with IOL in cases with small pupil, hard lens or advanced cataract who have opted for phacoemulsification. The operating surgeon may adopt any technique that will be safe for the patient.

Further, the explanation should be about the importance of the post-operative follow up and state the Do's and Don'ts in the immediate post-operative period. Group counselling might be appropriate and it is necessary to encourage questions.

Develop a proper consent form in local language. Explain the content in detail and get it properly signed. Written informed consent in patient's local language explaining the risks involved and the benefits expected to be signed by the patient and his / her relative in presence of a witness. The form is to be signed by the concerned nurse and ophthalmologist.

## 2.6 Pre-operative preparation

One eyed patient should be specially identified for extra care

2. One eyed and diabetic patients to be given preference in surgery list
3. All patients should wash their face with soap and water
4. The patients (at least from outreach camps) should be encouraged to take a bath with an antiseptic soap and to wash their hair
5. Hair cut and shaving (for men, where religion permits) prior to surgery
6. Clean clothes to be worn; change of street clothes to OR clothes is mandatory
7. For patient identification there are several methods in use – wrist band, identification badge for the patient etc. and for the identification of the eye – marking the eye with marker pen, pasting an adhesive strip on the eye to be operated, wrist band etc. are in use
8. Patient identity and the eye to be operated should be verified by the nursing staff at the time of sending the patient to the OT; by the staff giving block at the time of giving block and by the surgeon and assistant just prior to the operation. (WHO check list OR surgical safety checklist annexed at the end of the manual can be used for the purpose)
9. The clipping of eye lashes is no more practiced after hospitals have started using plastic drapes
10. The ward nurse should clean the brow region and lid margin with 10% povidone iodine solution
11. Broad spectrum topical antibiotics (such as Fluoroquinolones, Chloramphenicol) may be used during the pre-operative period. The recommendation is antibiotic eye drops six times a day prior to the surgery and every 20 minutes for two hours prior to surgery. However, recent ESCRS guideline does not consider topical antibiotics mandatory preoperatively. Instead, use of 5% povidone iodine eye drop is considered equivalent to topical antibiotic for 24 hours pre operatively
12. Diazepam 5 mg or similar anxiolytic medications may be considered for very anxious patients. It could be more useful in hypertensive patients along with their already prescribed anti-hypertensive medications
13. Povidone Iodine 5% topical applied in the conjunctival sac 5 minutes before surgery is the most important pre-operative measure
14. There is no evidence to suggest that pre-operative oral or parenteral antibiotics are useful. Antibiotics whether topically or orally, should be used very judiciously. The highest / latest antibiotic should be reserved for treating actual infection rather than using it for prophylaxis. Use of antibiotic should be as per hospital's antibiotic policy. The principles of antibiotic stewardship in the interest of preventing antibiotic resistance should be followed
15. Tropicamide 1% eye drops; 1 drop every 20 minutes - 2 to 3 times, about 90 minutes before surgery
16. Plain Tropicamide 1% for hypertensives and cardiac cases-preferably use for all cases to avoid mishap in undiagnosed cases
17. Ketorolac 0.5% eye drops 3 times every 15 minutes or nepafenac 0.1% twice a day for 3

days prior to surgery to sustain the pupillary dilatation and to minimize post-operative cystoid macular oedema, may be preferred

18. Ocular medications like PGA (used for glaucoma) may increase chances of inflammation as well as CME. It should be stopped at least one week before surgery at least in high risk cases – CME in other eye, posterior capsular tear in other eye etc. and switched over to some other antiglaucoma agent
19. Patients receiving Tamsulosin for benign prostate hypertrophy may be treated with atropine drop before cataract surgery. Pupil dilating mechanisms or iris hooks should be kept handy during surgery
20. Constrict pupil for secondary AC IOL implantation
21. Light food before surgery is advisable

## 2.7 Infection prophylaxis

Greatest concern for an ophthalmologist after successful surgery is the occurrence of endophthalmitis because of its serious consequences. Prevention remains the best measure to avoid it.

Risk for endophthalmitis can be lessened by reducing the number of microorganisms on the ocular surface. It minimizes the chance of contamination during or after surgery.

Prophylactic strategies that are commonly practiced include using topical antibiotic eye drops before surgery, applying 5% povidone iodine to the conjunctival cul de sac, preparing the periocular skin with 10% povidone iodine, careful sterile draping of the eyelid margins and eyelashes, adding antibiotics to the irrigating solution, instilling intracameral antibiotics at the close of surgery, injecting subconjunctival antibiotics and applying topical antibiotic eye drops after surgery.

Studies recommend use of a 5% solution of povidone iodine in the conjunctival sac pre-operatively as a very effective measure to prevent infection. Rest of the strategies is up to ophthalmologist's own decision.

Taking care of personal hygiene of the patient is very important. A thorough face wash/bath before surgery is recommended.

A surgeon should adhere to strict aseptic surgery techniques. Pooling of fluid at the medial angle of the eye during surgery should be avoided by proper head positioning.

Wound construction and closure should be meticulous. The surgery should end with a water tight incision and the surgeon should not hesitate to put sutures for security.

Toxic Anterior Segment Syndrome (TASS) is a noninfectious inflammatory disease with symptoms and signs that mimic infection. Inadequate or inappropriate cleaning of surgical instruments has been implicated as a factor in TASS outbreaks.





## Summary

Meticulous pre-operative preparation goes a long way in improving outcomes post cataract surgery. It is necessary to develop appropriate check lists. All the health care personnel in care of the patient must be involved in this process. Involvement of the family members helps a lot in getting patient's cooperation.



# 3

## Pre-operative Protocol for Systemic Disease Management

### 3.1 Pre-operative medical evaluation

All patients undergoing cataract surgery should have their history taken about common systemic diseases and undergo physical examination relevant to the risk factors for undergoing planned anesthesia and as suggested by a review of systems. For patients with certain serious / chronic systemic diseases (e.g. pulmonary disease, cardiac problems, poorly controlled diabetes or poorly controlled hypertension) a pre-operative medical evaluation by the patient's physician should be strongly considered. History of regular systemic medications is important, especially anticoagulant, tamsulosin / finasteride (for prostate enlargement and some other urinary tract disorders). Laboratory testing as indicated by the findings in the history and a physical examination should be done as appropriate.

Before surgery following parameters should be assessed

1. In case of non diabetic patients, random blood sugar should be below 200 mg/dl. In case of diabetic patients, FBS should be below 140 mg / dl. Preferably, HbA1C should be less than 7%. Urine sugar if performed should be NIL and if positive, fasting and post prandial blood sugar should be done.
2. BP should be adequately controlled and should be below 140 / 90 mm of Hg.
3. Regular pulse rate
4. No breathlessness

**The following guidelines are only recommendations and can be modified in consultation with the physician.**

#### 3.1.1 Diabetes

Blood glucose is checked for everyone who undergoes a cataract surgery. It is necessary to maintain a special record for the monitoring of blood sugar and medications in diabetics. The

recommended values are: In case of non diabetic patients, Random Blood Sugar (RBS) is < 200 mg % and in case of diabetics, Fasting Blood Sugar (FBS) < 140 mg% on the day of surgery. Following FBS, patients should be advised to have their normal breakfast. If they are on oral anti diabetic drugs, they should skip the morning dose of the medications only on the day of surgery. If on insulin, 1/3rd of the dose should be administered in the morning. This is done to avoid hypoglycemia during the pre-operative period. The subsequent doses should be taken as per the routine of the individual patient.

### **Glycosylated Hemoglobin (HbA1c):**

HbA1c is age appropriate. HbA1c of 7% or less is associated with a significantly lower incidence of post-operative infections. Therefore, if the patient has hyperglycaemia on the day of surgery, but has had 'good' long-term glycaemic control it may be appropriate to proceed with the surgical procedure.

### **3.1.2 Hypertension**

Blood Pressure (BP) is checked for everyone who undergoes a cataract surgery and this is rechecked on the day of surgery in the ward and in the preparation room, irrespective of hypertensive status. It is necessary to maintain a special record for the monitoring of BP and the medications in known hypertensive patients. The recommended maximum blood pressure is 140 / 90 mm of Hg or less on the day of surgery.

The following recommendations should be followed for all hypertensive patients:

The patient should take the prescribed anti- hypertensive medication on the day of surgery. Avoid adrenaline in local anaesthesia and phenylephrine eye drops for dilatation.

Use of sedative, a day before starting anti-hypertensive drug may work well in all out-reach patients.

It is prudent to check BP in the ward before sending patients to the OR.

A detailed physician evaluation is required and the physician's recommendations should be followed.

### **3.1.3 Common cardiac conditions**

1. Surgery may be done a minimum of 3-6 months after myocardial Infarction
2. Oral antiplatelet need not be stopped for routine phacoemulsification surgery. If on oral anticoagulants, check for Prothrombin Time (PT). Surgery can be done if PT is less than 18 seconds. Continue routine medication on the day of surgery. If the surgeon suggests, it may be stopped in consultation with the treating physician before SICS or combined procedures to avoid bleeding
3. Phenylephrine should not be used for pupillary dilation
4. Administer local anaesthesia without adrenaline in anaesthetic solution

5. Provide a stretcher or wheel chair to avoid exertion and stress
6. Monopolar Cautery should not be used in patients with pacemakers. Wetfield cautery can be used
7. It is preferable to have a stand- by physician or anaesthetist during the anaesthetic block and surgery for cardiac monitoring.

#### **3.1.4 Asthma**

1. Asthma should be under control with drugs
2. Continue the medicines during hospital stay
3. Minimal or no wheeze before surgery and if present, administer IV bronchodilators or steroids. Nebulization before surgery may also be helpful.
4. Avoid plastic drapes or plastic drape can be tented up to provide ventilation and take special care for ventilation while draping for surgery
5. Use oxygen / nebulizer during surgery if the patient is uncomfortable.
6. Inj. Deriphylline / Dexamethasone IV, SOS
7. Switch off the air-conditioner (optional)
8. Avoid acetazolamide, NSAIDS. If needed, use tablet paracetamol as analgesic.

#### **3.1.5 Renal diseases**

1. A physician should certify fitness for surgery
2. Avoid tablet acetazolamide and NSAIDS. If pain killers are required, paracetamol is safer
3. Avoid systemic aminoglycosides
4. If patient is already on maintenance dose of oral steroids following renal transplant, double the dosage for a short interval (one to two weeks) following surgery in consultation with the nephrologist.

#### **3.1.6 Septic Focus**

Dental infection, history of purulent discharge, skin infections etc. are absolute contraindication for surgery. Conditions should be treated adequately before surgery.

### **3.2 Examination and advice of a physician is essential for the following:**

1. Uncontrolled diabetes mellitus (RBS > 200 mg%)
2. Uncontrolled hypertension
3. Known cardiac patients
4. Recently diagnosed uncontrolled asthmatics
5. Renal failure / transplants
6. Liver disease
7. Known bleeding disorders
8. Haematological disorders
9. Obese or emaciated patients
10. Patients under immunosuppressive therapy

**Patients with systemic illnesses are encouraged to consult their treating physicians for control of their systemic problems before admission. In the absence of a physician in the vicinity (particularly in rural areas / small towns), a medical officer trained in ACLS / BLS can take care of this requirement.**

**Pre-operative check list should be prepared by the ward nurse to check whether all the above mentioned activities have been carried out.**

- The patient should take the prescribed anti- hypertensive medication on the day of surgery..**
- Avoid adrenaline in local anaesthesia and Phenylephrine eye drops for dilatation.**

### 3.3 Pre-Operative Check List

Name of Patient \_\_\_\_\_ Medical Record No. \_\_\_\_\_

1. Investigation

Hb (if under GA) \_\_\_\_\_ Blood Sugar \_\_\_\_\_ BP. \_\_\_\_\_

Weight \_\_\_\_\_ Others. \_\_\_\_\_

2. Eye examination: Eye to be operated \_\_\_\_\_

Vision \_\_\_\_\_ Sac \_\_\_\_\_ Xylocaine Sensitivity \_\_\_\_\_

IOP \_\_\_\_\_ IOL Power \_\_\_\_\_

3. Obtained written consent ? Y  N  Attached GVP consent form ?

4. Does the patient have DM? Y  N

5. Does the patient have Hypertension? Y  N

6. Eye prepared for operation? Y  N  Put Povidone Iodine drop ?

7. Eyebrows & Eyelashes painted with Povidone Iodine Y  N

8. Eye dilated for operation? Y  N  Dilated adequately?

9. Is it cataract (IOL) surgery? Y  N  IOL power correct? Y  N

10. Did medical officer examine? Y  N

11. Examination by Anesthetist: \_\_\_\_\_

12. Did patient have a bath / wash face? (Comment on patient hygiene)

\_\_\_\_\_  
\_\_\_\_\_

Suggestion of Doctor

\_\_\_\_\_  
\_\_\_\_\_

Date : \_\_\_\_\_

Signature of ward Nurse : \_\_\_\_\_

Signature of OR Nurse : \_\_\_\_\_





# 4

## Biometry (IOL Power Calculation)

At present there are several options to measure the IOL power. The commonly used techniques involve using the ultrasound for estimating the axial length and the keratometer to measure the corneal curvature. Recently, equipments based on partial coherence interferometry are used to measure both the axial length and the corneal curvature. Of the two, one using the keratometry and ultrasound (USG) is common. This is because a good number of patients in our country have advanced cataracts or posterior sub capsular cataracts, where the interferometry based techniques fail due to opaque media. The purpose of this chapter is to share guidelines regarding the procedure to ensure good quality and accurate biometry in every patient. When using the USG techniques, it is imperative to get good readings of corneal curvature with the keratometer before measuring the axial length. Optical biometers are more accurate, however, these machines cannot work in the presence of mature cataract or when media opacities are dense.

### 4.1. The following points should be noted when performing keratometry

- The keratometer should be calibrated for each observer
- Should be ideally recalibrated after 20 cases for single observer
- Calibration at 45 D / 7.5 mm - horizontal / vertical
- Adjust eye piece to make mires coincide
- Perform Keratometry before tonometry or any other corneal contact procedures / instilling anesthetic drops.
- Treat dry eye/ MGD, if any
- Centre of cornea and proper fixation
- Topography for post refractive surgery cases-Flattest central K is used for IOL power calculation

## 4.2. Re measure the corneal curvature of both eyes if

- Corneal curvature is less than 40 D or more than 47 D
- The difference in corneal cylinder is more than 1 D between eyes
- The corneal cylinder correlates poorly with the refraction cylinder

In practice, the biometry is commonly done using the ultrasonography technique using the applanation method. **The better option is water bath (immersion) technique.** With a water bath, one can eliminate the error induced by pressure associated with applanation technique.

## 4.3. Equipment setting

In either of the techniques, equipment setting is important

- The A-scan unit should be calibrated daily, before using it on the first patient for the day
- Use the test block provided by company
- Default settings of the unit should be used unless indicated otherwise
- If applanation technique is used, corneal compression must be monitored by Anterior Chamber Depth (ACD)

Important tips for Applanation technique:

- The probe should be perpendicular, centered and pointing towards macula
- No fluid between probe and cornea
- No depression / indentation of cornea

Irrespective of the technique, one should look for the characteristics of quality A – scan technique. Antibiotic eye drops must be instilled after USG A scan.

Axial length must be measured in both eyes.

## 4.4. Principal echo spikes on A scan

Normally five principal echo spikes are present

- Cornea
- Anterior lens
- Posterior lens

- Retina
- Sclera and orbital fat

The echo heights show the quality of the scan. The person doing the scan should be aware of it and check whether the echo heights are adequate:

- Anterior lens echo is 90% or more of maximum height
- Posterior lens echo is between 50% and 75% of maximum
- Retinal echo is 75% or more of maximum
- In addition, check whether each rise angle is clear; the take - off of the retinal spike must be clean and form a 90° angle from the baseline
- If spike from RETINA is not followed by multiple small spikes it means one is hitting optic nerve, so discard that reading
- If there is a reading where ACD and AL reduce, it indicates that in that particular reading one is compressing the cornea. It should be discarded

To get good results, obtain at least three scans (Ideally 5-10) on each eye that are within 15mm of one another. Average the 5–10 most consistent results giving the lowest standard deviation (ideally < 0.06 mm).

#### 4.5. Re – measure the axial length of both eyes if

- Axial length measurement is less than 22 mm or more than 25 mm in either eye
- The difference between the two eyes is more than 0.3 mm
- The axial length measurement does not correlate with the refraction, hyperopes should have short eyes and myopes should have long eyes
- When re-measurement is indicated, it should preferably be done by a second ophthalmic assistant masked to the first measurement

#### 4.6. Choice of IOL formulae

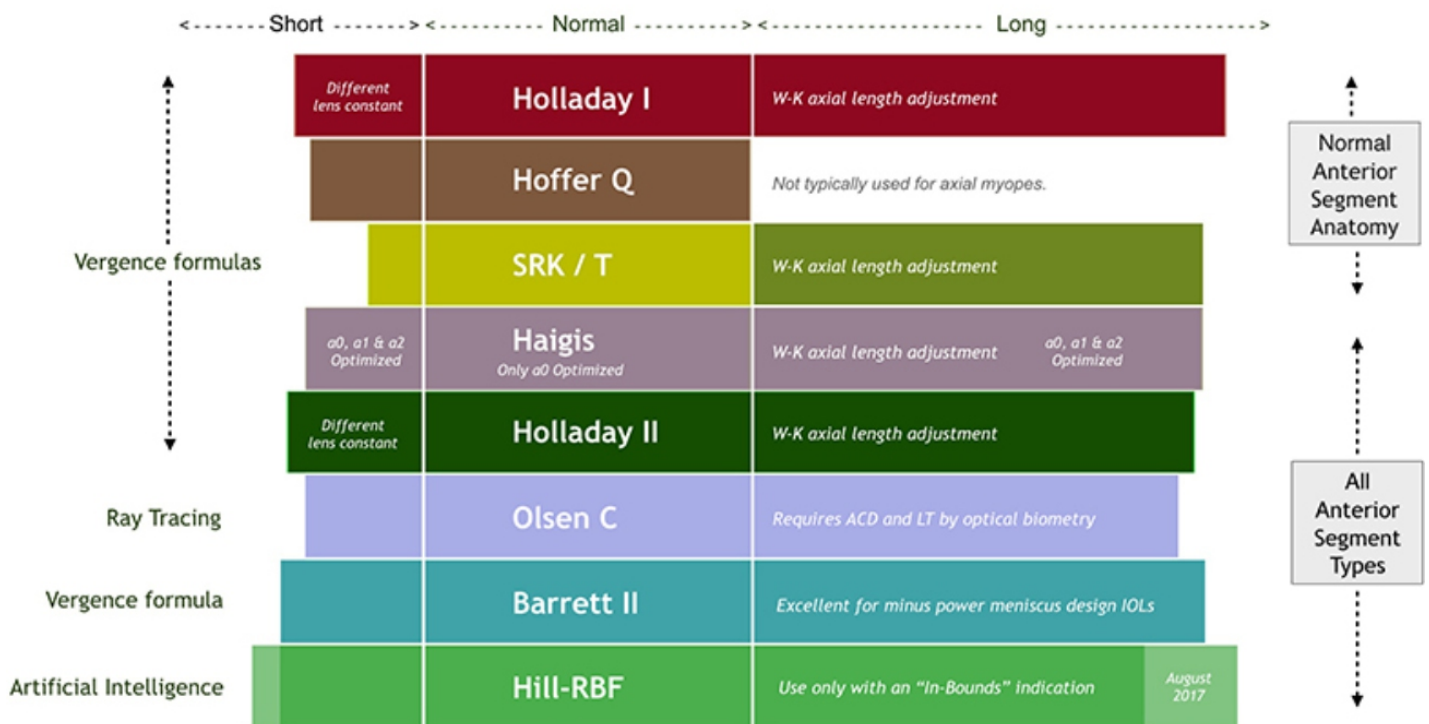
There are several formulas available for calculation of the IOL power. Based on the axial length, the following formulae are recommended to give the best results as per the guidelines published by the American Academy of Ophthalmology (AAO).

Axial length	Formula
< 22mm	Hoffer Q
22 - 24.5mm	SRK II
24.6 - 26 mm	Holladay I.

Circumstances	Choice of Formula
AL - < 20mm	Holladay II / Hoffer Q
AL - 22 - 24.5mm	Hoffer Q / Haigis
AL - 20 - 22mm	SRK/T, Hoffer Q / Holladay
AL - 24.6 - 26 mm	Holladay I
AL - > 26mm	SRK/T / Holladay I
Myopic LASIK	Haigis L
Post Refractive Surgery	Haigis L, Topgraphy with True net K and flattest K with formula according to the Axial Length
Nanophthalmos	Hoffer Q, Haigis

[https://eyewiki.aao.org/Biometry\\_for\\_Intra-Ocular\\_Lens\\_%28IOL%29\\_power\\_calculation](https://eyewiki.aao.org/Biometry_for_Intra-Ocular_Lens_%28IOL%29_power_calculation)

### Accuracy Range of Commonly Used Formulas by Axial Length



In extreme axial lengths, IT IS BETTER TO USE 2-3 formulas and compare before deciding. They are freely available online.

Optimizing the IOL constants for each IOL model for the method of axial length measurement (optical or acoustic) has a much greater impact on the predictability of the refractive outcome than choosing between modern IOL formulae.

## **The ophthalmologist should specifically counsel the patients in the following situations**

- In large deviations between eyes, one should also counsel the patient about possible amblyopia
- With astigmatism of more than 1.5 D cyl, the possibility of residual correction or the option of toric IOL should be discussed
- With short axial lengths, of less than 22.0mm (or) in long eyes of more than 26.0mm, the chances of intra operative complications are high and hence the surgeon should be aware of these values. This will help to take appropriate measures to prevent them.

## 4.7 Special Condition

### **1. Silicone oil**

In Silicone oil filled eyes, to check axial length,

- i. In IOL Master – Silicone oil filled eye mode is used.
- ii. A Scan Biometry – Axial length x 0.71  
(For example if the axial length measures to 26.00mm, the actual axial length is  $26.0 \times 0.71 = 18.46\text{mm}$ )
- iii. Difficulty of measuring the USG axial length can be overcome by increasing the SYSTEM GAIN

### **2. Previous Refractive surgery done (RK / LASIK)**

- i. Post refractive surgery eye (RK / LASIK) - LASIK formula should be used
- ii. The effective optical zone diameter can be significantly smaller than the measurement zone of manual keratometry, so Topography must be done to know central 2.5 mm K reading.
- iii. The clinical history method is generally considered gold standard but it requires pre-operative K-readings, which are usually not available
- iv. Online formula available if we don't have pre surgery records  
<http://www.doctor-hill.com/iol-main/keratorefractive-calculator.html>  
<http://iolcalc.ascrs.org/>
- v. Haigis formula is best and the most hypermetropic power should be considered and multiple IOL formulas should be used
- vi. Barrett's true K formula also can be used.

### **3. High myopic patient**

In high myopic patients, two refractionists should cross check biometry reading. SRK T formula should be used along with Holladay 1 & should be discussed with the surgeon.

### **High to Extreme Axial Myopia - IOL Power Calculations.**

The way in which we do IOL power calculations for the high to extreme axial myope has been evolving and for some surgeons and their staff, this is an area of some confusion. There are currently four approaches in use by surgeons around the world.

- i. Target a moderate amount of myopia. (Not recommended.)
- ii. Adjust the optical biometry axial length as recommended by Wang and Koch in the JCRS. (Recommended)
- iii. Use the Barrett Universal II formula with optical biometry, which is well suited to this task. (Recommended)
- iv. Use the Hill-RBF method for IOL powers of +6.00 D and above with an in-bounds indication. After August of 2017, the range of IOL powers has extended down to -5.00 D. (Recommended)
- v. High Hypermetropic patient

For Short Axial Length (<22mm) Hoffer Q Formula should be used along with Haigis, Holladay II and should be discussed with the surgeon

### **4. Aphakic Eyes**

- Two lens spikes are replaced by a single spike –anterior vitreous face and posterior capsule if it is intact
- Immersion technique is the method of choice
- Use Aphakic mode
- In ACIOL / SF IOL- the appropriate A Constant is used

### **5. Irregular Astigmatism / Mires not clear**

In irregular astigmatism / mires not clear, K-Reading of other eye should be checked. You may use VKG/ Pentacam values if available.

### **6. Miscellaneous**

- i. Retinal detachment patient- check manual method for K reading & A scan
- ii. When both eyes are operated within a 15 day interval, refraction should be done for the first operated eye and the spherical equivalent noted and correct for the fellow eye

### **7. Keratoconus eyes**

As cornea with keratoconus is steep, using K reading for such eyes will yield an overestimated reading due to ELP calculation error.

Formulas which consider ONLY axial length and NOT keratometry to calculate ELP, gives better prediction of true IOL Power-Hoffer Q, Haigis.

**To maximize the likelihood of getting better outcomes**

- 1. Optimize your lens constants**
- 2. Validate your measurements**
- 3. Don't remove yourself from the process-SIA.**
- 4. Spend extra time counseling patients with short eyes or previous refractive surgery**
- 5. Don't just keep doing what you've always done: Stay informed about the latest developments.**

## Summary

Biometry and correct IOL power calculation is one important key for a good visual outcome and a satisfied patient.

## Calibration and validation of optical biometer criterias

<b>IOLMaster - Calibration</b>	
Test Block (AI, K, ACD)	CORRECT, PRINTED & FILED
<b>Axial Length</b>	
Correct setting (phokic, acrylic, siliicone oil etc.)	CONFIRM
Patient able to see red fixation light	CONFIRM
Double peaks (anterior peak is likely the ILM)	DELETED
Poorly formed primary maxima	DELETED
Significant outliers (look at primary maxima)	DELETED
At least 5 measurements within 0.05mm	CONFIRM
Composite SNR > 10 (typically > 100)	CONFIRM
OD & OS AL within 0.30mm	CONFIRM
AL consistent with oldest Rx	CONFIRM
<b>Autokeratometry</b>	
Ocular surface (postpone measurements?)	NORMAL
K <sub>1</sub> & K <sub>2</sub> within 0.25D in each meridian	CONFIRM
Astigmatism lines up with Rx cyl & axis	CONFIRM
Astigmatism for each eye < 3.50D	CONFIRM
Avg K power for both eyes within 0.90D	CONFIRM
Avg K power < 47.00D or > 41.00D	CONFIRM
No "x" appearing in an LED location	CONFIRM
Soft contact lenses	OUT 1 WEEK MINIMUM
RGP contact lenses	OUT UNTIL TOPO & Rx STABLE
<b>Optical ACD measurement</b>	
Aphake & pseudophake	DO NOT MEASURE
5 consistent measurements (green light)	CONFIRM
ACD < 4.5mm and > 2.0mm	CONFIRM
<b>White to White</b>	
3 measurements within 0.2mm	CONFIRM
OD & OS within 0.2mm (check arc position)	CONFIRM
<b>Exceptions &amp; Additional Studies</b>	
AL < 22.0mm (ACD & LT for H2)	IMMERSION A-SCAN
AL > 33.0mm (is there reduced BCVA?)	STAPHYLOMA?
OD/OS AL difference > 0.30mm	MD CONFIRMS
Astigmatism > 3.50 D (KCN, PMD?)	TOP AXIAL MAP
Avg Ks > 0.90 difference	MD CONFIRMS
Avg K power > 47.00 D or <41.00 D	MD CONFIRMS
ACD < 2.0mm or > 4.5mm	MD CONFIRMS
White-to-White < 10.2 or > 13.0mm	MD CONFIRMS



# 5

## Operating Room Protocol for Cataract Surgery

### 5.1 Responsibilities of the person in charge of the preparation cum anaesthesia room

- Check the emergency trolley medications (adrenaline, atropine, deriphylline, dexamethasone, hydrocortisone, phenergan, mephentin, diazepam, oxygen cylinder with kit, I V Kit, syringes, plaster, scissors, I V normal saline, Intubation kit etc.) as per the checklist prepared by the physician / anaesthesiologist at least twice a week
- Check the case records to ensure patient identity. If there are two or more patients with the same name, confirm the patients residential address, and spouse / father's name and address
- Confirm the eye to be operated
- The type of surgery to be performed
- Check the case record to see whether all investigations have been completed
- Inform the surgeon about request by patients such as surgery by a particular surgeon and specific clinical problems like pseudoexfoliation (PXF), phacodonesis, prior surgery etc.
- Reduce waiting time for the patients; at the same time maintain an uninterrupted flow of patients to the OR
- Prioritize surgery for super senior patients, medically challenged, one eyed, diabetic patients etc.
- Check IOL power and check whether the specific IOL is available

## 5.2 Anaesthesia

### 5.2.1 Block Room Preparation

The table / trolley should be thoroughly cleaned everyday with a wet towel and dried. Then it should be cleaned with disinfectant solution. An autoclaved sterile towel should be placed over the table before arranging the required anesthetic solution, syringes, needles etc. Unsterile items should not be put together with sterile items. Better to place a disposable drape on the cloth towel.

- Hygienic hand wash before each block and hand rub should be applied on hand before giving the block
- Wearing gloves after hand wash protects us from getting into problems. But for aseptic purpose, it is advisable not to touch anywhere after hand wash and wearing gloves. If one does not want to use gloves, at least a hygienic hand wash before giving block is required and person should not touch anywhere else after the hand wash before giving the block
- All the cotton and linen used in the block area should be pre sterilized and strips to be applied over them
- Pulse oximeter can be used to monitor the patient while giving the block. More so if the anaesthetist is not present
- Only required medicines to be taken out on a day-to-day basis from the store
- An emergency tray should be kept ready
- Needles, syringes etc also needs to be changed for every patient
- A cross check of pre-operative work up should be carried (confirm the case, eye to be operated) before giving block
- Following anesthesia, povidone iodine (5%) eye drops to be instilled in the conjunctival sac



Anesthesia Trolley

### 5.2.2 Administration of local anesthesia

#### a. Selection of anesthetic solution

- Normal patients 2% Xylocaine mixed with adrenaline (1:100,000) and Hylase
- Patients with hypertension and cardiac diseases, 2% xylocaine and Sensorcaine (1:1) with hylase.

#### b. Quantity of anesthetic solution

- For facial block - 4cc
- For retrobulbar block - 2.5 cc to 3 cc
- For peribulbar block - 5cc

### **c. Needles**

- For facial - No.24, 1" disposable needle
- For retrobulbar and peribulbar block - No.22, 1.5 " hypodermic needle

### **d. Sterilisation of needles**

Use disposable needles only. Autoclaving of used needles is discouraged. Needle should be disposed off immediately after use according to the BioMedical Waste guidelines. Fresh needle to be used for each injection.

### **e. Anaesthesia**

- Peribulbar anesthesia is the preferred method for all patients
- One can use facial and retrobulbar blocks also
- Surgeries can be done under sub tenon block or topical anaesthesia also
- Patients should be counseled well if surgery under topical anaesthesia is planned

### **f. Hypotony**

- Massage is given digitally or by pinky ball applied for 3-5 minutes
- Massage is contraindicated in the following situations:
  - a. Subluxated lens; b. Resurgeries; c. Perforating injuryVigorous massage is contraindicated in
  - a. Pseudoexfoliation; b. Myopia and c. Traumatic Cataract

**g. Akinesia** should be checked before sending the patient for surgery

**h. Avoid corneal exposure.** If the palpebral aperture is open, close the lids with a mediatape across the lids

**i.** Detect, manage and refer complications of anesthetic blocks such as Retro Bulbar Hemorrhage (RBH), scleral perforation etc.

## **5.2.3 Managing Anesthetic Complications**

### **i. Vasovagal syncope is the commonest complication**

- a) The patient is made to lie down in supine position and the legs are elevated
- b) The room should be airy
- c) The patient's clothes should be loosened
- d) Monitor pulse, BP and airway
- e) To keep resuscitation equipment ready like - oxygen cylinder, endotracheal tube, laryngoscope, ambu bag, scalp vein set, emergency drugs
- f) To inform anesthetist or physician if patient does not show adequate recovery

## **ii. Seizures**

- a) Make the patient lie down
- b) Turn face to the side
- c) Insert a mouth gag
- d) Intravenous diazepam may be required
- e) Oxygen therapy

## **iii. Retro bulbar hemorrhage**

- a) Saline pad and bandage
- b) Start patient on oral acetazolamide
- c) Check IOP
- d) Lateral canthotomy, if needed
- e) Postpone surgery
- f) If the fundus is visible, check that the central retinal artery is not occluded
- g) Check the eye after an hour for corneal edema, arterial pulsation, globe perforation etc.,

## **iv. Globe perforation**

- a) Even if a globe perforation has occurred, surgery can be completed. This will help the retina consultant see the break easily on the next day and seal it effectively. However, on the recommendation of surgeon, the case can be postponed.
  - I. Criteria for postponement : Gross hypotony, hyphaema, grossly altered red reflex.

## **5.3 Administration of I.V.Mannitol**

### **5.3.1 Indications**

- a) Lens induced glaucoma / secondary glaucoma
- b) Raised IOP on table after giving block
- c) Glaucoma patients occasionally
- d) Secondary IOL implantation - optional
- e) IOL exchange/explantation - optional
- f) Subluxated cataract - optional
- g) Posterior polar cataract - optional
- h) Nanophthalmos - optional

### **5.3.2 Technique**

- 100 - 150 ml is given over 15 to 20 minutes half to one hour before surgery
- Patients have to avoid urine before starting IV mannitol
- Avoid in uncontrolled HT, cardiac patients, renal diseases
- Before starting the drip, check BP and do a CVS examination
- Patient is moved on the stretcher and is told to avoid ambulation for 6 hours.

## 5.4 Decision regarding postponing the case

- a) Diabetes mellitus–FBS>140 mg %
- b) BP - diastolic >90mm Hg; systolic >140 mm Hg (One can take physician / anaesthetist's opinion and support)
- c) Severe wheezing
- d) Any complication of local anaesthesia
- e) Positive conjunctival cultures
- f) Local factors - any infection of lids and adnexa, IOP >30mm Hg despite medications except lens induced glaucoma.

In all such situations, it is a good practice to discuss with the patient in presence of his/her family.

## 5.5 Different techniques of cataract surgery

- 5.5.1 Manual Small Incision Cataract Surgery – both foldable and non foldable IOL can be used depending upon the expertise of the surgeon.
- 5.5.2 Phacoemulsification using foldable / rollable IOL. Incision size can be reduced to less than 2 mm again depending upon the expertise of the surgeon.
- 5.5.3 ECCE and ICCE are now practiced very rarely.  
The technique of cataract surgery is beyond the scope of this manual BUT there are many different methods in use for incision placement and design which the surgeon needs to make one aware of. (Superior vs temporal incision, straight vs frown vs. smile incision etc.)
- 5.5.4 Surgeon should not come out of OT in the OT gown. If he / she does come out, must rescrub and change for the next case.
- 5.5.5 Document the sequence of surgeries.

## Summary

Good operative preparation demands a synergistic action of all health care personnel involved in cataract surgery. A good preoperative care and strict adherence to prescribed protocol builds confidence in the patient and the surgical team.



# 6

## Post-Operative Protocol for Management of Uncomplicated Cases Following Cataract Surgery

### 6.1. Care on the day of surgery

For cases operated under block, patching for 4-6 hours is recommended. Cases operated under topical anaesthesia can be given protective glasses right away.

Following uneventful cataract surgery, the patients may be given oral paracetamol 500 mg for pain relief, repeated after 8 hours, if needed. If oral Acetazolamide (500 mg) is not given before surgery, it may be given as the IOP is likely to rise during the first few hours after surgery. Three to four hours following surgery, one can start applying topical antibiotics (same as the one used preoperatively) every two to four hours along with NSAID (surgeon's choice – not mandatory) eye drops once every six hours. In addition cycloplegics, preferably tropicamide or homatropine 2% applied twice daily. After six to eight hours following surgery, topical steroids can be started once every four hours on the first day.

### 6.2. First post-operative checkup

The patient is examined the day following surgery. One should look for the following:

- Vision with and without pin hole
- Anterior segment of the eye
  - o Conjunctiva - Wound is covered properly or not
  - o Section - Apposition of Wound / Wound Leak / Gape
  - o Cornea - Epithelial Defect, Oedema, SK
  - o A.C. - Cells, Hyphaema, Hypopyon, Cortical Matter, Depth, Vitreous knuckle

- o Iris - Iritis, Fibrinous reaction
- o IOL - Centration and stability
- o Pupil - Shape , Mobility, peaking of pupil due to Vitreous
- o PC - Opacity, Rent, Zonular dialysis
- o Vitreous - Vitreous cells, Blood, Pigments
- Fundus
  - o Red Glow
  - o Fundus examination (slit lamp/ direct/ indirect)
- Specify the cause, if the visual acuity is poor (<6/18)

The aim of post-operative examination is to look for complications and any early sign of inflammation or infection.

### 6.3. Discharge timing

- Base hospital patients – 1st post-operative day / on the same day of surgery after a few hours
- Outreach camp patients – Ideally on the 1st / 2nd post-operative day. However, if we are sure that the patients will be able to reach hospital in case of any problem, we can discharge them on the same day also.

Keeping the outreach patients for one extra night helps for following reasons:

- A second opportunity for good post-operative counseling
- Health education
- Use them as future ambassadors

### 6.4. Post-operative medications

#### 6.4.1 Definite medications:

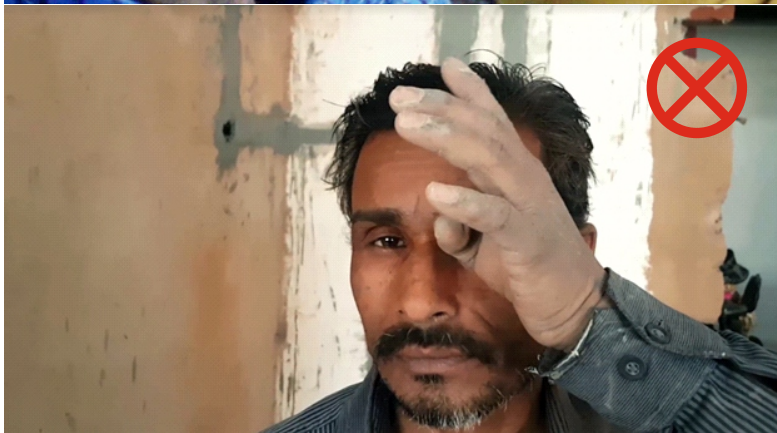
- a) Topical antibiotics 4 to 6 times daily for 7 days after surgery. Post-operative antibiotic is used as prophylaxis to prevent infection and so it should be withdrawn after a week.
- b) Steroid eye drops (40 – 50 days/could be tapered over 30 days too – surgeon to decide)
  - 5 times a day - 10 days
  - 4 times a day – 10 days
  - 3 time a day - 10 days
  - 2 time a day - 10 days
  - 1 time a day - 10 days



## Post-op care

### Instilling eye drops:

- Wash your hands with soap and water. Allow it to dry.
- Open the bottle dropper without touching the tip
- Request the patient to raise the chin
- Hold / Retract the lower eyelid down with your fingertips
- Gently put one drop of the drug into the lower fornix
- Release the lower lid and request the patient to close the eye gently
- Close the dropper. Do not leave it open
- Wipe the drug on the cheek. Do not rub the eye or wipe the lids



## 6.4.2 Optional

a) Cycloplegics (Homatropine/Tropicamide) – 2 -3 times a day for 2 weeks  
Systemic antibiotics are not necessary.

## 6.5 Precautions

- Early resumption of routine activities is encouraged
- Do not rub eyes after surgery
- Normal diet is allowed from the day of surgery
- Maintain lid hygiene after surgery. Clean eyes with boiled and cooled water and clean cotton over closed eyelids
- No head bath for 2 weeks with water poured straight on head. Can be allowed with precautions. Head can be washed by extending neck and ensuring water does not spill to the eye
- Avoid bathing in ponds or rivers for 3 months
- TV viewing and reading is allowed, if the patient is comfortable
- Avoid driving two wheelers without protective glasses
- Avoid lifting heavy weights for patients who have undergone ECCE with sutures
- Dark glasses should be used for one month for outdoor activities or till the time cycloplegic is being used
- Prostration or bending of head for saying prayers is permissible after 7 days
- After suture removal, avoid pond or river baths for at least 1 week and instill topical antibiotics 6 times a day for a week.



## 6.6 Danger signs for which the patient is advised to report immediately

- Redness
- Pain
- Sudden diminution of vision

## 6.7 Follow up Visits

- Following tests are recommended in the follow-up visits
- **First follow up – After 7 to 10 days (Optional)**
  - Vision with pinhole
  - Slit lamp exam
  - Fundus exam
  - If visual acuity is not good ( $< 6/18$ ) look for Cystoid Macular Edema (CME) and treat with topical NSAID (nepafenac)
- **Second follow up – After 30 - 45 days;**
  - Refraction, Slit lamp exam, Fundus exam
  - If visual acuity is not good ( $< 6/12$ ) look for the causes including CME
  - Further follow up when required or after 6 months (optional)

## 6.8 Spectacles prescription

Spectacles could be prescribed 3-4 weeks following phacoemulsification and 8 weeks following SICS/ ECCE. It is a good practice to see patients 3 months after surgery. ECCE- IOL patients will need suture removal during this visit.

- Patients are encouraged to read with current spectacle till new glass is prescribed. But if a patient needs a better correction to carry out important activities, glass can be prescribed after one week of surgery
- All high risk patients (myopia, eyes with history of operative complications, pre-existing retinopathies, traumatic cataracts) should have at least one indirect ophthalmoscopy during follow up period

## Summary

A well designed post-operative care regimen and adequate/effective management of complications, if any, is important for success of the cataract surgery.



# | Sterilisation Module

1. Protocols for operating room sterilisation for ophthalmic surgery
2. Protocols for sterilisation of instruments
3. Aseptic protocols for sterile procedures for staff in ophthalmic surgery
4. Monitoring and surveillance of sterilisation procedures
5. Annexure
  - Daily cleaning check list for eye OT
  - Weekly cleaning check list for eye OT
  - Monthly cleaning check list for eye OT
  - Quarterly cleaning check list for eye OT
  - Monitoring of the autoclaving procedure
  - Weekly autoclave report

# 1

## Ophthalmic Surgery OR Sterilization Protocol

Post-operative endophthalmitis is a devastating and potentially vision threatening complication following intraocular surgery. Despite improvements in aseptic techniques, sterilisation protocols and instrumentation, there are still incidences of cluster infection following cataract surgery. There are three possible factors: patient personal hygiene, deficiency in practicing no touch technique, contaminated surgical supplies and faulty sterilisation protocols individually or a combination of these factors. Prevention of post-operative endophthalmitis is important to ensure good post-operative results. Keeping in mind the diversity and economic condition of the country, we need a universally acceptable, evidence-based and cost effective protocol.

### **Sterilisation Practices**

Understanding the following basic terminologies and their subtle differences is essential before we discuss details of each step.

- **Sanitation** is a process capable of reducing the number of microbial contaminants to a relatively safe level. Compared with sterilisation and disinfection, sanitation provides the lowest margin of safety
- **Disinfection** kills or eliminates nearly all pathogenic micro-organisms on inanimate surfaces but not necessarily bacterial spores
- **Sterilisation** is the act or process of destroying all forms of microbial life, including spores

### **Sterilisation practices can be standardised as follows for the following areas:**

- Cleaning and decontamination protocols for environment and equipment
- Sterilisation of surgical instruments
- Sterile protocols involving OR staff
- Managing clinical wastes from the OR
- Monitoring of surgical supplies
- Monitoring Protocols
- Surveillance and outbreak control

## 1.1 OR layout and environmental control

A proper OR layout ensures effective and continued sterilization. One such simple schematic drawing of OR layout is shown below

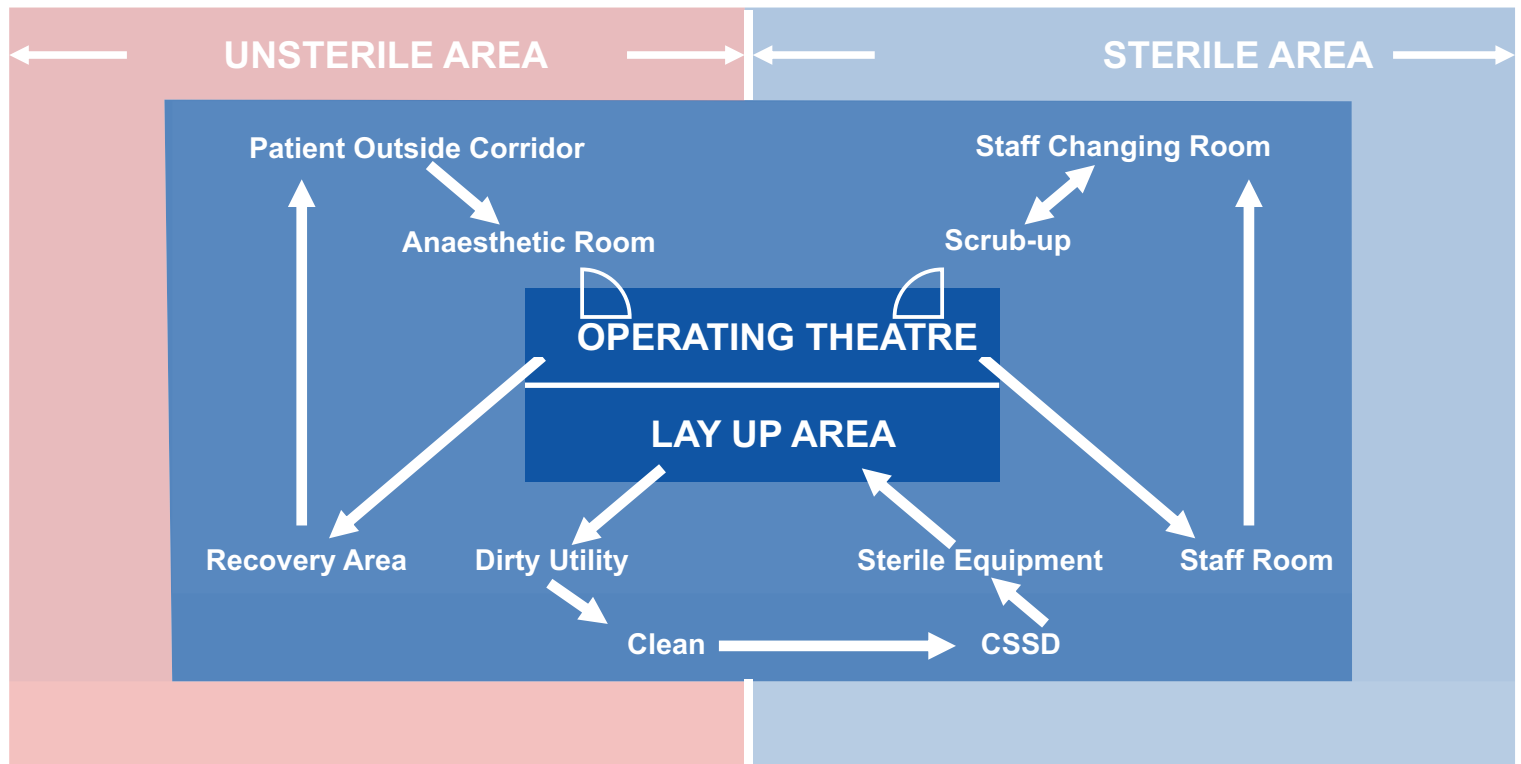


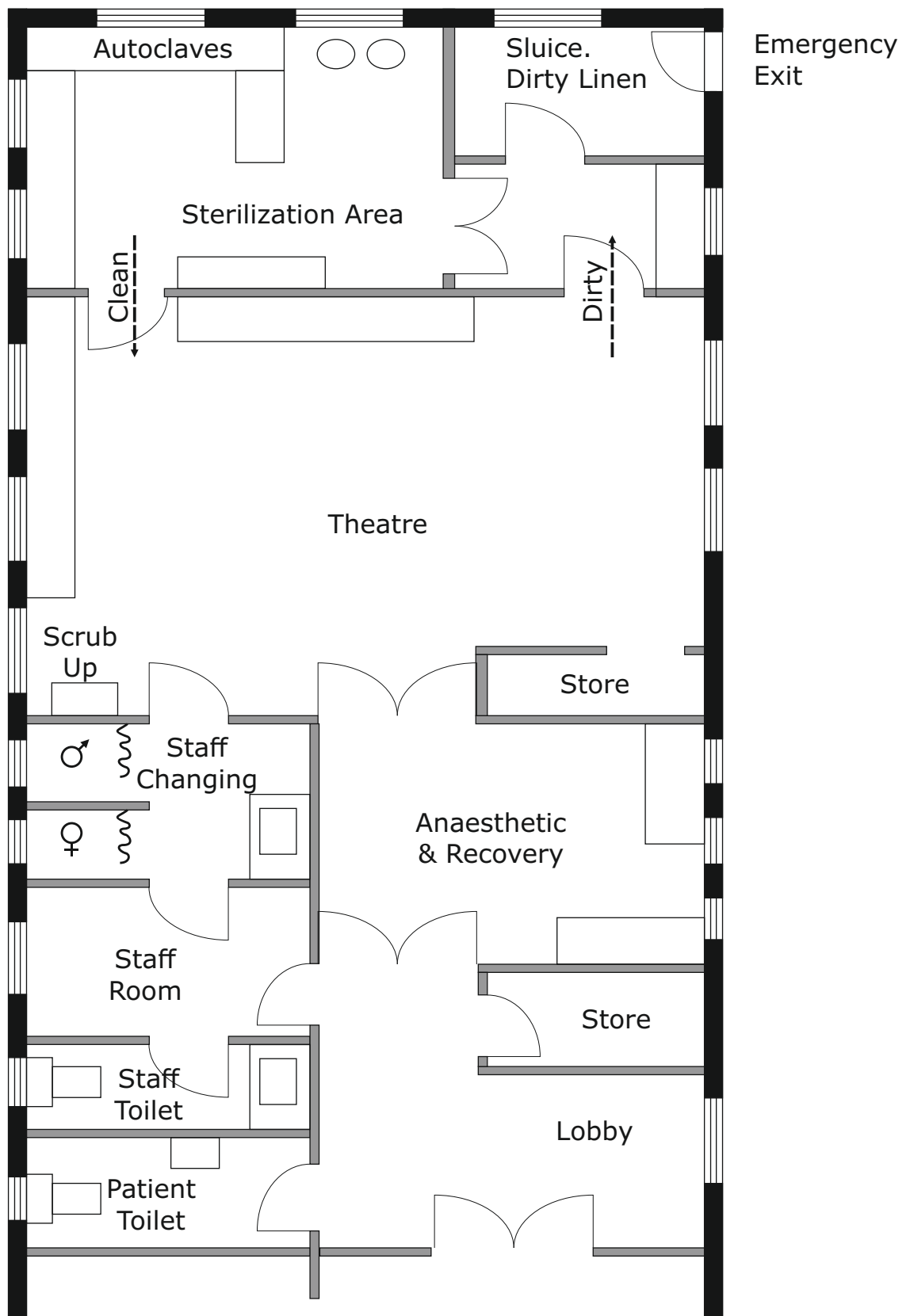
Figure. Schematic Drawing of the layout of the operation theatre

The OR should be situated in an area away from public movement and ideally should have the following features:

- The sterile and unsterile areas are segregated, preferably by an air lock or buffer zone
- The sterile and unsterile zones inside the OT are separated by coloured lines – scrubbed staff remains in the sterile zone and the circulating staff & patients remain within the unsterile zone
- Generally we use two tables per OT. However, NABH guidelines make one table per OT mandatory. There is not enough evidence to prove whether two tables increase the chances of infection or not
- Preferably, the entrances for patients and staff should be separate
- Separate areas for storing sterile and unsterile items
- The operating room should preferably have seamless walls and a non-porous floor. (Use of marble is contraindicated)
- There should not be any surface where dust might accumulate
- Doors of the OR are always kept closed and movement restricted
- Restrict the number of personnel to the minimum during surgery



Figure. Schematic Drawing of the layout of the operation theatre complex for small hospitals with one OT



Courtesy: 'Ophthalmic Operating Theatre Practice - A manual for developing countries' published by International Centre for Eye Health London.

Diagram 5.1: OT Design

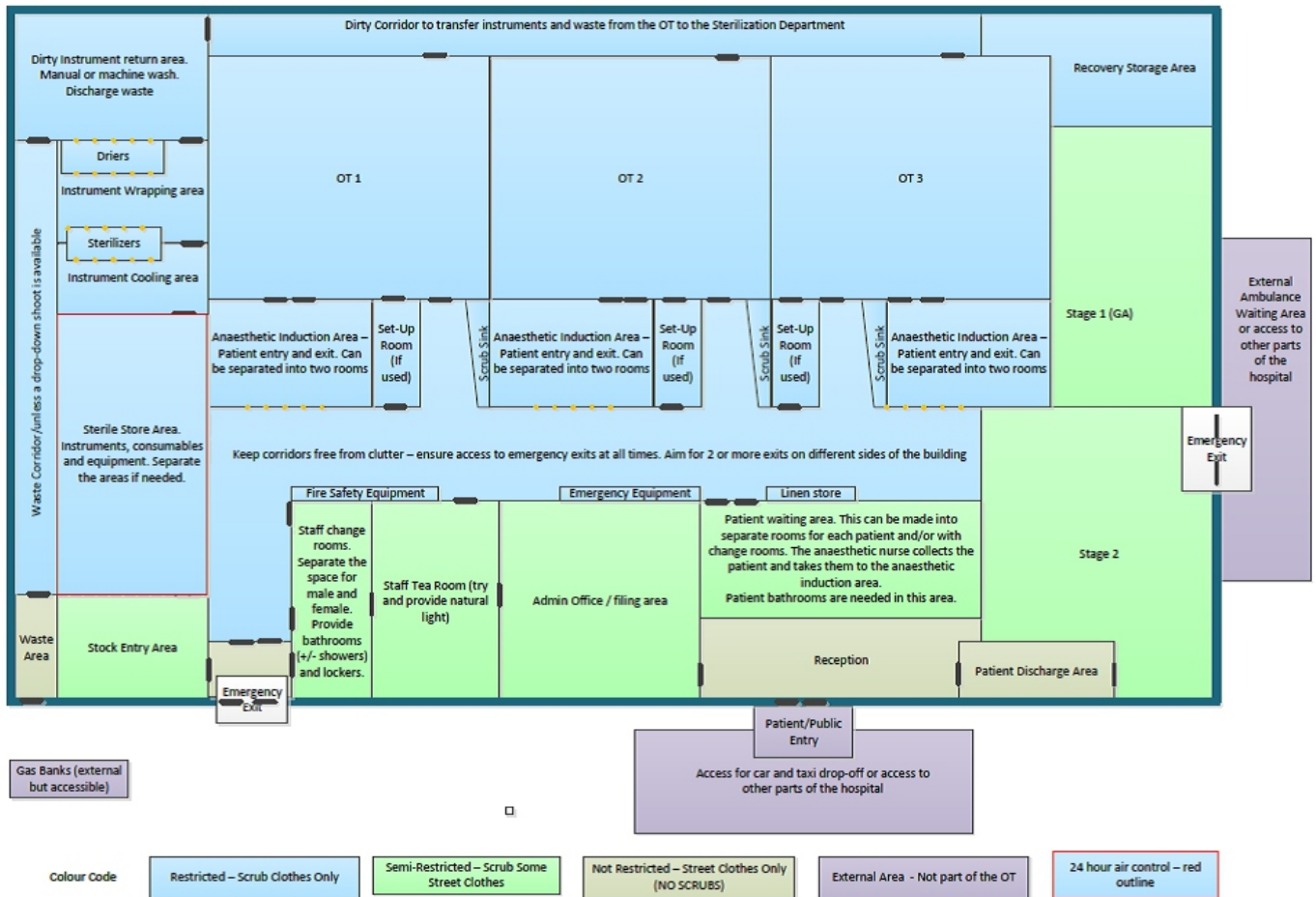


Figure. Schematic Drawing of the layout of the operation theatre complex for large hospitals with more than one OT

To incorporate the above features, the OR should be designed in a way that it incorporates four major zones:

- **Outer zone** acts as a reception area, and is accessible to all
- **Clean zone** comprises the changing room and patient preparation room. This is a transfer zone and is accessible only to OR staff
- **Aseptic zone** is a sterile area, and includes the space for scrub and gowning, the actual operating area as well as the area where instruments are cleaned and sterilized
- **Disposal zone** stores used linen before sending to the laundry. The used disposables are segregated and then disposed off
- **Waste disposal area** should preferably be outside Level III and IV. A prompt disposal of theatre waste is recommended

Level - I	<ul style="list-style-type: none"> <li>• Restricted entry</li> <li>• Changing rooms / offices / record keeping</li> <li>• Shoes / Foot ware to be removed and clothes changed</li> </ul>
Level - II	<ul style="list-style-type: none"> <li>• Entry only after changing for both the patients and staff</li> <li>• Caps / Masks to be worn</li> <li>• Administration of peribulbar blocks / pre-medication</li> </ul>
Level - III	<ul style="list-style-type: none"> <li>• Sterile area (separate slippers)</li> <li>• Entry restricted to minimal staff</li> <li>• Fumigated areas</li> <li>• Scrub room / gloving and gowning area</li> </ul>
Level IV	<ul style="list-style-type: none"> <li>• Sterilisation room</li> <li>• Instrument maintenance area</li> </ul>

## 1.2 Ventilation

Central air-conditioning of the operating room is ideal and in case where resources are not a constraint, Ventilation / Heating Ventilation Air Conditioning (HVAC) system may be installed. These systems include HEPA (High Efficiency Particulate Air) filters, which maintain indoor air temperature, humidity and odour, clean the contaminated air and minimize the risk of transmission of air borne microorganisms. When not possible, the ORs should be well ventilated and air conditioned with a split air conditioner. In addition, the air circulating inside the ORs should be filtered using readily available devices in the market. This can be done by equipments containing 0.3  $\mu$  filtering device such as a HEPA filter along with Ultra Violet (UV) lights. These are not very expensive.

### Parameters for Operating Room Ventilation

The following is recommended for operating rooms

Parameter -	Desired range
• Temperature -	20 - 23° C
• Relative humidity -	30-60%
• Air movement -	From clean to less clean areas Dehumidifier
• Air changes -	Minimum 20 total air changes per hour
• NABH guidelines: Minimum total air changes should be 20 per hour based on biological load and the location. The fresh air component of the air change is required to be minimum 4 air changes out of total minimum 20 air changes	
• Positive pressure (If available) – 2.5 pascal	



Dehumidifier

The above mentioned additional expense for ventilation also ensures better sterility of the operating room. This is likely to reduce the post-operative infection. The use of fans in the operating rooms is not recommended, as it adds to turbulence and lifts the dust particles.

## 1.3 Cleaning and Decontamination

**Cleaning** followed by **disinfection** are the corner stones for decontamination. In the OR, the floor, foot switch of microscope, surfaces, sinks and drains must be cleaned regularly as per the following protocol.

The ideal disinfectant should be broad spectrum, safe and economical. There is a wide choice available. Commonly used agents include sodium hypochlorite, iodophores, hydrogen peroxide (stabilized with silver), chlorhexidine gluconate combinations etc.

### Schedules for cleaning of Equipments & Environmental surfaces: OR Sanitation

#### 1.3.1 Before surgery

- Equipment like microscopes should be cleaned separately with Isopropyl alcohol except lens. Can use aldehyde / alcohol based solutions also. Lens to be cleaned with lens cleaning solution / isopropyl alcohol
- Instrument trolley, operating tables, saline stands, revolving chairs (surgeon's seat) should be cleaned daily with antiseptic liquid concentrate (Chlorhexidine gluconate 75% - 10 ml diluted with 500ml of water or 10% Benzalkonium chloride)
- Microscope and equipment like Phacoemulsifiers, cautery box should be sprayed with Bacillol 25 spray.
- Microscope head to be wiped with a hand towel dipped in disinfectant solution.

#### 1.3.2 During surgery

- Spills / blood splashed in the vicinity of the sterile field is to be cleaned with a cloth and then with a germicide as per spills management protocol. All instruments opened for a procedure whether used or not, are treated as contaminated
- Spill cleaning guideline – use tissue paper to absorb the spill, then disinfect the floor with sodium hypochlorite and then mop. The tissue to be disposed according to BMW guidelines
- The operating table /should be wiped with bacillocid, if wet

#### 1.3.3 Cleaning at the end of the list

Operating room, scrub utility, corridor, furnishings and equipment to be cleaned.

#### Furnishings

- The furniture, equipment, lights are damp dusted with a detergent germicide. Attention should be paid to horizontal surfaces, as dust and lint which transport microorganisms settle on them

## Corridor

- The floor must be cleaned by a dust controller followed by wet mopping followed by cleaning with antiseptic solution. In addition to the operating rooms, corridor, sterilisation area, patient holding areas also must be cleaned. Brooming is not recommended. Three bucket system can be followed: first clean with soap solution, then with clean water and third with antiseptic solution such as aldehyde / alcohol / chlorhexidine based solution in recommended dilution.

## Equipment

- Microscopes, except lens, are cleaned with 15% cetrimide and 3% chlorhexidine gluconate daily.

## Scrub utility

- Liquid soap and scrub solution dispenser is cleaned daily.
- Scrub sink is cleaned daily with brush and bleaching powder, dried and mopped with 1% sodium hypochlorite.
- Drain is cleansed with 1% sodium hypochlorite. (Low level disinfectant)

## Operating room

**Fumigation / Fogging: In our settings it is a common practice to fumigate the operating room with formalin once in a week.** This ancient routine is still widely practiced (though no longer in the western world) and remains a primary method of decontamination in our country.

It has no role in modern operating rooms with centralized air conditioning fitted with HEPA filters.

- Formalin 30ml of 40% Formalin dissolved in 90 ml of clean water for 1000 cft by aerosol spray – Keep OT closed for 24 hrs. Then clean with disinfectant before use
- If fumigator (oticare) is not available, use 35 ml. of 40% formalin with 10 gms. of potassium permanganate ( $KMnO_4$ ) in a basin for a space of 1000 cu. ft. and seal OT for 24 hours
- 10-15 ml liq. ammonia solution can be used next morning to remove the formalin fumes from the OT
- A new method of fumigation has been evolved using 'Aldekol'. It is a mixture containing 6% formaldehyde, 6% glutaraldehyde and 5% benzalkonium chloride. To sterilize 4000 cu ft., 325 ml. of aldekol is dissolved in 150 ml of water and sprayed by aerosol for 30 minutes. The room is then closed for 2 hours following which fumes are allowed to clear by putting on the exhaust or air-conditioning. In effect, the operation theatre is sterile in just over 3 hours
- Hydrogen peroxide based fogging system also can be used. The OT will be ready in one hour. (If we use prescribed quantity of formalin as per the textbook, it works out costlier than hydrogen peroxide.)
- A record of the date & time of fumigation and the name of person who has fumigated must be maintained. OT in charge should check and counter sign



Fogger Machine

- As mentioned above, if there is central AC with HEPA filters and a positive pressure is maintained, there is no need for fumigation. Deep cleaning is enough in these situations
- **This is not an alternative to mechanical cleaning of surface.** The fogging should be done only after thorough cleaning and mopping of the floor, walls and all the furniture in the OR

#### **1.3.4 Weekend cleaning**

- Ideally all the equipments including the furniture should be moved out of the operating room
- The floor and the walls should be mopped by detergents and by mopping with adequate amounts of water. All the areas should be subsequently disinfected with antiseptic solutions.
- The routine preventive maintenance of the equipments and furniture should be done at the end of the week
  - Lenses of the microscope are cleaned once a week with lens cleaning solutions
  - Fans, lights, clocks inside the OR are wiped once a week, with 1% sodium hypochlorite solution
  - If using split AC, filters should be removed, dusted and washed with copious amount of water once a week and sun dried. HEPA filter cannot be cleaned (to be replaced in case of loss of efficiency). Pre filters and fine filters in the return air duct and the AHU to be cleaned

#### **1.3.5 Water tank cleaning and disinfection**

Water is an important reservoir of microorganisms like *Pseudomonas* species. If the OR does not have a dedicated water tank, it is advisable to treat the water at the user end by some means prior to it being used in the OR. RO water is recommended for instruments washing and for autoclaving. Purified water should be used for scrubbing.

- Overhead water tank is cleaned with bleaching powder at least once a month and should be documented. After emptying the tank, apply 1% sodium hypochlorite solution all around and allow it to dry completely. Refill the tank after drying. The level of chlorination is checked regularly. During disinfection, 50 ppm chlorine should be used. Residual chlorine after the procedure should be 0.5 mg / l or less

#### **1.3.6 Pest Control**

It is essential to keep the OR free of pests like flies, mosquitoes, cockroaches and other pests. There has to be a regular schedule for pest control. The procedure should be carried out when the air handling unit is shut down. Commercially available products in domestic use will be sufficient.





## 1.4 Managing clinical wastes from the OR

The waste emerging from the operating room consists of the following:

- Patient contaminated waste viz. disposable plastics drapes, linen and gauze contaminated with blood and body fluids
- Sharps, gloves, wrapping paper and other wrappers
- Anatomical body parts and tissues following enucleation, evisceration etc.

All sharps including needles, IV cannula, scalpel blades etc. should be segregated into puncture proof containers at source. Infectious wastes requiring disposal like gloves, plastics, cotton, gauze etc. could be segregated into colour coded bags for transportation to the site of waste treatment plant/ site.

Biomedical waste segregation

Cat.	Type of Bag/ Container used	TYPE OF WASTE	Treatment /Disposal options
Yellow 	non-chlorinated plastic bags  Separate collection system leading to effluent treatment system ←	a) <b>Human Anatomical Waste</b> b) <b>Animal Anatomical Waste</b> c) <b>Soiled Waste</b> d) <b>Expired or Discarded Medicines</b> e) <b>Chemical Waste</b> f) <b>Micro, Bio-t and other clinical lab waste</b> g) <b>Chemical Liquid Waste</b>	Incineration or Plasma Pyrolysis or deep burial*
Red 	non-chlorinated plastic bags or containers	<b>Contaminated Waste (Recyclable)</b> tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles) and gloves.	Auto/ Micro/Hydro and then sent for recycling. not be sent to landfill
White 	(Translucent) Puncture, Leak, tamper proof containers	<b>Waste sharps including Metals</b>	Auto or Dry Heat Sterilization followed by shredding or mutilation or encapsulation
Blue 	Cardboard boxes with blue colored marking	<b>Glassware</b>	Disinfection or auto/ Micro/hydro and then sent for recycling.





# 2

## Protocols for Sterilization of Instruments

### **Sterilisation Process**

This is one of the most critical procedures requiring stringent monitoring. Appropriate packing of surgical instruments also needs attention. Ideally each operating table should have 4 - 6 instrument sets. Sufficient numbers of surgical instrument sets are needed in a high volume set up. Lack of them can lead to inadequate sterilisation of instruments in between surgeries.

### 2.1 Cleaning of surgical instruments

The used instruments are cleaned thoroughly in order to remove any tissue debris or body fluid deposits before they are re sterilised. It should be done at the end of the day after all surgeries as well as in between surgeries, the process of which is described as follows.

#### **Steps in Cleaning of instruments**

- **Separation:** The instruments are separated from the tubing and the sharp instruments are separated from the blunt instruments; also automated equipments need to be separately sterilised
- **Cleaning is done either by ultrasonic cleaner or by using four bowls, if done manually.**
  - o **Ultrasonic cleaner** is used to clean the tissue debris and body fluid deposits from the instruments. Distilled water is used in the chamber of the cleaner, to which an enzyme solution may be added to facilitate the cleaning process. The ideal cycle time for one batch of instruments is 30 minutes / as per manufacturer's guidelines. This should ideally be done for sharp instruments every day and for blunt instruments every week. Keep all the joints open so that it is exposed to the cleaning process. Manual timing as well as automated ultrasound machines are available.

- o **Four Bowl Cleaning** method is equally effective. Demineralised water is taken in four bowls. The instruments are placed in the first bowl containing surfactant cleaning solution. Correct concentration as recommended by the manufacturer should be used. After cleaning in the first bowl, the instruments are transferred to the next bowl and cleaned one more time. It goes through all four bowls. A clean soft toothbrush is used to clean the blunt instruments thoroughly. Special attention is needed to clean at the hinges, and the tips of fine and delicate instruments. The cannulated instruments should be flushed with sterile demineralised water or Ringer lactate solution or BSS solution thrice followed by air. After cleaning, the instruments are dried with hot air, tipped with individual plastic sleeves and packed in individual perforated boxes / trays. The toothbrush is changed weekly and should be disinfected daily by immersing in a chemical solution like 2% glutaraldehyde.
- **Packing of the instruments:** The instruments are put together to make the set and are kept wrapped using thick cloth and placed in a perforated tray. Silicone mats are available on which the instruments can be kept. The instruments trays for a particular operating room are then placed in a surgical drum for sterilisation. Double wrapping the sets in casement cloth is better, as air removal from drum may not be complete during autoclave and in that case, instruments may not get sterilised. Each instrument set should have an indicator tape to show the completeness of sterilisation.

## 2.2 Sterilisation of surgical instruments

Several methods of sterilisation like, steam under pressure (Autoclaving), dry heat (Hot Air Oven), chemical sterilisation (Glutaraldehyde / Acetone), Ethylene Oxide (ETO) and hydrogen peroxide are available.

Steam is the preferred method. It is the only method of autoclaving and to sterilize most of the instruments, not associated with any toxic reactions like TASS. Autoclaving is also economical.

**With every mode of sterilisation, maintaining adequate temperature, pressure, concentration, duration of exposure is important and can vary with different manufacturers. To guide the readers / users, the parameters in regular practice are given for the various methods. However, it is important to check with the suppliers about the ideal settings.**

### 2.2.1 Mode of sterilisation of instruments at the end of the day

For sterilisation at the end of the day, either **(i) autoclaving using long cycle exposure or (ii) gas sterilisation is preferred.**

#### **(I) Steam sterilisation under pressure (Autoclaving)**

Of the two methods, autoclaving is the most preferred method. This is dependable,

nontoxic, in-expensive, sporicidal and can penetrate fabrics well. It is called long cycle autoclaving and is the preferred method for regular sterilisation after cleaning and decontamination at the conclusion of all surgeries. It is a safe method of sterilisation, as it kills bacteria, viruses, fungus and their spores.

Benchtop steam sterilizer cycles are classified according to the types of load they are intended to process, which are summarized in table below:

Cycle Type	Air Removal	Load Type	Advantages	Disadvantages
N	Passive (gravity displacement)	Non-wrapped solid items.	Simplest type to operate and maintain.  Least expensive	Not to be used for: hollow devices or those with lumens; wrapped loads (e.g. items in pouches)
B	Active (forced) air removal	<p>Wrapped or non-wrapped solid items (e.g. forceps, dental probes)</p> <p>Wrapped or non-wrapped hollow items (e.g. cannulae within dimensions specified by sterilizer manufacturer). Porous loads (e.g. fabrics, swabs, dressings)</p>	Widest range of applications	Expensive to purchase and maintain. Additional periodic testing required. Post-sterilisation drying stage essential for wrapped items. Increases total cycle time
S	Active (forced) air removal.	Only suitable for types of loads specified by the sterilizer manufacturer..	Wider range of applications than Type N	Expensive to purchase and maintain. Additional periodic testing required. Post-sterilisation drying stage essential for wrapped items increases total cycle time.

**Note:** Ideally, only the highest specification cycle should be available to the operator. Other cycles should be disabled, until specifically needed.

**Traditional (gravity displacement) benchtop steam sterilisers** displace air passively from the chamber and load by steam generated within the sterilizer chamber or in a separate boiler within the sterilizer's casing. This is known as a 'Type N' cycle.

**Vacuum benchtop sterilisers** have a pump or some other active method to remove air from the chamber and load. This type of air removal is found in 'Type B' cycles and some 'Type S' cycles.

They are described variously as vacuum benchtop sterilizers, benchtop porous load sterilizers, Type B sterilizers or sometimes Type S sterilizers.

**Note:** Type S sterilizers should be used to process only the types of loads specified by the sterilizer manufacturer.

**Vacuum benchtop steam sterilizers** have a forced air removal stage prior to the sterilizing stage; a post-sterilisation drying stage.

**Alternative air removal systems** - Some sterilizers remove air by using a succession of steam pulses, in which the chamber is alternately pressurised and then depressurised to near atmospheric pressure (or to below atmospheric pressure where this process is augmented by a vacuum pump). Air can also be removed from tubular devices by injecting steam through the lumens.

**Type N** cycles are intended to be used to sterilize solid devices that are not wrapped. Devices that are wrapped (the term 'wrapped' includes sterilisation pouches) and devices that are hollow or have lumens cannot be sterilized in this type of sterilizer. These types of loads should ideally be sterilized in a SSD but alternatively may be sterilized in a properly functioning vacuum steam sterilizer that has been validated for the intended load (see section 4.1).

**Type B** cycles are intended for wrapped solid items (e.g. forceps, dental probes), hollow items (e.g. cannulae, tubing), whether or not they are wrapped and for porous loads e.g. fabrics, swabs and dressings. They are necessary for items that cannot be processed using a Type N cycle (or a Type S cycle, unless it is intended specifically for these load types). Type B cycles **must** have a drying stage to ensure that the load is dry before the door is opened, which can increase the total cycle time considerably.

**Type S** cycles are intended for types of loads specified by the manufacturer of the sterilizer. They have a forced air removal system. (Forced air removal can be achieved using a vacuum pump or super atmospheric pulsing or steam injection through the lumens of devices).

The effectiveness of the air removal stage determines the types of load they are designed to process. Some models have a drying stage, which will prolong the cycle time.

In a regular autoclave, linen wrapped articles are sterilized at 121°C + 20 Psi pressure.

The parameters for sterilisation are given below.

**The parameters for sterilisation of various items are;**

Items	Pressure (Pound per sq inch – psi)	Temperature	Holding Time
Blunt instruments, dressing, glass, silicon materials, linen, vessels	20 psi	121°C	20 Min
Rubber items	20 psi	121°C	20 Min
Liquids	20 psi	110°C	20 Min

- **Holding time; Time after attaining required temperature & pressure**

**After autoclaving, the instruments as well as other sterilized items should be used within 48 hours, unless they are kept wrapped inside air tight sealed bags. With surgical drums, once opened the contents must be used immediately.**

Indicator tape should be used in every cycle. Better to use class 5 indicator as it is equivalent to biological indicator. One strip to be placed in each set. If using class 5 indicator, class 1 indicator – chemical indicator strip can be pasted on the external surface of the drum to alert that the drum has been autoclaved. On the day of surgery, the assisting sterile nurse should check it and hand them over to the running nurse to place them in a register, which should be checked and signed by the surgeon and OT in charge before starting the surgery.

**(i) Gas sterilisation**

Several articles used in ophthalmic surgery cannot be autoclaved or placed in a chemical solution or in a hot air oven. These can be effectively sterilized using an Ethylene Oxide (ETO) sterilizer. The gas is extremely toxic, carcinogenic and potentially explosive. Instruments like Cryoprobe, Vitrectomy Cutter and Cautery wire can be sterilized using these gaseous agents.

**(a) Ethylene oxide sterilisation:**

- Remove all lubricants from instruments
- They should be cleaned and be absolutely dry
- Pack them in special polythene bags with indicator tape inside the bag
- As they are carcinogenic and also mutagenic, the equipment should be kept in an isolated room with an exhaust. The exhaust tube from the equipment should be taken and left above the roof of the building
- Due to their toxic nature, an aeration period of minimum 72 hours for the sterilized items is a mandatory requirement before they are used. However, time depends on manufacturer's recommendation and the type of steriliser (semi-automatic or manual)
- Sterilised materials should be packaged, labeled, and stored properly to remain disinfectant with each item marked with the date of sterilisation. A microbiological control is mandatory

## (b) Low temperature plasma sterilisation

### 2.2.2 Mode of sterilisation of instruments in between surgery

- In between surgeries, the instrument sets should be sterilised using short cycle autoclaving

#### Short cycle autoclaving

- In between surgeries, the instruments are ideally sterilised using a flash or high speed autoclave. If not available, a single drum autoclave can be used. Vertical autoclave should not be used particularly, if sterilising long tubings.



Flash Autoclave



ETO Gas



Horizontal



Vertical

- Adequate number of surgical instrument sets should be made available and the practice of boiling should be discontinued
- The instruments are cleaned using clean mineral or boiled filtered water and a clean brush. The cannulated instruments should be flushed with sterile BSS / RL solution followed by air before sterilisation
- The instruments are then placed back in the instrument tray. The trays are placed inside a surgical drum, which can hold up to 6 sets
- The drum is placed in the autoclave. It takes 10 to 12 minutes for the autoclaving to be completed
- The parameters are 134°C, +30 Psi, 7 to 10 minutes of exposure. This ensures adequate sterilisation and the whole process for cleaning and sterilizing six sets will take about 20 minutes
- In a high volume set up at least two nursing personnel should be allocated for this activity

#### Dry heat sterilisation (hot air oven)

It is for articles which can be damaged by steam, e.g. sharp instruments, glass syringes etc. Sterilisation occurs at 170°C for two hours or at 180°C for one hour. The method is seldom used and is useful for glassware used in the laboratories.

### 2.3 Shelf Life of Sterilised Items (Method of Sterilisation and Shelf Life)

Method	Shelf life
Autoclaving in drums or linen	48 hours
Autoclaving with double packing	28 days
ETO sterilisation with double packing	1 year
Plasma sterilisation	1 year

**To conclude**, autoclaving is suitable for all materials except plastic items, for which ETO sterilisation can be used. Aeration time after ETO sterilisation is a minimum of 24 hours (or follow manufacturer's instructions). In between surgeries again steam sterilisation using a high speed or flash autoclave can be done.

### 2.4 Disinfection of other articles used in patient care

Other instruments used in outpatient department as well as in wards should be kept free of infective agents. Disinfection is an adequate method of rendering instruments clean **which do not penetrate the skin** and high level disinfection is effective against microorganisms like M. tuberculosis and Enterovirus. Disinfection can be achieved by thermal methods. Tip of the applanation tonometer, footplate of Schiotz tonometer and A scan probe can be disinfected by wiping with 70% isopropyl alcohol.

**Thermal method** of disinfection is reliable. It is non-toxic, and can be easily controlled leaving no residue. Boiling at 100°C for 5 minutes is lethal for Hepatitis B and HIV viruses and Mycobacterium. Addition of 2% solution of sodium bicarbonate (NaHCO<sub>3</sub>) is helpful in preventing corrosion due to boiling. This method is no longer used in tertiary care hospitals but may still be relevant for secondary level hospitals in the periphery.

### 2.5 Disinfection and reuse of linen

- Contaminated linen may be a source of infection. They are placed in a separate plastic bin after the surgery, linens are placed in impervious bags for transportation to the laundry
- Aprons (preferably disposable) and drape sheets must be washed with detergent, dried in covered area
- The surgical coat should be autoclaved in a loosely packed, separate drum or packed into a bundle with an indicator strip pasted
- For linen infected with seropositive, disinfection of the linen immediately after use with low level disinfectant like hypochlorite should be done; then send to routine laundry after drying

<b>Area</b>	<b>Procedures</b>	<b>Accepted Practice</b>
No. of standard surgical sets	One surgeon with one OT table	4-6 sets
Cleaning Procedures	Manual Cleaning	Use four bowls. First wash in the disinfectant and cleaning with a soft toothbrush followed by three washes with distilled water
Blunt Instruments	Prior to Surgery Between Cases	Steam sterilization Flash Autoclave
Sharp Instruments	Prior to Surgery Between Cases Cryoprobe	Steam sterilization, ETO sterilization Flash Autoclave ETO
Heat Labile Instruments	Vitrectomy cutter Cautery	Ethylene Oxide gas sterilization
Linen	Surgeons Dress Aprons (Gowns) Drape Sheets	Steam Sterilization Steam Sterilization Disposable
Hand Washing	Prior to Surgery	Hand scrubbing with povidone iodine scrub or chlorhexidine for five minutes
Surgical Supplies	Irrigating Solution	Steam sterilization before opening the seal
Theater Sterilization / Disinfections	Floor	Chlorhexidine, Lysol, 1% sodium hydrochloride solution
	Fumigation of OT	Formaldehyde / Hydrogen peroxide
	Air Conditioners	Filters removed and washed with soap and water weekly
	Walls	Washed with water and disinfectant weekly
	Theatre Trolleys	Disinfectant
Patient	Dress for OR	Washed clean, fresh and laundered dress if provided by the hospital, shoe covers and cap



# 3

## Aseptic Protocols

### 3.1 Surgical Attire

The use of barriers like scrub suits, caps, gloves and gowns seems prudent to minimize the exposure of the patient to the skin, mucous membrane or hair of the surgical team member and to protect the surgical team members from exposure to blood borne pathogens of the patient.

All personnel working in the operating rooms must wear clean surgical attire in place of their street clothes. Operating room clothes are not worn outside this area.

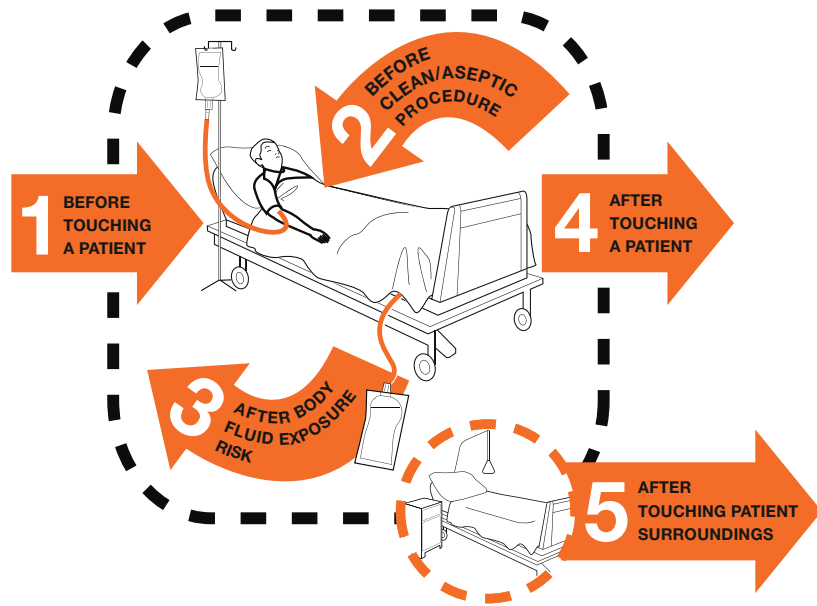
- **Scrub suits:** Surgical attire is designed for maximum skin coverage since skin squamers are a potential source of microbial contamination
- **Caps:** Head and facial hair must be covered
- **Masks:** Disposable well-fitting deflector masks should be worn. Cloth masks are ineffective barriers for microorganisms, particularly once they moisten during breathing
- **Shoes:** Dedicated footwear is recommended for use in the OR. The footwear should be designed to protect the wearer from spills of blood and body fluids.
  - o No shoe cover is allowed inside the OT – change to OT slippers
  - o Clean, washed OT dress - dress code has to be strictly enforced
  - o OT staff should not come out of OT in OT gown / dress
  - o Operating room staff should wear scrub apparel with long sleeves and tight cuffs at the wrist
  - o Slippers for toilet use and OR are kept separate. Slippers are washed daily with detergent and dried.
- **Sterile Gloves:** Sterile gloves are worn by all scrubbed members of the surgical team and should be changed for every case
- **Gowns and drapes:** create a barrier between the surgical operative field and potential sources of microorganisms. They are ideally made of material impermeable to liquids

## 3.2 Decontamination of hands

Hand hygiene plays a vital role in preventing nosocomial infections / hospital acquired infections. According to international literature good hand hygiene practice among hospital staff can reduce hospital acquired infections by half.

Social hand washing - simple procedures to wash hands with soap and water should be done frequently as suggested in the five moments of hand hygiene by WHO.

### Your 5 Moments for Hand Hygiene



## How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

Duration of the entire procedure: 40-60 seconds

<p><b>0</b></p> <p>Wet hands with water;</p>	<p><b>1</b></p> <p>Apply enough soap to cover all hand surfaces;</p>	<p><b>2</b></p> <p>Rub hands palm to palm;</p>	<p><b>3</b></p> <p>Right palm over left dorsum with interlaced fingers and vice versa;</p>
<p><b>4</b></p> <p>Palm to palm with fingers interlaced;</p>	<p><b>5</b></p> <p>Backs of fingers to opposing palms with fingers interlocked;</p>	<p><b>6</b></p> <p>Rotational rubbing of left thumb clasped in right palm and vice versa;</p>	<p><b>7</b></p> <p>Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;</p>
<p><b>8</b></p> <p>Rinse hands with water;</p>	<p><b>9</b></p> <p>Dry hands thoroughly with a single use towel;</p>	<p><b>10</b></p> <p>Use towel to turn off faucet;</p>	<p><b>11</b></p> <p>Your hands are now safe.</p>



World Health Organization

Patient Safety  
A World Alliance for Safer Health Care

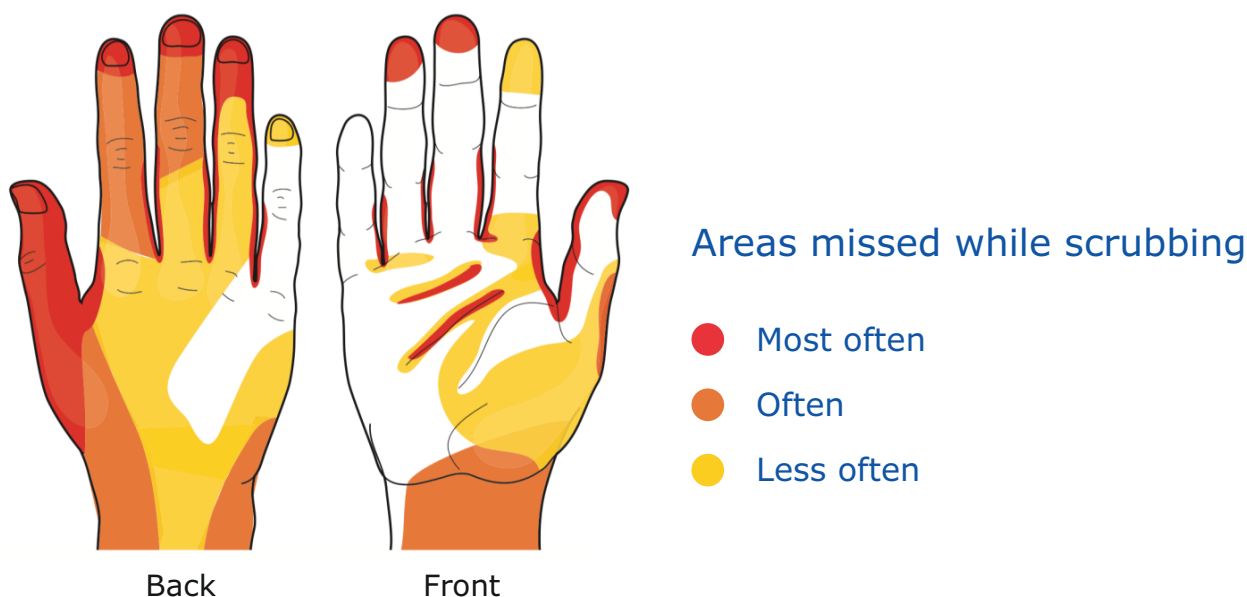
SAVE LIVES  
Clean Your Hands

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When hands do not appear dirty, applying hand rub solution and allowing it to dry for 30 seconds is also enough.

**Surgical hand washing**, as the name suggests, is required before performing any surgical procedure. Important points to consider are:

- All ornaments are removed from the hands at the time of scrubbing.
- **Quality of Water:** Clean, purified water is best for decontamination of hands. Alternatively, boiled water / chlorinated tap water can be used. RO filtered water also can be used
- Wash hands and arms to two inches above the elbow and clean finger nails under running water
- Wet scrub and apply antimicrobial soap solution
- **Surgical Scrub:** Chlorhexidine 4% or Povidone Iodine 7.5% is used. Using liquid soap is recommended before using the scrub solution
- Rinse the hand and arm, keeping the hand above elbow level. First scrub of the day includes thorough cleaning underneath the finger nails. Begin scrubbing palm, outer and inner aspect of each finger, the fingernails, the dorsum of the hand and circumferentially work up to the elbow
- Hands are dried before donning gloves. Sterile towels are used for drying. Drying should not be done all the way up to the elbow. Alcohol / chlorhexidine hand rubs should be used on dried hands before gowning
- **Other important factors** that influence the effectiveness of the scrub, besides the choices of the agent, are the techniques and the standard steps, the condition of the hands and the techniques used for drying



## Recommended Scrubbing Technique



1 Palm to palm



2 Rotational rubbing of the left and right wrist



3 Left Dorsum over Right Palm



4 Palm to palm with fingers interfaced



5 Right Dorsum over Left Palm



6 Rotational rubbing on the tips of fingers & thumb of right hand in left hand and right palm then opposite



7 Back of fingers into the opposite hand with fingers interlocked



8 Rotational rubbing of thumb with the opposite hand

### 3.3 Operating Room etiquettes

It is important to layout and follow some etiquettes in the OR depending on the role of the team member.

#### Gowning and Gloving Technique

##### Gowning

Sterile gowns are always folded inside out to avoid contamination. As it is impossible to render the hands sterile, they must not come in contact with the outside of the gown or gloves.

##### Procedure:

- Pick up the gown holding it well away from the trolley and your own body
- Hold the neck band and unroll until the sleeves are seen
- Slide both hands and arms into the sleeves at the same time
- The floor nurse / assistant slides her hands under the gown at the shoulder and pulls out and fastens all the back tapes
- Cover the back with the back flap with the help of the un-scrub nurse

**Remember:**

- Do not keep the hands lower than the waist line
- Do not keep the hands near one's neck or shoulder
- Do not touch the axillary area once gowned
- Do not touch the back of the gown

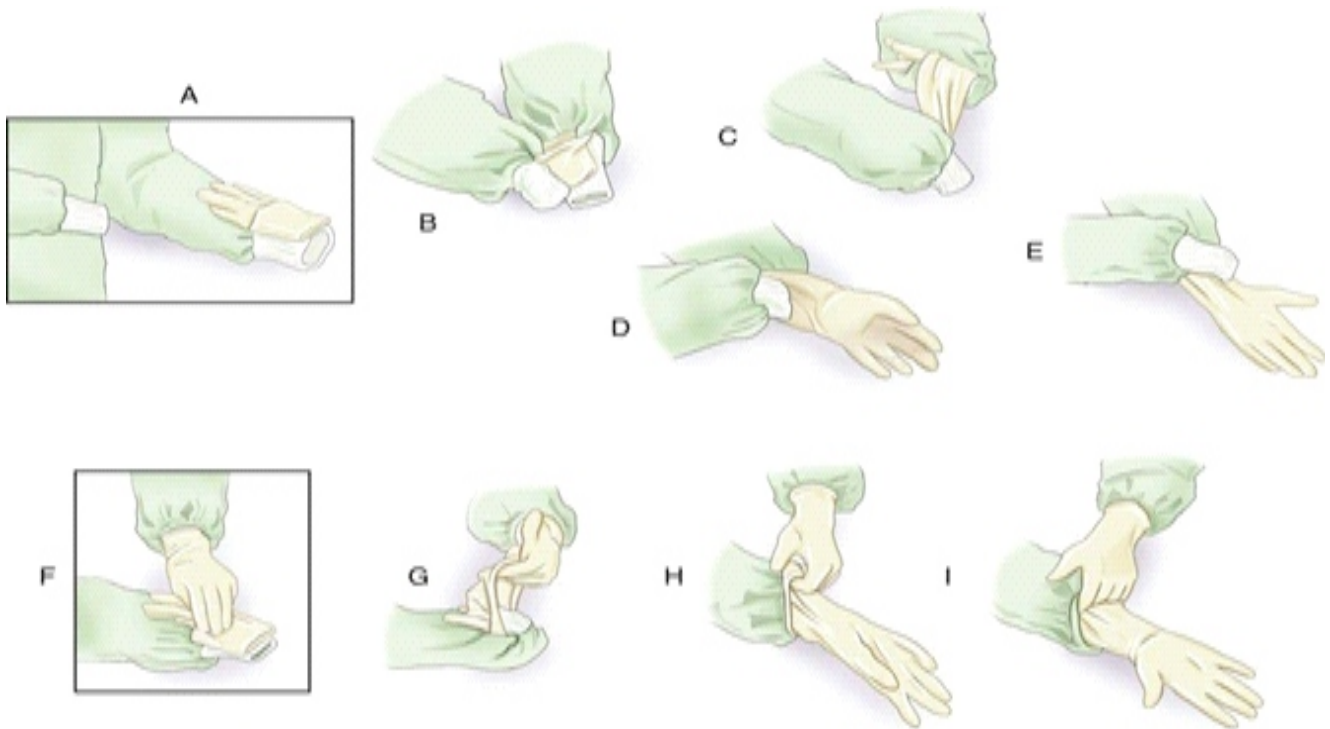
**Removal of Gown at the end of the Procedure:**

- The circulating nurse will unfasten the gown
- The gown is carefully removed by the scrub nurse leaving the gloves on
- The gown with the inside folded out is placed in the appropriate bin
- The gloves are then removed by holding the inside of the cuff and placed in appropriate container

**Gloving**

- Pairs of sterile gloves are packed in such a way as to facilitate handling without touching the outside of the gloves with bare hands
- A 2" cuff is folded on each glove
- There are two methods of gloving - The open method & the closed method

**Procedure for wearing gloves**



### Open Method:

- Always take chlorhexidine or its equivalent solution on bare hands before gloving
- Pick up the first glove by gripping its cuff with one hand and slip the other hand in
- With the gloved hand, pick up second glove by slipping hand under the cuff (outside of the glove) and slip the ungloved hand in and release the grip
- At this stage, adjust the fingers of the gloves properly
- If gowned, the cuff of the second glove is pulled over the stockinet sleeve of the gown
- The cuff of other glove is then pulled over the stockinet sleeve



### Closed Method:

- The hands are not pushed beyond the stockinet cuffs of the gown
- The cuff of the left hand glove is grasped through the stockinet part of the right sleeve
- The left hand is inserted into the glove and the glove grasped by the right hand is pulled over the left hand
- After stretching the cuff, the glove is pulled over the sleeve and the hand is forced through the stockinet cuff into the glove
- The second glove is put on in a similar manner except that the cuff can be grasped with the already gloved hand and the right hand is forced through the stockinet cuff into the glove
- Glove powder can cause irritation and induce post-operative complication (Sterile Uveitis). Hence, it should be wiped off with a sterile wet mop



**Removal of Gloves (for both types of gloving techniques):**

- To prevent outer surface of gloves from contaminating hands, the gloved fingers of one hand grips the outer surface of the cuff and pulls off inside out
- To prevent contamination of the ungloved hand, the inside of the cuff of the opposite glove is held and pulled off the hand
- Gloves are discarded into the designated container



### **Activities between two surgeries**

- After the surgery, the scrub nurse hands over the used instruments to the sterilization room nurse for cleaning and re-sterilisation
- RL, Visco elastics and SICS blades should not be passed on to next patients. Visco elastics should be discarded. Ringer Lactate should be discarded if it is affordable to do so or else can be autoclaved once. Balanced salt solution can be used if afforded cost wise
- SICS Blades must also be changed after each surgery which can be autoclaved
- Ideally one must re-scrub for 3 minutes between the two surgeries. However if we do not touch elsewhere and circulating staff remove the scrubbed person's gown. Else scrubbing for full 7 minutes is recommended. We must develop our own protocol
- Minimum requirement is to change the gloves after each surgery. It is recommended to wear double gloves for HCW's safety and change the external gloves after each surgery
- Each time a fresh trolley should be prepared (remove everything from the trolley at the end of the surgery and prepare it afresh for the next surgery)
- IV set; Visco elastics and Inj. RL should be used fresh for each surgery
- For each surgery, autoclaved set of instruments must be used. Flash autoclave can be used to sterilise the instruments in a short period of time in between the surgeries, if there are less instrument sets than number of surgeries.
- Microscope knobs must also be changed which should be autoclaved
- Ideally Phaco probe and tubings must also be changed after each surgery. However each hospital must develop their own protocol. At least tip and sleeve should be changed after each case

### **When a person is scrubbed for surgery**

- Follow correct gowning and gloving technique. In order to minimize the risk of contaminating the sterile operative set up during the process of gowning and gloving, a separate table should be used. Only the scrub nurse should gown and glove herself/himself. The rest should avoid self-gowning and gloving if adequate circulating staff is available
- Remember that the back of the gown, the area below the waist, region of armpit and the area around neck are considered unsterile once the gown is worn. Some experts suggest that the area of the sleeve above the elbow also is considered unsterile
- Gloved hands are kept above the waist and clasped in front or on top of the sterile field
- For coughing or sneezing, step back from the sterile field and turn away
- Avoid light banter, unwanted or irrelevant talks inside the OR
- When changing places with another scrubbed person, one has to do so back to back
- The sterile instruments should be kept above the waist level
- Do not let your mask hang loose around the neck and reuse the same
- Do not prepare all trolleys beforehand
- Moisture is a potential source of contamination - do not use moisture soaked linen packages



### When circulating for surgery

- The sterility of the sterile pack is checked before opening for expiry date, breach in the packing, holes in the packing and sterility indicator including expiry date. A sterile packet is not to be used if the sterility is doubtful
- Before giving any sterile items, staff will apply sterilium on hands and allow it to dry
- Items are not passed above the sterile field
- **A sterile package** may be opened on a flat surface or while held in the hands. A sterile item should be covered if it is not used immediately. Open the pack away from the body keeping fingers outside the wrapper
- While opening the flaps of a sterile packet, the farthest away is opened first with care not to reach over the sterile field. Then the side flap is opened and the flap nearest to the nurse is opened last
- **Pouring sterile solution** - The outer surface of the bottle and cap are considered unsterile, whereas the inside area and the solution are considered sterile. The nurse pours the sterile liquid into a sterile container without reaching over the sterile container. While pouring liquids, container is held 6 inches above the sterile field.

### Those observing the surgery (Including the circulating staff)

- Hands are kept behind the back
- Leaning over the sterile field is avoided
- Crossing or touching between sterile fields is not done
- One foot clearance from sterile area is strictly observed
- One should avoid passing between two sterile fields and lean over the sterile field
- Excessive coughing / sneezing inside the OR is best avoided
- Casual observers are not allowed inside the OR
- Woolen wear of any kind is not allowed inside the OR as it attracts and harbours dust and microorganisms

### Colonized or infected surgical personnel

- Personnel operating with active infection have been linked with outbreaks of infection. Healthcare organisations should implement policies to prevent the transmission of microorganisms from personnel to patients.
- Policies will depend on the infectivity of the person, the type of patient contact and when necessary the person may be excluded from work.
- The health care personnel may be encouraged to report their illnesses

### Infected health care workers in the OR: HIV, HBV, HCV

- Personnel affected with the above viral infection carry risk of transmitting infection to other health care personnel and to the patients, though actual transmission of any blood borne infection from infected health worker to patient is quite low.
- Strict adherence to standard precautions including hand washing, protective barriers and disposal of all sharps helps control any mishap.

All skin lesions on hands are covered with a waterproof dressing and the affected person should not enter the OR complex till the wound is healed. Isolation of infected personnel is important, and the staff is educated about these measures.



# 4

## Monitoring and Surveillance of Sterilization Procedures

**Surveillance and monitoring** are essential steps in maintenance of sterilisation. It is applicable to every facet of the entire process of sterilisation including cleaning, packing, autoclaving, antibiotic prophylaxis etc. Good monitoring protocols and surveillance systems enable us to detect deficiencies at an early stage and rectify them and thus prevent mass catastrophe. Sterilisation is dependent upon machines and humans; both are prone to error.

The causes of sterilisation failure can be:

- Inadequate cleaning
- Item not fully subjected to sterilisation process
- Load failure
- Pack failure
- Contamination during handling or storage

To ensure that the sterility of the OR is not breached or compromised, regular monitoring is essential. The following are monitored:

- I. Monitoring of OR environmental sterility (air, surfaces, water)
- II. Monitoring of sterilisation procedure (steam, gas)
- III. Monitoring of effectiveness of sterilisation process ( steam, gas)
- IV. Monitoring of surgical supplies (Irrigating fluids, Viscoelastics, intracameral drugs).  
Batch number of all consumables should be noted
- V. Surveillance of surgical infections and inflammations
- VI. Infection control committee to review outbreaks of infection and to revisit the protocols
- VII. Continuous training of personnel and procedures

## 4.1 Monitoring of OR environmental standards

- An air sample is tested using an open dish sedimentation method. In this method, culture plates are exposed to the environment for half an hour. Alternately bacterial counter can be used. Culture plate to be exposed at the head end of operating table. A fortnightly check is recommended. <10 colonies within one meter of the surgical field is considered OK. However, no fungal colony should grow on the plate.
- A swab for culture is taken both from sterile and unsterile items on a fortnightly basis
- Nasal and nail bed swabs of OR personnel are tested on a monthly basis. This is not essential – however, for small hospitals, it is a good idea to continue to do it to get an idea about the level of cleanliness. At the same time, interpretation of the results is also very important to prevent undue alarms.
- Performance monitoring of the OR ventilation:
  - Regular inspection of filter systems
  - Pressure differentials across the filters
  - Testing of low or medium efficiency filters and manometer tests for positive pressure
  - Particle counts
  - Pressure differentials qualitatively measured by the smoke test
  - Monitor as to whether intake air is kept clean and free from bird droppings
  - With centralized air conditioners, monitor the ducts for periodical cleaning

## 4.2 Monitoring sterilisation procedures

The sterilisation procedure is monitored by documentation of the cycle time, temperature and pressure gauge by a graphic record. Maintenance of log book is mandatory. The required details should be entered by the team involved in sterilisation either at the end of the day or in between surgeries. The autoclave machine should be validated periodically by the vendor or independent agency.

## 4.3 Monitoring of effectiveness of sterilisation process (Steam, Gas)

The effectiveness of the sterilisation process can be monitored using chemical or biological indicators.

### **Steam sterilisation**

**Mechanical monitoring:** Log book of autoclaving is maintained where the time, temperature and pressure are entered with the time and duration of the cycle recorded.

**Chemical monitoring:** The change of colour of the strips at the end of the cycle indicates attainment of the desired temperature during the cycle. The colour of the strip at the end of the cycle should be jet black otherwise the cycle should be repeated. However, ideally, we should use class V indicators in each cycle which are equivalent to biological indicators.

Once a week, if affordable, a Bowie Dick test pack or a vapour line indicator can also be used. However, ideally, Bowie Dick test pack should be used every day in the first cycle. Failure of chemical indicator test should prompt thinking about possible causes and another type of chemical indicator / other company's product should be tried and biological indicator should be used to confirm proper functioning of the machine.

**Biological monitoring:**

- Bacillus stearothermophilus spores for steam sterilisation and Bacillus Subtilis for dry heat and Ethylene Oxide (ETO) cycles
- The ampoule is to be put in the load along with other items
- Preferably should be done every fortnight and the results must be documented



Chemical Indicator Strips



Bowie Dick test Pack & Vapor Line Indicator



Biological Indicator Ampoules

- Generally done once in a month
- It is supposed to be a surprise check
- Failure of biological indicator test should be taken seriously and detailed check of the functioning of the autoclave machine should be done. In such cases, autoclave should not be used till it is validated by service provider and another biological indicator test is passed.

A basic summary of the monitoring requirements for steam sterilizers is listed below:

Process Recorder	Temperature Measurement	Chemical Monitoring	Other	Optional Monitoring
Every Cycle	Only during calibration and performance qualification of sterilizer	Every load and if required, every item	<ul style="list-style-type: none"> <li>• Pre-vacuum sterilizers - weekly leak test if sterilizer fitted with an automatic air detector, otherwise daily</li> <li>• Biological indicator for emergency - non validated loads</li> </ul>	<ul style="list-style-type: none"> <li>• Biological Indicators<sup>Σ</sup></li> <li>• Process Challenge Devices</li> <li>• Electronic Data Loggers</li> <li>• Internal Chemical Indicators</li> </ul>

∃ The condition here is that the record is generated automatically by the sterilizer controller system, and crucial details of every cycle are recorded in a permanent form. AS 4187, Section 8 makes note that existing sterilizers without process recorders need to be upgraded or replaced to ensure automatic parameter monitoring.

Σ any of the three types of biological indicators for steam sterilisation available in the Indian marketplace may be used, subject to sterilizer operators demonstrating the value of their contribution to sterilizer monitoring.

σ This involves use of an independent means of temperature measurement and the introduction of electronic temperature measurement leads (thermocouples) into the sterilizer chamber. The aim is to measure during the sterilizing stage, the chamber temperature and the inside temperature of a test pack / packs. Note; the placement of thermocouples within packs should be done considering the complexity of the contents; e.g insert thermocouples into cannulas and like places where steam penetration is likely to be impeded.

### **Different class of indicators:**

#### **Class 1 – Process Indicators**

Used to show exposure to a process. No information about the success or failure of the process

#### **Class 2 – Specific Test Indicators (e.g.BDT)**

#### **Class 3 – Single variable indicators**

- Respond to a single variable in the process e.g. temperature

#### **Class 4 – Multivariable Indicators**

- Respond to two or more variables in the process

#### **Class 5 – Integrating Indicators**

- Respond in a way which mimics the response of a BI if used in the same process

#### **Class 6 – Emulating Indicators**

- Respond to all defined critical variables of the process at levels associated with acceptable sterilizing conditions e.g. 134°C for 5minutes

*Important: classification is non-hierarchical!*

## **4.4 Monitoring of surgical supplies**

It is also an essential duty of the OR in charge to monitor the supplies used in surgery, which includes the irrigating solutions, viscoelastics, surgical gloves, syringes and other pre packed sterile articles. Sterility must be ensured and nothing should be used serially in more patients without re sterilisation between cases!

Some of the guidelines that will help in prevention of surgical site infection are:

### **Irrigation solutions**

- Should preferably use glass containers, rather than plastic. A collapsible bag is ideal. Better to use doubly packed pouch packing. Some hospitals autoclave the glass bottles for additional safety. If using glass bottle, vacuum test (bubbles on putting needle inside) to ensure that there were no micro cracks in the bottle. Some hospitals culture before using each new batch. However, the responsibility of ensuring sterility of anything that is used, lies with us.
- Check clarity of solution and look for any suspended particles. At the time of receiving it in the store, receiving it in OT, before placing it for autoclaving and just before using it.
- Check for leakage and quantity of solution
- In a high volume set up, it is preferable to culture Ringer lactate solution before routine use.

## **4.5 Surveillance of surgical infections & inflammations**

Surveillance of any type of surgical infections (wound infiltrates, scleral necrosis, endophthalmitis) and unexpected severe inflammations (TASS) with appropriate feedback to the surgeon is important to reduce the risk of such catastrophes. In designing a **surveillance protocol**, both clinical and microbiological data are essential. The method of data collection should be made easy.

- Periodic culture once a month from areas such as hand washing area, saline, cannula, distilled water. Swabs are taken from surgeon's and assistant's hands, floors, walls and air conditioner for culture once in 15 days. Interpretation is important. Swabs from non-sterile items will indicate only the level of cleanliness
- The Bacterial Carrying Particle (BCP) load in theatre is checked by open dish sedimentation plating technique by exposing the agar plate at the head end (within one meter of the operating field) of the operating table after switching on the AC for half an hour (the plate should be exposed for at least half an hour) every fortnight. <10 colonies is considered OK. However, no fungal colony should grow on the plate
- Whereas the swabs from sterile areas should not have any growth at all

### **Essential clinical data should consist of the following**

- Severity of infection or extent of bacteriological contamination
- Type of operation
- Time period between the procedure and the appearance of infection.

### **Microbiology laboratory data should be reliable and include**

- The complete identification of isolated organisms
- Their antimicrobial susceptibility tested

## 4.6 Create an infection control / quality control team

### Team comprises of:

1. Ophthalmologist
2. Nurse in charge of OR
3. Hospital Manager / Administrator
4. Laboratory In charge / Microbiologist

Periodical tests done by Infection Control Committee can go a long way in ensuring a safe and effective outcome for most patients undergoing cataract surgery.

- The monitoring protocols should be designed according to the needs of the organisation. Basic principles governing design of monitoring and surveillance have been outlined in the chapter. Readers are encouraged to modify their protocols based on this
- Both the sterilisation procedure and the effectiveness of the sterilisation process must be monitored in the following way
- Checklists of scheduled tasks for cleaning can be prepared on a daily, weekly, monthly and quarterly basis.

## 4.7 Microbiological parameters, proposed frequency of sampling & desired results

Microbiological parameters	Proposed frequency of sampling	Desired result
Monitoring of sterilization process by biological indicators	Monthly	No failures
Monitoring of the OR environment for BCP load	Weekly/Monthly especially where the theatre does not have air handling units with adequate filters etc. and physical parameters are not strictly adhered to and monitored	Bacterial load should be less than 180 per cubic meter or less than 10 colonies when done by sedimentation method using 10 cm diameter agar plate
Assessment of the OR surfaces for presence of Clostridium spores	Utility not very clear except for ensuring cleanliness	Clostridium spores be absent
Evaluation of operation theatre staff for carriage of Staph. aureus and Beta hemolytic streptococci	Twice a year or more	Carriers and shedders should be adequately treated and reassessed
Air-conditioning units for variable fungal contamination	In dry climatic conditions - 3-4 times in a year In humid climatic conditions- Monthly	Growth of fungi. Adequate disinfection and cleaning measures should be instituted in case of detection
Disinfectant in use	Monthly	Should adhere to established microbiological standards



# 5

## Checklist for Operating Rooms

1. Daily Cleaning Check List for Eye OT
2. Weekly Cleaning Check List for Eye OT
3. Monthly Cleaning Check List for Eye OT
4. Quarterly Check List
5. Monitoring of the Autoclaving Procedure
6. Weekly Autoclave Report

## Annexure 1

# Daily OT Cleaning Check List for Eye OT

Date -

1. Who checked Pre-operative check list?
2. Who checked autoclave strip register?
3. Who filled drum of gowns - gloves? Who checked it?
4. Who checked clarity of Inj. RL?
5. Who did preparation before arrival of surgeon? (Cautery & Microscope in order?)
6. Who did fumigation & with what? (Formaline, Ecoshield, Bacillocid)
7. Who did cleaning before leaving in evening? (doors should be cleaned every day)
8. Who checked operation & emergency medicines stock?
9. Who put on the U.V. light at night? Who put it off in the morning?
10. Was the chlorination of water tank done yesterday? Who did it?
11. Who checked anesthesia trolley?
12. Who replaced bed sheet of OT table in the evening?
13. Who cleaned equipments / Instruments (Cautery, Suction machine & OT Table) with Na – hypochlorite?
14. Special Note :

**Signature of OT – Incharge** : \_\_\_\_\_

**Signature of HOD** : \_\_\_\_\_

## Annexure 2

# Weekly Cleaning Check List for Eye OT

Date -

Week -

- Particulars Checked- Y  N
1. List of medicines checked? Y  N  Who did it? (Daily use + Emergency medicines) \_\_\_\_\_
2. Eye OT Check list checked? Y  N  (List except medicines ) By \_\_\_\_\_
3. Did In-Charge prepare the list of OT staff posting? Y  N
4. Who submitted Auto Clave report? Who checked it? Y  N
5. In charge checked the list of Sunday works done or not done ? Y  N
6. Cleaning done on Saturday by shifting things ? (Microscope, OT Table) Y  N
7. Walls and floor of OT cleaned with Sodium Hypochlorite ? Y  N  Who did it ? \_\_\_\_\_
8. Autoclave room fumigated on Saturday after cleaning ? Y  N  Who did it ? \_\_\_\_\_
9. A/C Filters cleaned ? Y  N  Who cleaned ? \_\_\_\_\_
10. Instruments cleaned ? Y  N  (Check blade and change it if necessary). Who cleaned? (Check two way cannula) \_\_\_\_\_
11. Staff nail checked ? Y  N  Who checked ? \_\_\_\_\_
12. Chlorination checked ? Y  N  Who did it ? \_\_\_\_\_
13. Water changed in autoclave machine ? Y  N  Who did it ? (Change every fortnight) \_\_\_\_\_
14. Bottle of surgical scrub and bottle of liquid soap cleaned & autoclaved ? Y  N  Who did it ? \_\_\_\_\_
15. Expiry dates of medicines checked ? Y  N  Who did it ? \_\_\_\_\_
16. Were the Operating Microscope lenses cleaned ? Y  N  By whom? \_\_\_\_\_
- 17 Special Note :

**Signature of O.T. – Incharge:** \_\_\_\_\_ **Signature of HOD:** \_\_\_\_\_

## Annexure 3

# Monthly Cleaning Check List for Eye OT

Date -

Month -

Particulars Checked -

Y

N

1. Overbook of change of OT assistant posting checked ? Y  N
2. Swab sample culture done on every second Saturday ? Y  N
3. OT A/C cleaned by air blower cleaner on last Saturday ? Y  N
4. Did in-charge check the washing of OT on last Saturday ? Y  N
5. IOL Report completed or not ? Y  N
6. Lecture delivered and exam conducted for OT staff ? Y  N
7. Who cleaned the water tank ? On which day ? Y  N

---

8. Drum cleaned ? Who did ? Holes checked ?

---

9. Windows cleaned or not ? Y  N

10. Special Note :

---

---

**Signature of O.T. Incharge:** \_\_\_\_\_

**Signature of HOD :** \_\_\_\_\_

## Annexure 4

# Quarterly Check List

Date -

Quarter -

1. Cock filters of scrub area changed ?    Y     N
2. Stock taking done ?    Y     N
3. Stock statement prepared ?    Y     N  Copy sent to store ?    Y     N
4. Acid cleaning of water pump of auto clave machine done ?    Y     N
5. Special Note :

**Signature of O.T. Incharge** : \_\_\_\_\_

**Signature of HOD** : \_\_\_\_\_



# Annexure 6

## Weekly Autoclave Report

Autoclave Report from \_\_\_\_\_ to \_\_\_\_\_ Report prepared on \_\_\_\_\_

Autoclave by		Eye OT	OPD	Total
Monday	Small			
	Big			
	Tray			
Tuesday	Small			
	Big			
	Tray			
Wednesday	Small			
	Big			
	Tray			
Thursday	Small			
	Big			
	Tray			
Friday	Small			
	Big			
	Tray			
Saturday	Small			
	Big			
	Tray			
<b>Total</b>				

Preparation as per no. of operations	Operations done	Autoclave No.				Total drums+ trays	When needed Started in morning	Note
		1	2	3	4			
Monday								
Tuesday								
Wednesday								
Thursday								
Friday								
Saturday								

Report Prepared By: \_\_\_\_\_  
 Signature of I/C : \_\_\_\_\_  
 Signature of HOD : \_\_\_\_\_  
 Note : \_\_\_\_\_

## Additional Check lists for OR efficiency

### Daily Check List

1. Daily posting of OT staff / Preparation of OT check list.
2. Daily OT Report
3. Anaesthesia trolley check list

### Weekly Check List

1. Weekly OT staff posting Report
2. Check list of work to be done by OT boy on Sunday
3. Weekly Medicine + Others Check List (Eye OT)

### Monthly Check List

1. Monthly over of O.T. Assistant
2. 14 WHO patient safety check list



## Annexure 7

# Daily Posting of OT Staff / Preparation of OT Check List

Date -

Particulars	Eye OT
No.of operations done	
Time of start of operation	
Time of end of operation	
How many Doctors attended OT	
No.of nurses + Field staff	
No.of OT Tables – Assistants	1.
	2.
	3.
No.of OT Assistant	
No.of PCA	
Note:	

Particulars		Kept		Used	
No.of Gowns					
No.of Sheets					
No.of instruments sets					
No.of RL/ Contasol/Irrigating fluid					
No.of gloves					
Inj.Visco	Vial Pf				
Phaco	Probe (No)				
	Needle (No)				
1 to 5 Operation	Gown - 1 drum	No. of gowns -8	6 to 10 Operation	Gown - 2 drums	No. of gowns -16
	Sheet - 1 drum	No. of sheets -20		Sheet - 1 drum	No. of sheets - 40
	Instrument sets - 1 drum	6 Sets		Instrument sets - 2 drums	12 sets
	Inj. RL - 1 drum	6 Nos.		Inj. RL - 2 drums	12 Nos.
	Inj. Viscomet	7 Nos.		Inj. Viscomet	13 Nos.

Report Prepared By : \_\_\_\_\_

Signature of in charge : \_\_\_\_\_

Signature of HOD : \_\_\_\_\_

Note:

\_\_\_\_\_

\_\_\_\_\_

# Annexure 8

## Daily OT Report

Date -                      Day OT Start Time -                      OT End Time -                      Total Time -

Name of doctor attended	Names of Nurses attended	Names of Assistants
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Note : Enter data in box  
 Information about patients  
 Operated

Adults: Age Group

**Male:** 15 to 35       **Female:** 15 to 35   
 35 to 50                       35 to 50   
 50 to 60                       50 to 60   
 Above 60                       Above 60

**Children Age Group**

Infant :      < 1yrs:   
 Boys :      1 to 15   
 Girls :      1 to 15

**Details about type of operation done:**

- A)
- B)
- C)

**Total No. of Operations:**

- |   |                          |                       |                          |
|---|--------------------------|-----------------------|--------------------------|
| 1. Total Cataract                         | <input type="checkbox"/> | 1. Squint             | <input type="checkbox"/> |
| 2. Phaco with IOL                         | <input type="checkbox"/> | 2. Lid Surgeries      | <input type="checkbox"/> |
| 3. Non-Phaco with IOL<br>(SICS / ECCE)    | <input type="checkbox"/> | 3. DCR                | <input type="checkbox"/> |
| 4. IOL                                    | <input type="checkbox"/> | 4. Glaucoma           | <input type="checkbox"/> |
| 5. Non-IOL                                | <input type="checkbox"/> | 5. Pterygium          | <input type="checkbox"/> |
| 6. Combined Cataract with AGS             | <input type="checkbox"/> | 6. Vitrectomy         | <input type="checkbox"/> |
| 8. Corneo / Scleral Tear Repair           | <input type="checkbox"/> | 7. Retinal Detachment | <input type="checkbox"/> |
| 9. Minor                                  | <input type="checkbox"/> |                       |                          |
| 10. Corneal Surgeries<br>(Keratoplasties) | <input type="checkbox"/> |                       |                          |

Complications: \_\_\_\_\_



# Annexure 10

## Weekly OT staff posting Report

Period from: \_\_\_\_\_ To \_\_\_\_\_

Day	Block	Circulation	Assistants						Field Staff	Note about leave
			1	2	3	4	5	6		
Monday										
Tuesday										
Wednesday										
Thursday										
Friday										
Saturday										
Sunday										

Remarks: \_\_\_\_\_

### **(2) OT Assistant**

Day	Eye OT		Autoclaving
	Main OT	Minor OT	
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			

### **(3) OT PCA**

Day	EYE OT	Cloth washing	Instrument cleaning	As per need
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

Remarks: \_\_\_\_\_ Prepared by: \_\_\_\_\_

Signature of I/C : \_\_\_\_\_ Sign. of HOD: \_\_\_\_\_

## Annexure 11

# Check list of work to be done by OT Assistant on Sunday

SL.No.	Particulars	Month/Date	Reason if not done
1	Autoclave of both OT		
2	Cleaning of preparation room of both OT		
3	Cleaning of both Autoclave room		
4	Rolling of linen		
5	Help if emergency OT happens		
6	Folding & arranging clothes in the changing room		
7	Leave for home after checking G/A Trolley with Oxygen / Nitrous oxide cylinder		
8	Chlorination of water in the tank		
9	Cleaning of povidone iodine bottle / liquid soap bottle & its autoclaving		

Report Prepared By: \_\_\_\_\_

Signature of I/C : \_\_\_\_\_

Signature of HOD : \_\_\_\_\_







## Annexure 13

### Monthly hand over of O.T. assistant

S.No.	Particular		Month / D. O. C
1	Are coils of all autoclave machine in order ?	Y/N	
2	Are Rings of all autoclave machine in position?	Y/N	
3	Are E.T.O. machine & high speed machine functional?	Y/N	
4	Is table for preparation clean and well set?	Y/N	
5	Is autoclave room thoroughly clean?	Y/N	
6	Are broken punctured drums, tray segregated?	Y/N	
7	Is daily autoclave report prepared everyday?	Y/N	
	NOTE:		
	Name	Designation	Signature
	Signature of person handing over		
	Signature of person taking over		
	Signature of O.T. In charge		



## Summary-Infection Control Protocol

### **A. OT Lay Out**

- A. Segregation of sterile and un-sterile area should be ensured in OT lay out
- B. Dedicated Eye OT which should be away from septic OT
- C. Separate entry for both scrubbed staff and un-scrubbed staff / patients
- D. Air changes should be at least 20 per hour (Split AC) which should preferably be passed through a series of dust filters and then enters the room through a HEPA filter
- E. Humidity should be controlled and maintained between 50-60% with de-humidifier
- F. Temperature should be controlled and maintained between 20-23 degrees Celsius
- G. Space - minimum 180 sq. ft. for one OT table, maximum 5 personnel per 180 sq. feet

### **B. Preoperative Preparation**

#### **(a) Patient preparation -**

- Pre-operative topical antibiotics - broad spectrum on previous day
- No sac syringing, ROPLAS is sufficient
- No contact procedures like (Biometry / Tonometry ) on the day of surgery
- Eyebrows and lids to be cleaned with 10% Povidone Iodine before block & in wards also
- Allow patient in to the OT after taking bath and wearing washed caps, gown and leggings
- After block, one drop of 5% Povidone Iodine is instilled
- If Infection of Lids, Adnexa & Surroundings, unusual congestion or discharge - No Surgery. Treat with antibiotics, defer surgery until the local condition is clear. If surgery is required, delay the cataract surgery by at least three weeks.
- Use plastic adhesive drape
- Patient with systemic illness should get a clearance from physician. R/O dental infection
- Blood sugar and blood pressure to be adequately controlled
- High risk cases, one eyed patients & combined surgeries to be done by senior consultant
- Blocks to be given by trained personnel using sterile items, ensuring no touch technique after doing a hygienic hand wash.
- Pulse oximeter should be used to monitor patients and emergency drugs should be present at the site

## **(b) Personnel Preparation - Attire, Scrubbing, Gowning & Gloving**

### **1. Attire**

- Mask should cover nose properly and OT cap should cover all hairs
- Clean, washed OT dress should be worn. No shoe covers allowed – change to OT slippers

### **2. Scrubbing -**

- To scrub from a clean area (hand) to less clean area (arm)
- Hand to be washed with purified water + liquid soap & surgical scrub solution (Povidone iodine 7.5% or 4% Chlorhexidine liquid scrub) for seven minutes
- Re-scrub after 2-5 surgeries for 3 minutes if one doesn't touch anywhere & circulating staff removes scrubbed person's gown. (Highest ideal is to rescrub after each surgery)
- Nobody should come out in OT dress.

### **3. Gowning and Gloving -**

- Members of the team should be gowned and gloved as soon as they enter the room
- When donning gown & gloves, ensure that bare hands touch only inside of gown & gloves
- After wearing sterile gloves, wash hands with irrigating fluid to remove talc from the gloves. Preferable to use powder free gloves.
- During any waiting period, keep the hands above waist level upright in front and never sit, place the hands on lap or fold the hands

## **(c) Instruments and Equipments Preparation-Cleaning & Sterilisation:**

### **1. Instruments -**

- Instruments should be cleaned as soon as possible after their use
- Instruments should be thoroughly cleaned by washing in distilled water / mineral water. Surfactant cleaner can be used for effective cleaning
- After removing the instruments from ultrasonic cleaner, it will be washed in four bowls containing mineral water; dried; tipped with plastic sleeve and packed in individual trays
- Ideal is to autoclave everything required for one surgery in separate drum

### **Blunt Instruments**

- Normally 3 indicator tapes (bottom, middle and top - within the drums) are placed. One more tape is placed on to external surface of the drum
- Autoclaved instruments should be used within 48 hours

## **vitrectomy Cutter, Cautery wire, Sutures**

- Vitrectomy cutter, Cautery wires & sutures are autoclaved / ETO Sterilized

## **Irrigation Solutions**

- Look for suspended particles against light, note batch no. & use one bottle for one patient. Sterilise irrigating fluid before use.

## **Viscoelastics**

- Viscoelastics may be autoclaved before surgery & left over is neither re-autoclaved nor reused

## **Equipments**

- Fans, light, watches etc. inside theatre are wiped weekly, with 1% sodium hypochlorite
- Equipment like microscopes should be cleaned separately with 15% Cetrimide and 3% Chlorhexidine gluconate daily, except lens
- 0.1% Ethanol, 0.1% 2-Propanol and 0.06% I-propanol mixture (Bacillol 25 spray) is used to clean the head of the microscope daily
- Lenses should be cleaned once a week with lens cleaning solutions

## **Furniture**

- Tables, saline stands, revolving chairs (surgeon seat) cleaned daily with antiseptic liquid
- Not to keep wooden furniture inside the OT as it can harbor the organisms
- Tops of all furniture to be at the same height as the operating table. (the level of sterility)

## **Air conditioning Unit and Water tank**

- Air conditioner filter must be cleaned with detergent and sun dried once in a week
- Water tank should be cleaned with bleaching powder once a month

## **(d) OT environment Preparation - Cleaning & Fumigation**

### **Operating room & Corridors**

- Daily OT floor is wet mopped with 1% sodium hypochlorite solution
- After washing, formalin fumigation is done once a week, theatre is closed for 24 hours
- Alternately Gluteraldehyde + formaldehyde combination, 1% Hydrogen peroxide with silver nitrate or Aldekol are used every 15 days.

- Sterile quality of air in the OT is better achieved & maintained by employing air cleaner, air curtain & ultraviolet lights & through improving the overall cleanliness in & around the OT
- Complete cleaning of the theatre including walls, doors and floors is done daily up to six ft. height with 1 % sodium hypochlorite solution
- Block room, changing room, doctor's room cleaned daily thrice with 1% sodium hypochlorite
- Starting OT for the first time - 3 fumigations & preferably get 3 negative cultures of OT
- The sink area should be cleaned several times daily with 1% sodium hypochlorite solution and kept as dry as possible
- The outside of autoclaves should be cleaned daily with 1% sodium hypochlorite solution while the inside surface is cleaned weekly

### **C. During Surgery**

#### **On Table**

- Trolley should not be burnt but cleaned with spirit using unidirectional strokes
- Painting-Povidone Iodine 10 % for 3 minutes, on skin and periorbital area
- Direction-From medial to lateral canthus, in semi-circular motion, inside out
- Alternatively chlorhexidine (2 %) should be used
- Disposable Adhesive Drape should be used to isolate lashes
- 5% Povidone-iodine solution put in conjunctival cul de sac & allowed to act for 3 minutes
- Should keep sharp instrument on towel such that tip is facing up

#### **Between cases**

- Apply 2.5% Chlorhexidine hand rubs
- Change the gloves after each case or when it comes in contact with un-sterile surface.
- Remove everything from the trolley and re-do the whole trolley
- Use high speed autoclave to sterilize instruments in between the surgery

#### **At the end of Surgery**

- Sub Conjunctival antibiotic steroid – in the Inferior fornix – preferable. Alternately intra cameral antibiotic / topical antibiotic can also be used
- End of surgery put 5 % Povidone iodine eye drop

## **D. OT Etiquettes**

### **While observing surgery**

- One should keep hands behind back & should not stand behind the surgeon
- One should never touch or pass hand over the sterile field
- One should maintain at least a one-foot clearance from the sterile field
- One should avoid passing between two sterile fields and lean over the sterile field

### **While circulating for surgery**

- A sterile packet is not to be used if the sterility is doubtful. Check the package for holes or breaches and expiry date before opening the pack
- Open a sterile pack away from yourself, keeping your fingers on the outside of the wrapper
- When pouring sterile liquid, hold the container approximately 6 inches above sterile field

### **While scrubbed for the surgery**

- The back of the gown and from the waist below is not considered sterile, hence one has to remain facing the sterile area
- When changing places with another scrubbed person, one has to do so back to back
- The sterile instruments should be kept above the waist level
- Gloved hands are to be kept above the waist level and below the chin level
- If the hands are idle, one has to clasp them together in the front or place them on the sterile trolley
- When a cough or sneeze is inevitable, step back from the sterile field and turn head away
- Do not let your mask hang loose around the neck and reuse the same
- Don't prepare all trolleys beforehand
- Moisture is a potential source of contamination - don't use moisture soaked linen packages

### **General:**

- Nails should be trimmed regularly
- All OT dress, OT Slippers should be washed with detergent daily and dried
- Stretcher & wheel chair for inside OT & outside OT should be separate
- Periodic Assessment and training of OT personnel
- Slippers for toilet use and theatre are kept strictly separate (Colour coding)

- Keep the doors of theatre always closed
- Garbage should be disposed after each session
- Anyone with Upper Respiratory Infections, draining skin lesions or infections of the eyes, ears or mouth should not be permitted to work in the OT
- Restriction of surgeries per surgeon to 25 per surgeon per day per theatre to give sufficient time to the staff for O.T. preparation for the next day
- Prefer SICS for mass surgeries and avoid corneal incisions
- OT closed on last Saturday of every month for OT washing after removing all the movable items outside the OT
- Restrict surgeries on Saturday to allow time for weekly cleaning & OT meetings

### **E. Monitoring**

- Periodic culture is done once in a month from sterile and un-sterile area of the OT
- The Bacterial Carrying Particle (BCP) load in theatre is checked by open dish sedimentation plating technique every fortnight
- Log book of autoclaving is maintained where the time, temperature and pressure are entered with the time and duration of the cycle is also recorded – countersigned by OT in charge
- The colour of the indicator strip at the end of the cycle should be jet black else repeat the cycle
- Once a week if afforded cost wise, a Bowie Dick test pack / vapourline indicator can also be used
- Bacillus stearothermophilus spores for steam sterilisation and Bacillus Subtilis for dry heat and Ethylene Oxide (ETO) cycles are put in the load once a month – biological indicators

### **F. Surgeon's factor**

- Don't use same irrigation line for several surgeries
- Preferably avoid corneal Incisions
- When in doubt apply sutures (Improper valve, Wound gape) – wound should be water tight
- Phaco – Tips and sleeve to be changed for each case
- Not more than 25 cases / surgeon / day 8 hours



### **G. Post-operative Follow Up**

- F/U on 1st, 4th, 14th, 45th days with Visual acuity with pin hole, slit lamp examination and document all Post-op findings. Second and third follow ups are optional.
- Topical antibiotics for one week. Steroid / NSAID eye drops for a minimum of 4-6 weeks
- Must report- Excessive redness / Pain, Watering, Discharge, Sudden blurring of vision

### **H. OPD**

- Instruments once used in OPD must be autoclaved
- Instruments used on infective cases are autoclaved twice before use
- Slit lamp should be cleaned with spirit after an infective case is seen and every day. It is preferable to clean the slit lamp after examining each patient.
- Floors should be swept thoroughly and then mopped with Phenyl mixed with detergents (disinfectant cleaning solution) at least 3 times a day
- Hand should be washed before applying eye drops & eye drops bottle should not be kept uncapped

### **I. Ward**

- Floor cleaning to be done daily with phenyl mixed with detergents (disinfectant solution)
- The drops should be kept clean and the tip of the dropper should not be touched.
- Date of opening to be mentioned on each eye drops bottle.

## Annexure 16

# Preferred practice patterns for evaluating and managing adults with cataract during COVID-19 pandemic: Excerpts from the AIOS Guidelines

Salient changes needed in any ophthalmic setup involved in management of cataract:

- Unidirectional flow of patients should be ensured, i.e., entry and exit must be different if there are two doors.
- Minimize the amount of time the patient spends in the clinic.
- Decrease the number of visits that patient has to make to the clinic.
- Minimum number of required staff to be posted at a particular time.
- Implement physical distancing at all-time points everywhere (reception, waiting areas, consultation chamber, pharmacy, optical shop etc.).
- Fix prior appointments, if possible and function with a fixed number of patients per hour to minimize the number of patients and one attendant per patient to be allowed in the waiting halls.

If patients come to hospital without prior appointment, their consultation may be scheduled according to flow of patients.

- To take history of any symptoms of active COVID that is TOCC (history of travel, fever, cough, difficulty in breathing, loss of taste, loss of smell) and also of any primary /secondary contacts.
- COVID consent form and declaration form to be signed by the patient
- Online payment methods to be encouraged to minimize contact with currency.

### **Patient related:**

- All patients and attendants should have a mask or equivalent.
- All should use sanitizer at the entry.
- Minimize baggage to the clinic.
- To be seated in designated seats only so as to maintain physical distancing.
- Block the middle chair in a three-seater.
- Avoid talking to other patients/ attendants.

### **Employee related**

- All staff should have mask, and hand gloves on at all time points (face shield to be used during patient examination).
- All staff should be checked for fever at the entrance point.
- Any staff member with any of the symptoms of fever, cough, cold, difficulty in breathing to avoid joining duty until cured.
- Staff also to be checked for fever at the entrance point. Any staff member with any of the symptoms of fever, cough, cold, difficulty in breathing to avoid joining duty until cured.
- Keep the doors open to allow free flow of air and minimize contact with doorknobs.
- Reduce workforce-patient contact time.
- Keep more than one meter distance from patients except where clinical examination/investigation/ surgery is performed.
- Hand sanitizing protocol to be followed during the examination and also in between patient examinations.
- Avoid/ minimize re-examination of patients who have already been assessed.
- Clean all surfaces (chair units, stool, slit lamp, desk, keyboard, computer monitor, trial

frame etc.) with appropriate cleaning solution before starting clinics. Same should be repeated after each patient examination. Sodium hypochlorite solution may be used to clean chair, stools as well as desks and alcohol swab for slit lamp, computers and keyboard etc).

- Maintain appropriate distance while talking to the patient and keep the mask on while talking.
- Minimize the need to touch documents with the patient.
- Avoid touching the patient while instilling dilating drops and instruct patient to pull lower eyelid down by themselves while drop is being instilled.
- Use of appropriate Personal Protection Equipment: Check for availability and also follow the evolving policies for the health care workers and specific procedures.
- The entire multidisciplinary cadres (surgeon, anaesthesia, nursing, biomedical, housekeeping) of OT staff should be made aware of the most updated protocols. Mock drills may be done to assess their acquaintance with new protocols before commencing the OT.

## **Diagnostics in cataract surgery**

### **General Guidelines**

- Patient to be allowed into the room which has diagnostic instruments after wearing mask covering the nose and mouth of the patient.
- All instruments head rest to be attached with a breath shield.
- All instruments in diagnostic area to be cleaned once in the morning before the start of OPD and once in evening after the completion of OPD.
- Minimal touching of surfaces by the patient and attendant in the diagnostic premises.

### **Biometry for IOL power calculations**

- Prefer non-contact method like optical biometry over ultrasound biometry
- If not entirely possible, and ultrasound biometry has to be used, then the tip of the probe should be cleaned with alcohol swab after every case and sufficient time to dry should be given.
- Immersion scan is best to be avoided.

### **Keratometry**

To measure the keratometry any keratometer can be used. The breath shield can be customized and placed as a barrier. The joystick, locking screw for the instrument base, headrest, chin rest, handlebar should be cleaned using alcohol swab after examining each patient.

### **Optical Biometry**

Clean the main instrument panel using a soft, lint-free cloth dampened with alcohol at maximum 70%. All necessary cleaning protocols as per the manufacturer should be followed.

Breath shields should be incorporated between the technician and the patient to prevent direct contact with the aerosols generated. Following parts to be cleaned with alcohol swab after every patient: joystick, locking screw for the instrument base, head rest, chin rest, handlebar which the patient holds, keyboard and touch display.

### **Counselling**

Once a patient has been diagnosed with a cataract and scheduled for surgery it would be preferable to complete the discussion and minimize the patient mingling with other people.

### **OT schedules**

The schedules may be staggered over a period of time and the team /facility should be ready to accommodate the influx of ophthalmic cases, if any. The scheduling efficiency can be improved by opening up extended hours and weekend working schedules, if required. Preference may be given to one eyed/bilateral blind patients.

### **Operation Theatre**

In addition to routine operation theatre aseptic process and protocols, there is a need to:

- Overhaul cleaning of all OT zones as per protocol followed by the hospital
- Air sampling (open/split plate) for culture sensitivity (C/S)
- Ensure 4-5 air changes between two patients.
- Only one patient to be taken at a time.
- Thorough cleaning of OT between cases should be ensured.
- Swabs and C/S as per the protocol of the Health care organisation/ Small health care organisation / E y e c a r e o r g a n i s a t i o n

### **Recovery Room/Pre-Anesthetic room staff attire/Housekeeping staff attire**

- Cap
- 3-ply mask
- Nitrile gloves
- Protective Goggles/face shield
- Linen OT attire
- Separate zoning for staff

### **OT staff and surgeon attire**

- Cap
- N 95 mask/ 3-ply surgical masks
- Sterile gloves
- Protective Goggles/face shield depending on microscopic / non-microscope surgery
- Normal OT footwear
- Linen OT attire with surgical gown

### **Patient flow in OT recovery rooms**

- Physical distancing to be followed.
- Inside the OT the patient should wear a mask if not impossible. That mask should preferably be a fresh one provided by the hospital.
- Floor/Instruments/Furniture to be disinfected by surface mopping
- Linen changed as and when required.

### **Operation Theatre (Topical/Regional Anesthesia)**

- Minimal staff (Surgeon/OT nurse/Anesthetist/Running nurse)
- Segregate Bio Medical Waste at the source with proper colour-coded covers and handled as per guidelines.
- Ensure safe use of consumables
- Surface cleaning of equipment, OT table and floor in between cases and allow appropriate time for the disinfectant to act. (time taken for the disinfectant to act and dry up)

### **For those who are having HVAC systems Ventilation in OT**

- Air handling units (AHU) can be functional in-between cases
- Temperature and humidity to be appropriate.
- Maximize air changes and fresh air intake as per your HVAC.

### **For those having Split air conditioners**

- Non - COVID OT can have stand-alone room air-conditioners
- Re-circulate air within a single occupied zone in the OT complex.
- Temperature and humidity to be appropriate
- Clean air filters (indoor AC unit) frequently.

### **Operation Theatre for GA cases**

- Surgical team to enter the OT after intubation and induction of anesthesia
- Anesthetist team to wear PPE which includes a 3 ply or N95 mask, Cap, Sterile gloves, Goggles or Face shield.
- After surgery, the surgical team to wait outside the OT and de-gown only after the patient is shifted to the recovery room safety

### **Bio-Medical Waste (BMW) disposal**

- Use appropriate color-coded covers
- Follow the current guidelines on the color coding for the biomedical waste disposal.
- BMW should leave the hospital within 48 hrs.
- Soiled Linen should be separated and disinfected as soon as possible.

### **Instrument cleaning**

- Instruments should be handled safely by the staff for cleaning. The cleaned instruments are then packed to be autoclaved appropriately.

### **Anesthesia**

Use Topical anesthesia (preferable) or block anesthesia, as appropriate.

### **Cataract surgery**

Cataract surgery including phacoemulsification has not been proven to be an infective aerosol generating procedure till date. However, some steps (marked with \* below) have been advocated to minimize the risk of aerosol generation during phacoemulsification.

### **During Surgery**

- Scrub and put on sterile linen gown /disposable gowns and gloves.
- Instill povidone iodine 5% in the operating eye (2 minutes of contact time) before applying sterile drapes as it inactivates any virus in the tear film\*.
- Drape the eye appropriately; taking care that the draining pouches is open and not leaking\*.
- Perform irrigation and aspiration for a minimum of six seconds prior to starting active phacoemulsification\*. This is to ensure that all the aqueous humor has been removed before ultrasonic energy is initiated, which is implicated in generation of aerosols, that may contain virus particles in COVID positive patients.
- Smaller incision of 2.2 mm or less produces almost no aerosol\*.
- Viscoelastic may be used frequently over the cornea (preferably every minute during active phacoemulsification over the wound) as this may avoid need for frequent instillation of balanced salt solution/ ringer lactate over the cornea\*.
- Handle equipment carefully so as to avoid injury with sharps to self and others.
- Avoid spillage of body fluid or blood particularly when squirting ringer/viscoelastic from syringes\*.
- Assisting team must handle patient with gloved hands wearing the mask and a linen gown.
- Sterilized phacoemulsification tip and sleeve should be changed for each case.
- Avoid delivering of ultrasound energy when the phacoemulsification probe is not in the anterior chamber\*.
- Ensure that all the fluid is collected in the pouch and not spilled on the floor.
- All sheets on the operation table should be changed in between patients and the tables should be sanitized using appropriate disinfectants.

- At the conclusion of the surgery discard used disposable instruments following biomedical waste policy.

### **Postoperative care and follow up**

- Accessibility to patient and customization as per patients' requirement is the key to successful delivery of postoperative care.
- Health care facility may engage the patients through other technologies such as teleconsultation etc.

### **Role of Tele-Ophthalmology during COVID-19 pandemic**

Tele-Health is defined as health care delivery over distance or time using electronic communication technology. It serves to enhance health-care access, quality and patient satisfaction. Telemedicine is provision of traditional clinical service using electronic communication technology, often in live format. It should adhere to the tele-medicine guidelines issued by the Government from time to time and should target problem cases, postoperative cases and complicated refractions.

**As evidence on COVID-19 keeps evolving, the guidelines will be further updated as and when required.**

Disclaimer: This document contains a set of guidelines for quality management of cataract in India. VISION 2020: The Right to Sight INDIA does not in any way claim that this is the only way to manage cataract, there will be newer techniques that will develop with time. The contents of this document should not be quoted as authority in any court of law or dispute. VISION 2020: The Right to Sight INDIA will not be involved, either directly or indirectly, in any way for any damages to any persons / group of persons in the event of carrying out any of the activities mentioned in this document.

## A VISION 2020: The Right to Sight INDIA Publication

VISION 2020: The Right to Sight – INDIA is a registered not-for-profit forum and is a key driver of the global initiative of the World Health Organization (WHO) and International Agency for the Prevention of Blindness (IAPB) for reducing avoidable visual impairment.

### **Vision**

An India free of avoidable blindness, where every citizen enjoys the gift of sight and the visually challenged have enhanced quality of life as a right.

### **Mission**

To work with eye care organizations in India for the elimination of avoidable blindness by provision of equitable and affordable services as well as rehabilitation of visually challenged persons through development of appropriate policies, quality standards, advocacy, training, and promotion of best practices with a special emphasis on the poor and marginalized sections of society and underserved areas.



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This document was initiated, conceived and developed in 2011 with support from



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We thank Orbis India for supporting the printing of these guidelines in 2020

