

No. T. 12011/09/2016-NCD(BC)  
Government of India  
Ministry of Health & Family Welfare  
[Department of Health & Family Welfare]  
NCD/BC Section  
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Nirman Bhawan, New Delhi  
Dated 19:08.2016  
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To,

**Secretary (Health)**  
All States/UTs.

**Subject:-** Guidelines for Eye Surgery under National Programme for Control of Blindness (NPCB).

A meeting of experts to reassess the existing guidelines for Eye Surgery under National Programme for Control of Blindness (NPCB) was convened under the Chairmanship of Dr. Arun Kumar Panda, AS(H) in Nirman Bhawan, New Delhi on 21.01.2016. The committee in its meeting deliberated on each and every aspect of surgeries being performed under NPCB and recommended the revised guidelines.


2. Please find enclosed herewith a copy of the minutes of the said meeting and a copy of the revised Guidelines for Eye Surgery for information and necessary action.
3. This issues with the approval of Secretary (HFW)

Encl; As above

  
(Amarjeet Sroa)  
Under Secretary to the Govt. of India

Copy for similar action to,

- (i) Director, Health Services of all States/UTs
- (ii) State Programme Officers of all States/UTs

  
(Amarjeet Sroa)  
Under Secretary to the Govt. of India

Copy for information to:

- (i) PS to HFM/ PS to MOS
- (ii) PPS to Secretary (HFW)/DGHS/AS(H)/JS(KCS)/DDG(O)/AC(BC)

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**T.12011/14/2015-NCD/BC**  
Government of India  
Ministry of Health & Family Welfare  
Department of Health & Family Welfare  
NCD/BC Section

**Subject: - Minutes of meeting of experts to reassess the existing guidelines for Eye Surgery under National Programme for Control of blindness (NPCB).**

The meeting was convened under the Chairmanship of Dr. Arun Kumar Panda, AS (H) in (Room No. 445-A), Nirman Bhavan, New Delhi at 2.30 PM on 21.01.2016. The welcome address was given by Mrs. Dharitri Panda, JS (NPCB) and she briefly mentioned the purpose of the meeting. The following members attended the meeting:-

- I. Prof. Atul Kumar, Professor, AIIMS, New Delhi
- II. Prof. J.S. Titiyal, Professor, AIIMS, New Delhi
- III. Prof. T.P Lahane, Dean Grants College, Mumbai
- IV. Dr. Ramesh Dhankad, DPM, Haryana
- V. Dr. Ravindran, Arvind Eye system, Madurai
- VI. Dr. Alok Sen, HOD, Sadguru Netralaya, Chitrakoot
- VII. Dr. N.K. Agarwal, DDG (o), Dte.GHS, Nirman Bhavan, New Delhi
- VIII. Dr. V. Rajshekhar, AC (NPCB) MOH&FW, Member Secretary of the Committee

AS (H) mentioned that in view of the large number of eye mishaps, there is a need to review the existing guidelines and issue fresh set of guidelines for implementation during cataract surgeries. These Guidelines should prescribe standards in OT, and preoperative and postoperative procedures. Further, proper plan of capacity building and certification should also be implemented at various field levels.

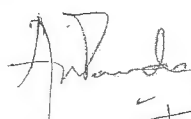
### Introduction

NPCB was launched in 1976 to tackle the burden of avoidable blindness due to cataract, Trachoma, Refractive errors and other eye disease like diabetic Retinopathy, Glaucoma, and corneal Blindness. 6 million cataract surgeries are performed per year in the country and out of these approximately 40%-50 % surgeries are performed by community outreach in various states. Now as the surgical volume per year is on the rise with more and more voluntary organisations participating in conducting eye surgeries, there is an increase in the number of mishaps being reported. These mishaps in eye surgeries are where people who have been operated upon lose vision due to eye infection (Endophthalmitis). These cases of eye infection are mostly due to lapses while conducting surgeries' in huge numbers, which compromises on the sterility condition during cataract surgery. All NGOs and voluntary organisation falling under the definition of NGO as published in "Guidelines for Voluntary organisation" available on the website, participating under NPCB need to sign a MOU with the district authority as per National Guidelines issued by NPCB. All the other NGOs operating but not registered under NPCB and not claiming funds from NPCB need to be monitored by the State Health Authorities and NGOs need to obtain the

necessary permission from the state Health authorities for approval of the hospital and the operation theatres for eye surgeries and OPD work. The States need to develop their own guidelines and implement them on those NGOs working in the state. All the Government and private eye surgeons in all districts of states/UTs have been sensitized to strictly adhere to norms of NPCB and observe universal surgical precautions. The preoperative guidelines have been first published in 2008. Now there is a need to revise these guidelines and issue a fresh set of guidelines for implementation. A committee of experts has been constituted under the Chairmanship of Shri Arun Kumar Pánda, Additional Secretary, Ministry of Health & Family Welfare to revise the guidelines. The constitution of the Committee is as follows:-

- I. Prof. Atul Kumar, Professor, AIIMS, New Delhi
- II. Prof. J.S. Titiyal, Professor, AIIMS, New Delhi
- III. Prof. T.P Lahane, Dean Grants College, Mumbai
- IV. Dr. Ramesh Dhankad, DPM, Haryana
- V. Dr. Ravindran, Arvind Eye system, Madurai
- VI. Dr. Alok Sen, HOD, Sadguru Netralaya, Chitrakoot
- VII. Dr. N.K. Agarwal, DDG (o), Dte.GHS, Nirman Bhavan, New Delhi
- VIII. Dr. V. Rajshekhar, AC (NPCB) MOH&FW, Member Secretary of the Committee

The Committee in its meeting held on 21/01/2016 deliberated on each and every aspect of surgeries being performed under NPCB and recommended the revised guidelines as annexed.

  
21/1/16

**GUIDELINES FOR PRE-OPERATIVE/OPERATIVE AND POST OPERATIVE PRECAUTIONS FOR INTRA OCULAR EYE SURGERY**

Post-Operative Endophthalmitis is a devastating and serious complication of Intraocular Surgery. Fortunately, in recent times, due to better surgical techniques and improved sterilization and aseptic methods, the incidence has come down to very low levels. However, sometimes despite all precautions, infections do occur. The risk factors for developing post-operative endophthalmitis are multifactorial.

It is essential to understand the difference in causes or risk factors that lead to cluster or sporadic endophthalmitis. For sporadic, it is usually contamination from the patient's own conjunctival flora or deficiency of the aseptic protocols like pre op antibiotics, gloving, gowning, patient hygiene, OT ventilation systems and surgical techniques.

**In cluster endophthalmitis, it is usually due to sterilization failure or contaminated surgical supplies.**

**(A) Operation Theatre**

Surgery for the patients selected for surgery should be preferably organized in a dedicated routine functional eye care facility having an enclosed, air-conditioned, functional eye-OT with operating microscope and separate scrub area with running and tested water facility. The following layout is preferable to ensure aseptic processes and minimize contamination.

**(B) Operation Theatre Layout**

To be arranged in levels

<b>Level-I</b>	<ul style="list-style-type: none"> <li>• Restricted Entry</li> <li>• Changing rooms/offices/record keeping</li> <li>• Shoes/footwear to be removed and clothes changed.</li> </ul>
<b>Level-II</b>	<ul style="list-style-type: none"> <li>• Entry only after changing for both patients and staff.</li> <li>• Caps/masks to be worn.</li> <li>• Scrub room/gloving and gowning.</li> </ul>
<b>Level-III</b>	<ul style="list-style-type: none"> <li>• Sterile area (Separate slippers)</li> <li>• Entry restricted to minimal staff</li> <li>• Fumigated areas</li> <li>• Ultra-violet light at night if possible</li> <li>• Floors, walls, surfaces to be scrubbed and carbolised</li> <li>• OT must be air-conditioned</li> </ul>

<b>Level-IV</b>	<ul style="list-style-type: none"> <li>• Waste disposal area</li> <li>• Sterilization room</li> <li>• Instrument maintenance (Under supervision of the Staff Nurse/OT Technician</li> <li>• Cleaned and washed with Savlon/soap ultrasonic cleaning</li> <li>• Examined under magnification for defect/for repair/packing for sterilization •</li> <li>• No. of sets: Minimum 5 sets (more if volume increases)</li> <li>• One set to one patient only</li> <li>• Sharps to be cleaned and Autoclaved (ETO sterilization)</li> <li>• Tubes to be rinsed, air dried, flushed, air injected and then autoclaved.</li> </ul>
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**(C) Patient Screening & precautions:**

A screening eye camp to be held at least 1 day prior to scheduled surgery date

**(D) General Examination**

**(i) Thorough checkup (Physician's referral if required) Investigations**

- Blood pressure.
- Blood sugar
- ECG – (especially of cardiac and hypertensive cases).
- Urine (R/M, Albumin)

**(ii) Check up for systemic illness**

- Diabetes
- Chronic Pulmonary Conditions (COPD)
- Hypertension & Cardio vascular Condition
- Renal conditions etc.

All High risk patient including patients with uncontrolled systemic illness like diabetes, hypertension, CAD etc. should not be enrolled for surgery when doing on a mass scale and should be advised to consult a physician before surgery.

**(E) Ocular Examination**

- Special care should be taken for all the one eyed patients, where surgery will be performed in their only functioning eye.
- Chief complaints and History of the problem. Complete ophthalmic examination
- Intraocular pressure

- All patients should be screened to ensure patent nasolacrimal duct and negative regurgitation test. A blocked nasolacrimal duct/positive regurgitation test should not be enrolled for cataract surgery and referred for further examination
- Syringing – Not to be done on day of surgery.
- Adnexal infections present to be treated with systemic antibiotics.
- Lid conditions & Sac related conditions such as entropion, trichiasis, and Daryocystitis to be treated first.
- Intraocular surgery to be delayed by at least three weeks after these surgeries.
- All investigations including contact biometry to be done at least 1 day prior to surgery, thus avoiding contact procedure on the day of surgery.
- Pre-op topical second or fourth generation fluoroquinolone group of antibiotics should be started in both eyes, 4-6 times a day starting at least 1 day prior to the surgery.
- A written-informed consent should be taken in all cases undergoing surgery after explaining the procedure and the risks involved.
- On the day before surgery date, patient should have thorough face wash with soap and if required head bath and shaving.

## (F) OPERATION THEATRE PREPARATION

### (i) Sterilization of OT, instruments and consumables:

- Floors of the operating room should be mopped on the day before surgery with antiseptic solutions, used for OT cleaning purpose.
- On the day before surgery, the surgical instruments, required linen must be autoclaved using long sterilization cycle parameters following the standard protocol.
- Proper functioning of the sterilization process like autoclave should be monitored by the operating surgeon and the senior nurse by checking the colour change of the sterilization indicator.
- A minimum of 4-5 instruments sets (trays) per OT should be autoclaved and kept available.
- Proper sterility of the consumables like dyes, viscoelastic solution, irrigating fluid should be ensured by checking for expiry date, suspended or floating particles.
- The surface of trolleys, operation tables should be wiped each day with antiseptic solutions prior to starting the surgery.

- After each day, all the instruments and linen after thorough cleaning and drying should be autoclaved.
- OT air conditioner filters must be removed and cleaned once a month.
- The irrigating fluid bottle batch number should be noted. Lab report of random sample from the batch of all intraocular use solution like irrigating solution/ viscoelastics should be made available to the surgeon team.

(ii) **Sterilization of instruments between surgeries**

- Strictly avoid chemical sterilization using either Glutaraldehyde or Acetone.
- A high speed sterilizer or flash autoclave should be used for sterilization of surgical instruments (trays) in between the cases, thus rotating the 4-5 instruments sets (trays) per table, providing uninterrupted supply of autoclaved instruments for each surgery and to sustain high volume of surgeries.
- For phacoemulsification, the phaco needles for every five cases and sleeves and irrigation/aspiration (I/A) handpieces for every case should be sterilized.

(iii) **Documentation of sterilization process**

- For each load, additional sterilization indicators should be placed individually in the surgical bins or in linen packs. These additional indicator stickers should be pasted in a register maintained for the purpose.
- Similarly, for each instruments set, there must be indicator tapes, which should be pasted in the case record with load details and date.
- Date of fumigation of OT should be documented in registers

(iv) **Surgical supplies**

1. **Irrigating Solutions:**

- Both Ringer lactate solution (RL) or balanced salt solution (BSS)) can be used for the cataract surgery as intraocular irrigating solution. To use only those which are packaged in flexible bag or in bottle container. Should not use solutions supplied in rigid, plastic, non-transparent containers.
- If packaged in flexible bag, then it should be supplied with outer flexible sterile steam permeable pouch / nylon pack for aseptic handling in OT. The outer pouch should be opened

only inside the OT. The circulating nurse should check for any visible suspended particles or any leaks and if found the solution should be discarded.

- If glass bottles are used, the bottle should be checked and autoclaved on the previous day. Before autoclaving, the bottle should be inspected for the quantity, any crack and for any suspended particles. If the quantity is less or a crack or any suspended particles are seen it should be discarded. The bottle should be autoclaved on the day before surgery. The outer surface of the bottle should be cleaned before autoclaving. The parameters for autoclaving bottles is 121<sup>0</sup> C temperature, 21 PSI pressure for 20 minutes.
- Any leftover solution should be discarded at the end of the day after the surgeries. Should not be stored nor reused on the following day.

2. **Ocular Viscoelastic Device, dyes, and other sterile consumables** ( HPMC, NaHy, Trypan blue)

**Packaging:** Should be packed in glass syringe / glass vial to maintain uniform sealing integrity to maintain the sterility. The glass syringe/vial should be packed further by sterile outer pouch pack for aseptic handling in OT.

OVD packed in plastic disposable syringes should be avoided due to its compromised sealing integrity which may lead sterility failure. Also it will lead to severe sterile reactions due to chemical leachable of plastic syringe get in to the OVD. (Variation in PH, inorganic impurities etc., which cause undue toxicity)

**Handling:** The outer pouch should be opened in OT and the syringe/vial shall be received by the sterile OT staff or placed in a sterile tray. Scissors or other instruments should not be used to open the pouch

***For any intraocular injection, including trypan blue dyes packed in the glass vial can be used for multiple times in the same day provided the aluminium seal should not be removed from the vial.***

***The rubber bung is self sealable for maximum ten pricks. After that it should be discarded.***

HPMC is made up of plant cellulose and prolong exposure may attract and enhance aerobic microbes. Hence, any leftover solution should be discarded after the surgeries. Should not be stored and reused

3. **Others:**

- Cannulas used for viscoelastic solution should not be reused, as it is difficult to clean the cannulas of viscoelastic.
- 10% Povidone iodine shall be used for surface painting/cleaning. This should not be diluted in OT for any other purpose.



- 5% Povidone iodine solution used as eye drops shall be used for conjunctiva sac cleaning. Once the container is opened, use the solution in 48 hours to avoid iodine loss and its efficacy as it lacks strong stabilising agents.
  - The batch numbers of the supplies used must be noted down in the case sheet and also a designated register.
- (G) **Patient preparation:**
- (i) **On the day of surgery**
- On the day of surgery, patient shall continue to receive topical antibiotics before and after surgery.
  - Each patient should be given protective cap and booties before entering the preoperative holding area/operating room.
  - In the preoperative holding area, the periocular skin should be cleaned with povidone-iodine 10% solution prior to administering the regional anesthetic block.
- (ii) **Scrubbing and gowning**
- Surgeon should wear washed OT clothes, OT slippers, cap and mask. Other staff working inside the OT area also to wear sterile OT gown
  - Surgeon should perform 3 scrubs with a solution equivalent to 4% w/v of chlorhexidine gluconate for at least 3 to 5 minutes under tested running water.
  - A clock to be placed in the washing area.
  - To proceed in a methodical manner from distal to proximal i.e. Hand/Palms/fingers/ Medial, lateral, dorsal, ventral aspects. Fore arm-Medial, lateral, anterior, posterior up to beyond elbow. Scrubbing from distal to proximal.
  - Hands always above waist and elevated so that water drains away from hand.
- (iii) **Cleaning & Draping**
- 5% povidone iodine for instillation into cul de sac with contact time of at least 3 min. Surgical area should be draped using sterile linen and separated plastic eye-drape for each patient to isolate the field. The eye to be washed with Ringer lactate or BSS before the start of surgery.
  - Separate instruments trolley lined with sterile cotton linen and covered by sterile plastic sheet should be used. The linen and plastic sheets should be changed if it gets wet due to spill over of fluid.

(iv) **During surgery**

- Wounds which are unstable and leak should be sutured to avoid hypotony and thereby minimizing risk of infection.
- Subconjunctival injection of antibiotic / (and steroid) should be administered at the completion of surgery in all cases.
- At the completion of surgery, topical fluoroquinolone antibiotic should be instilled in the conjunctival sac before the eye is bandaged.
- Minimal handling of tissues
- Instruments used for extra ocular manipulation not to be used inside eye
- No wick left into anterior chamber-uvea/capsule/vitreous and complete removal and formation of anterior chamber with irrigating fluid/Air.
- No foreign material to be left in surgical area.
- Gloves to be changed after every case and scrubbing and gowning to be done after every 5-6 cases. If no touch techniques used, but if gown gets wet due to accidental contact with unsterile area, it should be changed immediately.
- Separate surgical set to be used for all patients.
- Intra-cameral antibiotics may be administered in high volume surgeries.
- Sharps - Keratomes/blades/needle not to be reused unless sterilization procedure undertaken.
- Intraocular instruments and cannulas not to be reused if possible unless properly sterilized. Disposables, wherever possible, to be disposed after single use.
- The operative time should be limited to continuous eight hours after which a minimum break of two hours may be given for cleaning, sterilization and fumigation of the Operation Theatre.

(H) **Post-operative precautions:**

- Proper lid hygiene should be maintained in the post-op period
- Topical fluoroquinolone antibiotics 4-6 times per day should be administered for 7 to 10 days along with topical steroids in tapering doses for 6 to 8 weeks. Cycloplegics if required as prescribed by the surgical team.
- All patients should be given a discharge card mentioning the surgical details and postoperative instructions including date for follow up examination and location.
- Regular follow-up of the patients is necessary. Patients should be referred to a referral centre immediately upon early symptoms (e.g. pain, redness, dimness of vision, discharge) and

signs (e.g. circumcorneal congestion, anterior chamber cells and flare, hypopyon, reduced fundal glow, vitreous exudates) of infection/endophthalmitis.

- Personal hygiene to be emphasized.
- Avoid dust, smoke and sunlight.
- Wear protective dark glasses outdoors.
- Frequency of instillation of Eye drops as advised to be ensured.
- **Regular follow-up of the patients** is necessary as below:
  - 1<sup>st</sup> post Operative day by surgeon mandatory.
  - 2<sup>nd</sup> or 7<sup>th</sup> day
  - 30 to 25 day with refractive correction.

**(I) Emergency Consultation**

- Patients should be referred to a referral centre immediately upon early symptoms:
- Excessive pain & Redness.
- Watering/discharge
- Sudden Blurring of vision/Decreased or loss of vision
- Floaters/Flashes
- Excessive photo phobia

**(J) Waste Disposal**

**All Doctors and staff (Medical & Paramedical) should receive formal training in Biomedical waste Management.**

**Segregation**

- Infected material to be handled only by gloved staff.
- OT to be washed /scrubbed before use and surfaces carbolyzed.
- Fumigation at frequently timed intervals or after an infected case has been done/large volume cases operated.
- Bi-weekly cultures of the OT to be sent from specified points of the OT.
- Ultraviolet light is recommended for overnight use.
- Infected cases to be done in a separate OT along with other extra ocular surgeries.

**(K) POINTS TO REMEMBER**

**Pre-operative, Operative Precautions**

- Preoperative antibiotic drops.
- Bath for patients/Head wash/Face wash.
- Special note of eye brow/medical canthus area/nasal area.
- Eye to be washed with BSS and Betadine 5%.

- Sharps – Keratomes/blades/needle not to be reused unless sterilization procedure undertaken.
- Intraocular instruments and canulas not to be reused if possible unless properly sterilized  
Disposables wherever possible to be used.
- OT to be washed/scrubbed before use and surfaces carbolized.
- A drop of Beta-dine to be put in conjunctiva before starting the surgery.

### **Post-Operative Precautions**



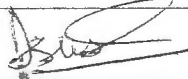



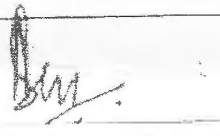
- Sub-conjunctival Antibiotics, single Drops of 5% Betadine in the conjunctival Sac after completion of surgery.
- Systemic antibiotics only if adnexal infections present.
- Topical antibiotics to be given post operatively with anti-inflammatory-steroidal/non steroidal agents.
- Personal hygiene to be emphasized to the patient
- The patient should avoid dust, smoke and sunlight.
- The patient should wear protective dark glasses outdoors.
- Routine weekly/ if necessary, more frequently postoperative visits should be ensured.
- Frequent instillation of Eye drops to be ensured.
- Dilating drops once daily to keep pupil mobile.

**(L) Minimum Equipments / Infrastructure that should be available in Eye OTs for sterilization and for maintaining aseptic standards;**

1. Horizontal autoclave
2. High speed autoclave for sterilization in between surgeries
3. Ethylene Oxide sterilizer
4. Basic RO water plant
5. Large drums for boiling of water
6. Chemical sterilization indicators
7. Indicator guns

**(M) Training of OT staff in Eye OTs in district hospitals**

It will be appropriate to plan a systematic auditing of the facilities in the district hospitals to identify the areas of deficiency and also institute appropriate training for the staff. At least two of the staff members must be well trained in sterilization techniques.

Sr. No	Members of the Committee	Signature
1.	Dr. Arun Kumar Panda, Additional Secretary. Ministry of Health & FW, Government of India.	
2.	Prof. Atul Kumar, Professor, New Delhi AIIMS,	
3.	Prof. J.S. Titiyal, Professor, AIIMS, New Delhi	
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