Accreditation of Eye Centres

AIOS CME Series (No 34)
All India Ophthalmological Society

AIOS CME series (No 34)

ACADEMIC AND RESEARCH COMMITTEE

Accreditation of Eye Centres

AIOS ARC CME series on Accreditation

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Foreword

Dear Friends,

It gives me immense pleasure to pen the foreword for this very pertinent CME Series on the Accreditation of Eye care Organizations; authored by Dr. Nirmal Fredrick and brought by our Chairman AIOS - Academic and Research Committee, Dr. Partha Biswas. As mentioned in my Presidential Address during Annual Conference of AIOS, we have wealth of Knowledge in the country. The clinical experience is unparallel in the world. However, we lag on the documentation and quality control.

Quality shall be an obsession. While aiming at high quality, one needs periodic assessment. Self assessment will help us improve to a certain level. An external third party assessment helps greatly in improving the standard of clinical care. This has been perceived as a big step towards improving the standards of health care in the West. Slowly the importance of accreditation process been perceived at all levels. Currently the Accreditation process is Voluntary, but I will not get surprised, if Government makes Accreditation process compulsory for the health care providers.

National Accreditation Board for Hospitals and Health Care Providers (NABH) is a voluntary body used to have uniform standards of Accreditation for all Health care providers including Eye care. Through the efforts of All India Ophthalmological Society with NABH, now Accreditation process for Eye care has become a separate chapter and has been tailored to Eye Care providers.

This CME series contains different chapters of Accreditation process and been simplified for the understanding of every Ophthalmologist. This will ease the apprehensions of many Eye care providers and I am sure it will encourage many single eye care providers for applying for Accreditation process. Accreditation changes one’s thinking process from patient care to standardized high quality patient care. There are several advantages of Accreditation, well enumerated in the book.

I am very confident that this book is very useful and will be of great help to all Practicing Ophthalmologists to understand the importance of documentation, Quality Control, establishing the standards of care, so that both the health care systems as well as the patients, benefits from it.

Our Chairman AIOS – ARC, Dr. Partha Biswas brought out this CME series and got it peer reviewed. I want to congratulate Dr. Nirmal Fredrick and Dr. Partha Biswas, for their efforts. I saw the end product, I am very confident that it is going to be very useful to all the Members of AIOS. I request every member to go through the Book and start the process of Accreditation, if you have not got it done already.

With Best Wishes

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“Primum non nocere” or “first, do no harm” is one of the principal tenets of bioethics which every medical student is taught in the journey of becoming a doctor. The fact is, this holds true for every individual associated with the healthcare profession, starting from the paramedical team to the surgical support staff, and from the counsellors to the housekeeping team. Together, the hospital or healthcare staff constitute a crucial team, on whose behest the patient places their faith, and often their lives. Hence it becomes absolutely imperative that each healthcare professional be adequately trained in their job. Patient satisfaction has been seen to be related not just to the outcomes of a medical or surgical procedure, but it is affected by a multitude of factors in which every member of a healthcare institute plays a vital role.

However, the sad reality of our country is that there is a huge variation in the quality of services offered at various institutes. The NABH guidelines brought for the first time the prospect of a uniform set of regulations which a healthcare institute is expected to adhere to, and which over time, restores faith of the patients regarding the safety protocols being followed in an institute. However, it was difficult to lay the same rules for primarily day care centres like ophthalmological institutes, whose functioning is much different from hospitals catering to general and emergency services. Hence, the need for a new set of regulations, designed exclusively for eye care centres and hospitals, which allowed these hospitals to become NABH accredited and improve their services.

This CME, excellently put together by Dr. T. Nirmal Fredrick, discusses in detail the necessity and utility of NABH accreditation for eyecare institutes, as well as the steps to be taken for the process. Being a part of an institute which is currently in the process of incorporating the NABH requirements step-by-step, we realised how intricately the guidelines have been formed, and how a complete transformation right from the grassroot level is required. But these are small steps which go miles in increasing the credibility of the institute, having happier patients and ensuring safety both for the patients as well as for the healthcare professionals.

Dr. Partha Biswas
Chairman ARC
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The International Society for Quality in HealthCare defines Accreditation as

“A self-assessment and external peer assessment process used by health care organizations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health care system.”

The accreditation movement is flourishing worldwide because of the global growth in the exchange of health services. It will prospectively evolve as a means for an international classification and recognition of hospitals. Patients, providers, and the public do feel the need to better understand the purpose and outcome of the accreditation process.

Accreditation previously known as a private and voluntary process, is swiftly evolving towards public regulation, and is rapidly leaning to become compulsory. Hospital and other types of health care organizations must be on guard.

This CME series highlights the different constituents and right tools to gain a good understanding of the subject of accreditation. It also explains why accreditation is growing to be the universal language for delivering standardized, high quality healthcare services.

The selection of the topics for each chapter is directed toward meeting the specific objective of providing a blend of an easy to understand basics and practical application for the busy clinicians and the quality team.

Intent of each chapter is highlighted, and detailed description of structure and process required to implement accreditation standards has been incorporated.

The accreditation phase with its three constituting subprocesses:

(1) preparation for the assessment, (2) Assessment process; and (3) evaluation, is thoroughly discussed.

Eye Hospital accreditation is comprehensively presented, giving
the reader an easy and implementable set of guidelines to read and implement. The Annexures of important sample document and checklist of core areas will help the clinicians, leaders and quality team to integrate quality standards in their day to day practice. I thank all the authors and co-authors for the wealth of information from a multitude of references and their personal experience. I thank the authors of each chapter for their time and effort to share their expertise and knowledge with their colleagues.

I thank the President, AIOS, Secretary and the Governing Council for giving this opportunity and the Chairman ARC Dr. Partha Biswas for the constant encouragement, guidance and support.

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Advances in technology and understanding of many diseases have created an immensely complex healthcare system. This complexity adds to the risks, inherent to Medicine and variability in the delivery of healthcare leading to Medical errors, cause devastating emotional and physical consequences for patients and their families. For the staff involved too, incidents can be distressing, while members of their clinical teams can become demoralised and disaffected. Safety incidents also incur costs through litigation and extra treatment.

Quality and safety of patient care are intimately interlinked with clinical and organisational governance and management. Quality and safety are intuitively recognised when present and glaringly obvious, when absent. Patient safety and quality of care thus constitute the foundations of care and of service provision.

Owing to a large number of patients undergoing ophthalmic surgical and outpatient care, the complexity of care and delivery of care through a National Programme, it is inevitable that some clinical errors or adverse patient safety incidents can or will occur. Patients requiring ophthalmic surgery are often of a higher clinical risk profile. Errors in Eye care have huge physical emotional and health economic consequences for all concerned. Increasingly, it is believed that systems failures, or organisational failures, underlie many patient safety incidents.

The quality of ophthalmic care in India has greatly improved with Programmes like NPCB, V2020 and involvement of NGOs and Private sectors. New technologies advanced surgical techniques, Day care surgeries, shorter patient referral to treatment and waiting times have all contributed to this. However, despite the above mentioned, clinical and non-clinical, or organisational errors, incidents, and complications continue to happen and often recur. Such events often provide a rich opportunity for learning, if properly considered.
Quality of health care and the initiatives taken to address various risk and safety issues in the hospitals have become a subject of debate. External assessment is increasingly used to regulate, improve and market health care providers, especially hospitals. The commonest models are peer review, accreditation, statutory inspection and evaluation of the ‘business excellence’ framework. Each of these is progressively adapting to meet the changing demands of public accountability, clinical effectiveness and improvement of quality and safety, but the most rapid development is in accreditation.

Hospital Accreditation is

“**A public recognition of the achievement of accreditation standards by a healthcare organization, demonstrated through an independent external peer assessment of that organization’s level of performance in relation to the standards.**”

Accreditation is a formal process by which a recognized body, usually a non-governmental organization (NGO), assesses and recognizes that a health care organization meets applicable pre-determined and published standards. Accreditation standards are:

- Optimal and achievable
- Designed to encourage continuous improvement efforts within accredited organizations than adherence to minimal standards
- Accreditation is granted following a periodic on-site evaluation by a team of peer reviewers, typically conducted every two to three years
- Accreditation is often a voluntary process in which organizations choose to participate, rather than one required by law and regulation.

Accreditation would be the single most important approach for improving the quality of hospitals. Accreditation is an incentive to improve capacity hospitals to provide quality eye care. Confidence in accreditation is obtained by a transparent system of control over the accredited hospital and an assurance given by the accreditation body that the accredited hospital constantly fulfils the accreditation criteria.

Improving patient safety is a multi-faceted task and requires individual responsibility, and multi-disciplinary and organisational commitment. Simply stated, it is everyone’s responsibility. This is now further explored by NABH, to include Professional Organisations and
Association. Professional bodies and associations in Eye Care are critical for generating the energy, flow of ideas, and proactive work needed to maintain a healthy profession that advocates not only the needs of its members, but also the society at large.

**Benefits for Hospitals**

Accreditation of a hospital stimulates continuous improvement. It enables hospital in demonstrating a commitment to quality care. It raises community confidence in the services provided by the hospital. It also provides an opportunity to healthcare unit to benchmark with the best.

**Benefits for Hospital Staff**

The staff in an accredited hospital is a satisfied lot, as it provides for continuous learning, good working environment, leadership and above all ownership of clinical processes. It improves the overall professional development of Clinicians and Para Medical Staff and provides leadership for quality improvement with medicine and nursing.

**Benefits of paying and regulatory bodies**

Finally, accreditation provides an objective system of empanelment by insurance and other third parties. Accreditation provides access to reliable and certified information on facilities, infrastructure and level of care.

**National Accreditation Board for Hospitals and Healthcare Providers (NABH)**

National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of Quality Council of India (QCI), set up to establish and operate accreditation programme for healthcare organizations. NABH has been established with the objective of enhancing health system & promoting continuous quality improvement and patient safety. The board while being supported by all stakeholders, including industry, consumers, government, has full functional autonomy in its operation.

NABH provides accreditation to hospitals in a non-discriminatory
manner. Regardless of their ownership, legal status, size and degree of independence. International Society for Quality in Healthcare (ISQua) has accredited “Standards for Hospitals”, 3rd Edition, November 2011 developed by National Accreditation Board for Hospitals & Healthcare Providers (NABH, India) under its International Accreditation Programme for a cycle of 4 years (April 2012 to March 2016). The approval of ISQua, authenticates that NABH standards are in consonance with the global benchmarks set by ISQua. The hospitals accredited by NABH have international recognition.

About NABH

ISQua is an international body which grants approval to Accreditation Bodies in the area of healthcare as a mark of equivalence of accreditation program of member countries. NABH is a member of ISQua Accreditation Council. NABH is an Institutional Member as well as a member of the Accreditation Council of the International Society for Quality in HealthCare (ISQua). NABH is the founder member of proposed Asian Society for Quality in Healthcare (ASQua) being registered in Malaysia. NABH is a member of International Steering Committee of WHO Collaborating Centre for Patient Safety as a nominee of ISQua Accreditation Council.

NABH Eye care Standards

The available HCO and SHCO Standards put in place by NABH for accreditation were meant for Multi-Speciality Hospitals and elements like obstetrics, radioactive drugs, intensive care unit etc. were not applicable for eye care organizations. Categorization of the hospital was based on the basis of number of beds and was not specific to the speciality.

On demand from Eye care service providers and All India Ophthalmological Society AIOS, NABH accepted the proposal for separate Eye care standards for accreditation. AIOS and NABH constituted an expert group to discuss and formalise the Eye care specific standards. NABH Eye Care Standards has been formulated, keeping in view the limited resources available in the small Eye care hospitals, functional requirements of Eye care service providers, with emphasis on standards for infrastructure such as building, equipment’s, manpower,
medication management, infection control and patient safety norms.

After several rounds of meetings by the expert group the following key points were incorporated in the NABH ECO standards after Public Opinion and Technical Committee approval it was released in September 2016 at the AIOS headquarters.

**Highlights of NABH ECO Standards**

1. It was decided to create NABH ECO standards exclusively only for standalone Eye Care Organizations.

2. The Statutory needs that were required for NABH HCO and SHCO were downsized and standardized to almost that of NABH Entry Level Standards. Main statutory needs would be
   a. Building Plan Approval
   b. Fire Department NOC or 3rd party certification
   c. Pollution Control Board License and MOU with BMW management facility
   d. Lift License
   e. Pharmacy License
   f. HOTA & Eye Bank License

3. Scope of Services for Eye Hospitals were developed and optimal requirements for following sub specialities in Ophthalmology were defined.
   a. Comprehensive Ophthalmology
   b. Cataract Services
   c. Cornea (Transplant)
   d. Refractive Surgery
   e. Orbit & Oculoplasty
   f. Glaucoma
   g. Vitreo-Retina Clinic
   h. Paediatric Ophthalmology and Strabismus
   i. Neuro Ophthalmology
   j. Uvea Clinic
k. Contact Lens  
l. Low vision and rehabilitation etc

4. Given the enormous number of surgeries being conducted in ophthalmology the need to customize OT standards with respect to air quality, reusing single use devices and protocols for sharing of multidose vials were customized

a. Standardization of minimal OT size  
b. Requirement of Air quality were specified to suit Eye Hospitals  
c. Requirement of unidirectional flow of men and material have been defined  
d. Autoclaving and Sterilization techniques including in-between cases sterilization with Flash autoclaves and rapid sterilizers were approved  
e. Protocols for use Multi-dose vial like Anti VEGF and Xylocaine usage have been defined

5. The actual need for Licensed qualified nurses in regular standards was very high as per bed ratio. Hence Standards were modified to accommodate and credential Refractionists, Optometrists and Mid Level Ophthalmic personnel.

a. Paramedical personnel can be privileged to apply drops, administer medication, prepare and assist surgeries etc  
b. Qualified nurses would be needed to perform procedures like starting Intra Venous lines, assisting GA, helping in BLS and ACLS etc

6. In Eye Care Standards importance was given for Doctors belonging to the team instead of the surgeon alone for various aspects of Perioperative Care

a. Pre-operative Assessment  
b. Taking Consent  
c. Administering Local Anaesthesia  
d. Performing Surgery  
e. Post-Operative Care  
f. Discharging the patient
7. The Role of Anaesthesia in Ophthalmology, protocols for Local/Topical Anaesthesia, General Emergency management of patients during hospitalization were developed to suit Ophthalmic hospitals
   a. Pre Assessment for GA
   b. Assessment on the Day of Surgery
   c. Monitoring and documentation of GA
   d. Post Anaesthesia Recovery and shifting
   e. Adverse Events Management, Recording and Follow up

8. Ophthalmic imaging services were redefined in ECO (E.g. OCT, FFA etc)

9. ECO determines the minimum requirements of a prescription (Medical prescription, spectacle prescription or contact lens prescription etc.)

10. Telemedicine process is added in ECO

11. Standardization of abbreviations has been done

12. Customized list of Key Performance Indicators and Clinic Audit Protocols were created

We hope with these initiatives and the new eye care standards in place, the leaders of eye hospitals will come forward to implement the standards in their facility.
“Accreditation is a statement to our patients and our stakeholders that we care, a statement to the community that we are accountable, a statement to the legal system that we have taken the initiative to be aware of and comply with the law, and a statement to our industry that we are interested to improve our quality and dedicated to quality care”.

In the background of renewed interest in Hospital Accreditation due to Insurance Incentives and medico-legal challenges, that can be effectively countered by a good accreditation system, it is essential to know the myths that doctors have about Accreditation and the reality.

**Myth No: 1 - We Don’t Have Enough Time Right Now to Prepare, May be if it’s made mandatory later.**

**Variations on This Theme**

- Getting accredited takes too long . . . needs too many people . . . takes too much work.
- We are a small hospital now and we can’t do that, while we’re doing everything else.
- We are in the midst of an expansion . . . building phase . . . staff restructuring . . . and need to wait until that’s over to begin.

**Reality**

In today’s world, we’ll never have enough time, to do all we want to do. We do what we make time to do.

- Think about how many times you’ve had to explain procedures or correct mistakes made by new employees or even old staff, because they were unsure how it’s been done.
• How many times have you said to your assistant, or colleague or Director, “We need to get that organized?”

Yes, Preparing for accreditation involves some work. But much of the Accreditation work can be delegated to staff or administrative people who are involved in the day to day operation of the Hospital.

Most of the hospitals, in operation currently with any degree of success, have most of the system and processes that are required for accreditation. They just need to be organised and documented.

Rather than perceiving preparation for accreditation, as an intrusion on available time, think of it as an investment, on your practice, staff and patient care, which will pay off in time.

**Myth #2 - Our Facility Needs too Much infrastructural changes**

**Variations on This Theme**

• We need to do a major renovation of our Theatre and reception areas.
• All our facilities are old and not accessible.
• Our hospital is not posh and interiors are not good

**Reality**

Accreditation standards do not require modern buildings with the latest equipment or amenities. Hospital facilities can be old fashioned with old cots/toilets or manual, as long as they are in good shape. Cabins don’t need plush interiors or air conditioning or LED lights, as long as they are well ventilated, clean and dry, stairs well supported and easy for patients and other support services well maintained. Some infrastructure requirements are of course dependent on the scope of services.

**Myth #3 - Accreditation Costs too much**

**Variations on This Theme**

• It will cost too much to update our facility and provide training to our staff (see Myth #2).
• Our management thinks the accreditation fee is too high and recurrent cost that does not yield any returns.
Reality

**Accreditation costs:** The total cost of accreditation of a hospital is required by the management for two reasons.

1. Cost Benefit analysis - The total cost spent on accreditation and the quality/benefits to the institution.
2. The budgeting requirement - to plan for actual cost at each stage over a period of time.

The total cost may be calculated like this:

A. Cost Payable to Accreditation Agency e.g. NABH

+ B. Consultancy charges/Training (if you avail the services, payable in stages)

+ C. Cost of implementation....varies from hospital to hospitals
  - E.g. Creation of infrastructure + new staff + staff training +
  - New forms/brochures/case sheets…. Printing charges +
  - Miscellaneous expenses

**TOTAL COST OF ACCREDITATION = A + B + C**

**Myth # 4 - We Don’t Need Accreditation**

**Variations on This Theme**

- The central/state licenses and permissions are more than adequate.
- Patients don’t ask or care if we’re accredited.
- We’ve been in existence/operation for years and have never had a problem.
- We follow standards - we don’t need someone to come in and tell us how to operate.

**Reality**

Central and state licenses, are based on minimum standards that have to be available in the hospital for functioning. But for patient safety and safe medical practice, hospitals has to incorporate certain systems and processes and also train the healthcare workers to provide consistent care. In Medico legal defence, Court accepts your version favourably
when you have a valid accreditation certificate. Courts and lawyers do not accept your own protocols and standards unless they are in tune with regulations, guidelines of professional and national accreditation bodies.

**Don’t Buy Into Myths**

As you discuss your reasons for not getting started with accreditation, make sure you are not following those Myths. Look for the benefits to you, your staff, your patients and the brand image you get. Although a seemingly intimidating process, if looked at with an open mind and an educated perspective, our hope is that Doctors and staff can learn to embrace NABH standards implementation as a challenge that will enhance their workplace, promote quality care, and help them to take pride in their profession.

As of now in India, NABH standards is the only system for evaluating medical standards and management standards. Its India specific and has been developed by Indian Nurses, Doctors and Administrators who have the expertise and experience working in Indian hospitals. NABH accreditation is a pre-requisite, for various empanelment’s like CGHS/ECHS and can get you higher rates from the insurance companies.

Accreditation benefits accrue to all stake holders in healthcare industry

- To patients,
- To the Staff – HR
- To the top management
- To the Government

To the Hospitals implementing accreditation, the benefits are enormous:

- Direct/Indirect benefits
- Short term/Long term benefits
- Monetary/non-monetary benefits
- It’s an effective Branding tool
- Accreditation is also a legal protection tool
- It can help you in Benchmarking with the best of Indian hospitals
- It can push you and your hospital towards excellence and star rating of hospitals
Any health care organization excel in their operations only if they maintain the quality of clinical care and excellence in service delivery. The various aspects of service excellence, clinical quality is well brought out by the Institute of Medicine (IOM), USA incorporating safety, patient centeredness, efficiency, effectiveness, timeliness and equity as six quality aims. This is well depicted through a quality pyramid as shown in the Figure 1. The healthcare organisation must pursue all six quality aims to provide best possible care.

As can be seen in the figure 1, the patient safety forms the base of the quality pyramid. Safety is the fundamental cornerstone of the health care system. If care is not provided in a safe manner in a safe environment, the chances for a good outcome are lessened significantly. As mentioned in IOM report, “Patients should not be harmed by the care that is intended to help them, nor should harm come to those who work in health care.” Our goal must be to prevent harm from reaching patients and those involved in providing care to those patients. This requires everyone
involved in following the safety protocols and identifying opportunities for patient care to be made safer. It requires everyone to be continuously involved in learning from medical errors and near misses.

In eye care, patient safety is about ensuring that patients under our care are not harmed due to surgery or treatment on the wrong eye or performing a wrong procedure on the correct eye. We also need to ensure the patients receive the correct IOL implant in cataract surgery or the correct intravitreal drug of the correct concentration. It also encompasses preventing surgical complications that can result in loss of vision like expulsive haemorrhage or globe perforation or infections. However, in real practice, we the surgeons are concerned about good clinical outcomes, minimising surgical complications and using the best class technology. On the other hand, the patients are concerned about reliable service, appropriate cost, transparency in pricing and being treated with dignity and compassion. Often, the issues related to patient safety are not there in the minds of patients or the providers.

However, there aren’t much publications in this area regarding the incidence of patient errors in eye care. Publication in the year 2007 reports about 62 cases out of 900,000 consecutive surgeries, which are reported to the New York Patient error occurrence reporting and tracking system.² All the patients who are operated between the year 2000 and 2005. This amounts to 7 per 100,000 procedures, which includes wrong eye surgery, wrong intra ocular lens power, wrong injection etc. In another publication from Rotterdam Eye Hospital reported about 29 wrong site sentinel events in 115,000 procedures over a nine-year period from 2000 to 2009. They also reported around 39 near misses involving wrong site during the same period (Table 1)³.

The evidence from these limited publications still show that the ophthalmic speciality is unsafe and is prone for errors. The chances of safety errors are high in ophthalmology as we deal with bilateral organs and because of the patient volume we tend to handle. Ophthalmology care also involves teamwork and we must depend on several technicians for investigating and preparing the patients for surgery. With several treatment options for a given procedure and the various choices of implants and IOL power calculation formulas, the chances of error occurring are quite high. The errors which occur vary from hospital to hospital and are based on the work process one follows.
Table 1: Quality and Safety Statistics. The Rotterdam Eye Hospital 2000 -2009

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of Surgeries</th>
<th>Wrong site (sentinel events)</th>
<th>Wrong site (Near Misses)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>9,701</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>2001</td>
<td>9,955</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>2002</td>
<td>10,328</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>2003</td>
<td>10,428</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>2004</td>
<td>11,199</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>2005</td>
<td>11,864</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>2006</td>
<td>12,692</td>
<td>0</td>
<td>7</td>
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<tr>
<td>2007</td>
<td>12,610</td>
<td>0</td>
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<tr>
<td>2008</td>
<td>13,338</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>2009</td>
<td>13,242</td>
<td>1</td>
<td>9</td>
</tr>
</tbody>
</table>

The challenges are considerable in protecting patients as providing care is a team work and several members are involved including those from several other specialities and support services. We must first acknowledge that medical errors do occur and that they can happen to anyone from the most junior to the most senior staff. Only by acknowledging the dangers and then utilizing established protocols with a commensurate level of diligence can we begin to eliminate medical errors.

In this scenario, it is important to understand the various such errors and how we can overcome through instituting certain protocols and processes. It is also important to have clarity and what we need to achieve in eye care.

- Ensuring correct patient, correct eye, correct procedure
- Ensuring correct implant, design or any drug to be used
- To prevent mortality and morbidity due to systemic diseases.
- Elimination of post-operative infections
- Eliminating sight threatening complications
- To eliminate medical or diagnostic errors
- Ensuring correct medicines/ spectacles
- Preventing falls and ensuring physical safety of the patient
To ensure that we operate on the correct patient, correct eye and correct procedure

**Proper documentation**

Whenever a patient is advised to undergo a procedure, the advice for treatment should be documented in the clinical record prominently without any ambiguity about the laterality of the eye and the nature of the procedure. In addition, other additional medications that need to be used and the expected outcome also should be documented.

The errors tend to happen when we change the eye to be operated or change the procedure for the eye to be operated on subsequent visits. Hence a standardised protocol to document such changes is also important.

**Patient Identification**

We rely on the clinical records for the information regarding the eye to be operated and the procedure, when we undertake surgical or treatment procedures. To ensure we operate on the correct eye and do the correct procedure, it is important that we check the identity of the patient, to make sure that the patient we are operating/ examining/ investigating, is the same as clinical document or medical record we are referring to. This can be done by ensuring verification of at least 2 patient identification characters namely the patient name and by matching the record number on the clinical record with the with the identification or registration card the patients have. This is important as we tend to have patients with the same name on any given day. With electronic medical records (EMR) if the patient’s face is captured it will be an additional option to identify.

Use of wristband or RFID tags also will be useful for inpatients or who undergo surgery where frequent checks required and especially in high volume set up like medical colleges and other institutions.

In addition to verifying the clinical record, having a proper informed consent by the patient as well as marking the eye to be treated help to prevent these never events. In addition, use of check lists to document the verification process during the time out sessions are also critical in ensuring patient safety.
Informed Consent

Having a proper informed consent given by the patient is the first step to prevent such errors related to wrong site and procedure. It is important to actively involve the patient and patient’s relative or representatives to ensure agreement with them on the eye or the site to be operated. The consent form should be written at a level that the patient is able to understand and interpreters should be available wherever necessary. The eye to be operated and the procedure should be documented prominently in the consent form duly signed by the patients who are adults. For adult patients who are either unconscious or mentally unstable and paediatric patients, a first degree relative can sign. This will help to prevent any miscommunication or misunderstanding of the patient or their relatives about the nature and site of the surgery.

Marking the surgical site

Marking the surgical site should be done to ensure surgery is conducted on the correct eye or site. The surgeon or a responsible member of the surgical team should be responsible for marking the site. In eye surgery, the mark is normally placed either above or below the eye. It is preferable to mark both above and below the eye. It should always be done in the presence of the patient’s relative preferably in the patient’s room or in the day care holding area after verifying the details from the case record and verifying it with the patient. Patients undergoing bilateral surgery should have a mark over both eyes. The person who marks the eye should use written documentation in the clinical record with verbal confirmation by the patient or guardian to determine the operative eye. Marking can be done either with marking pens or stickers as per the protocol. If the eye is to be dilated, it should be preferably done before dilatation. The whole process should be documented in the check list.

Sign In, Time out & Sign Out in the operating Room

Nursing staff in the OT must not assume that marking is always correct, because mistakes do happen. Nurses should check the chart and ask the patient too.

To help in this process of ensuring correct procedure and site, the World Health Organization’s (WHO) Safe Site Surgery Guidelines was developed4.
The guidelines suggest that checks are done at three points in time: before anesthesia (sign in), before incision (time out), and before the patient leaves the operating room (sign out). These are the points in time when everybody involved stops what they are doing to focus on the safety of the patient. The time out is the moment created to ensure that they are all preparing for the proper surgical for the proper eye. The patients should be identified by using two identifiers - name and ID number. The site verified by the marking and the procedure from the clinical record.

The checklist should be completed by all members of the medical team, including the surgeon, assisting nursing personnel and Anesthetist. These checklists have now been incorporated into hospitals around the world.

**Surgical safety check lists**

It is important to use the surgical safety check lists of the WHO and ensuring Time out in the operating room before surgery.

Figure 2 shows the WHO surgical safety checklist that has been adapted to suit the cataract surgery by National Patient Safety Agency of National Health System of England. Before starting the operation, all members of the team within a particular clinical area must check that the patient’s details in the chart correspond with the patient in front of them and that they have all the equipment, stock, medications, IOLs and instruments.
required (the medication and stock must be in-date) and that any issues for each department have been raised, discussed and followed up as needed.

**Ensuring correct IOL design and power**

Cataract surgery carries a greater risk of inserting a wrong implant than any other procedure requiring an implant. For every IOL procedure, multiple elements of the data must be measured accurately by trained technicians using special instruments. A retrospective review of ‘wrong IOL’ patient safety incidents (PSIs) reported to the National Reporting and Learning System (NRLS) in UK in the period from 1st February 2010 to 31st May 2014 showed 178 wrong IOL incidents. In addition to the wide power range of IOLs, we use both indigenous and imported IOLs and the availability of various designs of IOLs based on the material and optic design has further complicates issues related to wrong IOL implants in India. The way the IOL power is documented also can give raise to errors especially with the lower power and negative power IOLs. Exchange of biometry records or print outs between patients also leads to errors in several instances.

The following needs to be done to avoid errors related to implanting wrong IOLs.

- As a routine protocol it is helpful to have biometry done in both eyes to double check the IOL power of the eye to be operated.
- Wherever the IOL power appears to be inaccurate or beyond the normal range, it should be rechecked by another technician and if possible with another equipment.
- The biometry and keratometry equipment should be calibrated at defined time intervals as per the protocol.
- Using Zero before for single digit power IOLs prevent confusion and again using four boxes to enter the value will also avoid confusion related to interpreting values.
- Ensuring that the biometry printout belongs to the same patient is also important as chance for mix up of records is common in any surgical set up, where more than one patient is operated on a day.
- If there is no option for generating a printout is available, then making sure to have protocols to prevent transcription
errors while documenting the data from the machine to clinical record.

- During Sign in, Time out and Sign out period, those who are assigned should check the IOL power, model and type. One should check all documents and make sure to check whether the biometry data matches the patient and the opposite eye if it has been operated earlier.

- In Toric IOL makes sure that the correct model of Toric IOL is being used.

- Always verify the IOL type with the payment he has made or the approval that has been received from the third party/insurance agencies.

- Have policies to avoid transcription errors and for negative power IOLs clearly denote by writing “Minus” instead of using the signage.

- Availability of the selected IOL should be confirmed before the patient enters the operating room and should be available before the surgery starts.

- Avoid having more than one IOL available outside especially in ORs where the IOLs are stored inside the OR.

- Staff should be encouraged to challenge any issues or concerns regarding IOL selection.

**Other safety issues in eye care**

With large number of patients being above the age of 60 with a higher prevalence of systemic diseases like hypertension, diabetes and cardiac diseases, the chances of systemic complications like pulmonary oedema or myocardial infarction are also areas of major concern. The other area of major concern is cluster or sporadic postoperative infections due to sterilisation failure or violation of aseptic protocols, which needs constant monitoring and auditing of the sterilisation process at regular intervals. In the outpatient area, the safety issues relate to missing certain clinical conditions like retained intraocular foreign bodies or retinal detachment which needs immediate attention. It is also important not to overlook conditions like postoperative infection or high intraocular pressure that can cause vascular occlusions. It is necessary to keep in mind these issues and have processes in place to identify them and address them.
Incident reporting system

Even in the best institutions in the developed countries, patients are sometimes harmed. It is important that staff learn from any critical incidents and institute necessary measures to prevent similar incidents occurring again and preventing further patients from being harmed. One of the key principles in ensuring patient safety and creating a local culture of patient safety is ‘no blame’. Our usual reaction when something goes wrong is to try and find someone to blame. However, in many cases there are wider issues that have led to the mistake or incident. Understanding the reasons behind mistakes helps the hospital to put procedures and protocols in place to try and prevent them from happening again. It is necessary to put in place a system to document and report these errors to the leadership. A simple incident reporting form can be created and in larger institutions, an online reporting system can be put in place. Capturing this information online will help in analysis of the data as well. With every incident and near misses, it is also important to do a root cause analysis to understand the contributing factors and institute necessary measures for prevention.

Conclusion

System wide improvements must continue to be made as we learn more about mistakes through incident reports. However, the human element of health care will remain, and with that human element, the danger of human error will persist. Accepting that mistakes are a part of human nature is important in forgiving ourselves and learning from mistakes. But we must always push ourselves to do better and to look out for one another as a team. By never settling for anything less than our best effort and working as a team, we can eliminate all errors and successfully achieve our mission of safe & high-quality care.

References


It’s important to understand the basics of terminologies associated with Accreditation. Given below are such terminologies and intent of each chapter of NABH accreditation standards.

What is a policy?

- Policy (n)
  - Plan of action, statement of aims and ideals, especially one made by a government, political party, business company etc.
  - Written statement of the terms of a contract of insurance.
- They are the guidelines for decision making, e.g. admission, discharge policies, antibiotic policy etc.

What is a procedure?

- Procedure (n)
  - (The regular) order of doing things, especially legal & political.
- A specified way to carry out an activity or a process.
- A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources & efforts to achieve the desired output.

What is a process?

- Process (n)
  - Connected series of actions, changes etc.
  - Series of operations deliberately undertaken.
  - Method
• A set of interrelated or interacting activities which transforms inputs into outputs. (Para 3.4.1 of ISO 9000:2000)

**Quality Assurance is a:**
• Part of quality management focused on providing confidence that quality requirements will be fulfilled. (Para 3.2.11 of ISO 9000:2000)
• A planned and systematic set of activities to ensure that variances in processes are clearly identified and assessed; improving the defined processes for fulfilling the requirements of customers and product or service makers.

**Quality Control is:**
• Operational techniques and activities used to fulfil requirements for quality (e.g. ISO)
• **Internal quality control (IQC)** – set of procedures for continuously assessing laboratory work and the emergent results; immediate effect, should actually control release of results (WHO, 1981)

For ease of understanding and implementation all NABH standards are divided into 10 chapters. The first 5 chapters are patient centric and last 5 chapters are organization centric. Each chapter begins with the intent of the chapter. This provides a brief explanation about meaning and importance of standards in the chapter. Each standard is a statement about structure, Systems, procedures and policies the hospital should have in order to deliver and quality patient care. To give an idea what NABH standard comprises of, some of the 500-plus objective elements in general standards and 305 elements in Eye care standards are listed here. The requirements have been grouped for easy understanding.

**NABH accreditation criteria**

**Information to patients**
1. The patients and/or family members are explained about the proposed care.
2. The patients and/or family members are explained about the expected results.
3. The patients and/or family members are explained about the possible complications.
4. The patients and/or family members are explained about the expected costs.

Rights of the patient and family

1. Respect for personal dignity and privacy during examination, procedures and treatment.
2. Right to refusal of treatment.
3. Informed consent before anesthesia, blood and blood product transfusions and any invasive or high-risk procedures.
4. Information on how to voice a complaint.
5. Access to his/her clinical records.

Quality in investigations

1. Adequately qualified and trained personnel perform and/or supervise the lab investigations.
2. Policies and procedures guide collection, identification, handling, safe transportation and disposal of lab specimens.
3. Laboratory and imaging results are available within a defined time frame.
4. Critical results are intimated immediately to the concerned personnel.
5. The lab and imaging quality programme addresses verification and validation of test methods.
6. The lab and imaging quality programme includes periodic calibration and maintenance of all equipment’s.
7. The lab and imaging programme includes the documentation of corrective and preventive actions.

Surgical services

1. Surgical patients have a pre-operative assessment and a provisional diagnosis, documented prior to surgery.
2. Documented policies and procedures exist to prevent adverse events like wrong site, wrong patient and wrong surgery.
3. The operating surgeon documents the post-operative plan of care.
4. There is a documented policy and procedure for the administration of anesthesia.

5. All patients for anesthesia have a pre-anesthesia assessment by a qualified individual.

6. During anesthesia, monitoring includes regular and periodic recording of heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, airway security and level of anesthesia.

**Medication**

1. Documented policies and procedures exist for prescription of medications.

2. The organization defines a list of high-risk medication.

3. High-risk medication orders are verified prior to dispensing.

**Infection control**

1. The hospital has an infection control team.

2. The hospital has designated and qualified infection control nurse[s] for this activity.

3. Hand-washing facilities in all patient care areas are accessible to health care providers.

4. Compliance regarding proper washing of hands is monitored regularly.

5. Isolation/ barrier nursing facilities are available.

6. Adequate gloves, masks, soaps, and disinfectants are available and used correctly.

**Facility and infrastructure maintenance.**

1. The organization’s environment and facilities operate to ensure safety of patients, staff and visitors

2. There is a documented operational and maintenance [preventive and breakdown] plan.

3. Up-to-date drawings are maintained which detail the site layout, floor plans and fire escape routes.
4. The provision of space shall be in accordance with the available literature on good practices [Indian or International Standards] and directives from government agencies.

5. There are designated individuals responsible for the maintenance of all the facilities.

6. Maintenance staff is contactable round the clock for emergency repairs.

7. Response times are monitored from reporting to inspection and implementation of corrective actions.

**Others**

1. Defined procedures for situation of bed shortages are followed.
2. Ambulance[s] is appropriately equipped.
3. Ambulance[s] is manned by trained personnel.
4. There is a checklist of all equipment and emergency medications in the ambulance.

Each standard is divided into measurable objectives elements or steps to help in implementation and measurable compliance. The compliance to an individual objective Element can be measured and scored. The compliance to individual Objective elements determines the overall compliance to the standard.

To understand this further, let’s discuss the first standard (AAC 1) of NABH Eye Care Standards.

AAC1. The Eye care organisation defines and displays the Eye care services that it provides.

AAC 1a. The Eye care services being provided are clearly defined.

AAC 1b. Each defined service should have appropriate diagnostics and treatment

AAC 1c. Facilities with suitably qualified personnel who provide outpatient, inpatient and emergency cover.

AAC1d. The defined Eye care services are prominently displayed.

AAC1e. The staff are oriented to these services.
The intent of this standard is to make patient aware even before they enter hospital regarding what services are to be provided.

Different Eye Hospitals, differ in kind of service they provide for e.g. corneal transplant, paediatric facilities, surgical retina etc. The head of ECO should take inputs from other department heads and define the scope of services. The scope should match the manpower, equipment and support facilities required for it. The ECO should also comply with statutory and regulatory requirements e.g. registration under HOTA for Keratoplasty.

Each department can also define their departmental scope of service for e.g. paediatric Vitreo-retina could be sub scope under vitreoretinal Services. Dactylology could be a sub scope of ophthalmic plastics services.

The scope once defines can be included in AAC manual and Apex manual of the hospital. The scope should be displayed prominently (at least bilingual) at the hospital entrance and should be visible to patients before registration area. In case a hospital has multiple entrance & registration areas, it should be displayed in all these locations.

The staff should be made aware of the scope of services and most importantly exclusions through training.

The suggested implementation and audit check points for this standard could be

1. Scope of services in AAC manual, Apex manual
2. Manpower, equipment and facilities commensurate with the defined scope
3. Permanent bilingual display at hospital entrance/registration area for the patients
4. Staff awareness of scope of services
5. Staff training on scope of services

To understand further, we can take a second example, AAC 7 standard regarding discharge summary and process

AAC 7. The eye care organization has a documented discharge process.
Now this is a statement of intent regarding discharge a patient from hospital. In order to implement, monitor and to assess or check compliance this is divided to further small measurable Objective elements as follows

AAC 7a. Discharge summary is provided to all patients at the time of discharge.

AAC 7b. Discharge summary contains the patient’s name, unique identification number, date of admission and date of discharge.

AAC 7c. Discharge summary contains the reasons for admission, significant findings and diagnosis and the patient’s condition at the time of discharge.

AAC 7d. Discharge summary contains information regarding investigation results, any procedure performed, medication administered and other treatment given.

AAC 7e. Discharge summary contains follow-up advice, medication and instructions about when and how to obtain urgent care.

AAC 7f. In case of death, the summary of the case also includes the cause of death.

This standard and its objective elements are self-explanatory. NABH guidebook provides a short interpretation for each of these objective elements. For e.g. AAC 7 a. Specifies all patients i.e. discharge summary is to be provided to all patients before they leave the hospital including LAMA, DAMA and transfer patients. These elements list out minimum Discharge process and summary requirement for NABH ECO Standard AAC 7. The hospital can modify its existing discharge summary to incorporate these requirements. The ECO also can also add more information to discharge summary based on need or patient care demands.

During an Internal or an external assessment these elements can be scored as 10 for full compliance, 5 for partial compliance and 0 for noncompliance.

Thus a standard along with its objective elements provide framework for attaining, maintaining, monitoring and improving quality in hospital.
Access, Assessment and continuity of care – Intent of Chapter

1. Patients are well informed of the services that an organization provides. This will facilitate in appropriately matching patients with the organisation’s resources. Only those patients who can be cared for by the organization are admitted to the organization.

2. Emergency patients receive life-stabilising treatment and are then either admitted (if resources are available) or transferred appropriately to an organization that has the resources to take care of such patients. Out-patients who do not match the organisation’s resources are similarly transferred or referred to organizations that have the matching resources.

3. Patients that match the organizations resources are admitted using a defined process. Patients cared for by the organization undergo an established initial assessment and periodic and regular reassessments.

4. Assessments include planning for utilization of laboratory and imaging services. The laboratory and imaging services are provided by competent staff in a safe environment for both patients and staff. These assessments result in formulation of a definite plan of care.

5. Patients care is multidisciplinary in nature and encourages continuity of care through well-defined transfer and discharge protocols. These protocols include transfer of adequate information with the patient.

Example of an Assessment process

**Initial Assessment:** The assessment process comprises a number of steps

- Eye history and examination by ophthalmologist.
- Explanation of intended procedure and anesthetic with patient or responsible adult.
- General health evaluation including appropriate investigations.
- Documentation of current medication and allergies.
- Assessment of communication to include hearing and language.
- Assessment of patient’s ability to cooperate e.g. lies flat.
• Identification and planning for potential social and transport problems for surgery and review
• Follow-up arrangements
• Instruction on instillation of eye drops.
• Consent process.
• Date /scheduling for surgery

Guidelines - Preoperative Assessment

Mandatory:

Ocular

• Intra Ocular Pressure:
• Keratometry Both eyes:
• A Scan Biometry:
• Retinal Exam /Macular Function test:

General:

• Blood Sugar: F /P /HbA1c
• Blood Urea:
• Serum Creatinine:
• Electro-Cardiogram:
• Duct Syringing
• Physician Consultation

Preferable: (depends on surgery/risk factors)

• B scan
• Conjunctival Smear
• Complete Hemogram:
• HIV/HBsAg (Relevant to type of surgeries, co-morbidities/high risk)

These guidelines form part of the standard operation procedure for the medical and allied health professionals to perform their duty as per standards.
The intent of the second chapter of NABH that deals with CARE OF PATIENTS:

The organization provides uniform care of patients in different settings. The different settings include care provided in outpatients units, various categories of wards, diagnostic areas and operation theatre. When similar care is provided in these different settings, care delivery should be uniform. Policies, procedures, applicable laws and regulations, guide emergency and ambulance service and cardio-pulmonary resuscitation

Policies, procedures, applicable laws and regulations also guide care of vulnerable patients (elderly, physically and/or mentally challenged and children), administration of anaesthesia and patients undergoing surgical procedures.

References

1. NABH accreditation standards for eye care organization 1st Edition
2. NABH Guidebook for Hospital standards 4th edition
3. NABH website
Introduction

For improvement in quality services, there are two approaches. First a voluntary effort by the health care providers to improve the quality of services to the acceptable standards by adopting and implementing some system of quality assurance and continuous improvement such as TQM, ISO-9000 or the NABH certification. Second approach is through regulatory measures by the govt. to force the hospitals to improve the quality of services. The approach to quality in health care in India, until recently, has been through regulatory measures. Laws on various aspects of healthcare have been enacted from time to time to regulate the functioning of the hospitals, nursing homes and private practitioners, if their implementation will remove the inadequacies and malpractices.

The list of laws applicable to the hospitals is very exhaustive. For ease of understanding and the minimum requirements for the single speciality units, the following classification of the legal requirements is given below:

1. Building and Special Norms

Allotment of land or approval for use of land for hospital purpose, is required under the Urban Land Act or other local regulations. The planning and building the hospital is controlled by the local municipal laws (like DDA rules/MCD rules in Delhi) and the national building code. The Building plans must be approved by the local bodies/concerned Govt departments. Once the building is ready, a no objection certificate from the fire department, a certificate from the electricity department, a certificate of fitness for operating the lifts must be obtained.

Regulation related to land allotment, building norms and space allocation for various facilities are statutory obligations and unless they are fully met the hospitals are not permitted to operate. Pharmacy services must
be approved and licensed by the Drug Controller’s office (the Blood Bank Rules, the pharmacy Act and the Drug & Cosmetics Act).

2. Safe Environment
Safe and hazard free environment are the prime necessity for expeditious healing. The BMW Management and handling Rules, regulate the safe disposal of infectious waste, so that it does not pose a hazard for the patients, staff and public inside the hospital or for the community in the vicinity. Air (Prevention and control of pollution) Act acts as a deterrent from the pollution of air by fumes from the DG sets/incinerators or other toxic gases and the noise pollution act forces the hospitals to cut down the noise by DG sets /AC plant/manifold room etc by acoustic treatment of the enclosures.

3. Safe Operation of Facilities
Provision of hazard free lifts, fire safety, slip/trip free surfaces, equipment free from electrical hazards, continuous stable power supply potable water supply round the clock, adequate sanitation facilities, infection free wholesome food etc, obligatory. Periodic inspection of facilities by the registering authorities are aimed at ensuring that the services are being provided in a safe manner.

4. Conduct of Doctors and Nurses
Indian Medical Council Act and code of Medial Ethics-1956, Indian Nursing Council Act-1947 are the regulations covering the practice of medical and nursing profession. They expect the doctors and nurses to follow the ethics strictly and conduct themselves in correct, professional and honourable manner. While the code of ethics has a moral authority, the code of conduct is legally binding. Any serious violations may render the individuals liable to cancellation of registration and/or penal action under the law of Torts/Negligence or even IPC.

5. Hygiene, Cleanliness and Infection Control
Bio-Medical waste management and handling Rules-1998, Play a very important role in maintenance of hygiene and cleanliness, more importantly, in making the disposal of waste (chemical, Microbiological, human, animal) safe and harmless for the patients, staff and the community at large. If the hospital has a canteen, a licence must be obtained, and the food handlers must be examined, and fitness obtained.
6. Safe Medical management of patients

“Above all do not do any harm to the patient” is an old dictum. However, the instances of medical negligence keep occurring in the hospitals. The law (Tort law, Medical negligence, Law of consents, code of conduct for Doctors) are quite a deterrent for the erring doctors so much so that the doctors and the hospitals must have a professional indemnity cover.

7. Security of Patients

Security of patients, especially the vulnerable groups (women, infants, children, old, and unconscious patients) while in hospitals, from any physical assault, abuse, kidnapping, rape or murder etc. by anyone, is a very essential aspect of the quality of care and is the prime responsibility of hospital management.

8. Safe Medication

The Drug & Cosmetics Act, Pharmacy act, narcotics and psychotropic Substances Act, provides for safe storage, preservation, prescription dispensing of drugs by qualified and authorized personnel only. They also regulate the use of dangerous drugs (narcotics, psychotropics, chemotherapeutics). Every hospital must create and earnestly implement the standard protocols for medication administration that is the only way to prevent such untoward incidents and ensure quality. Its necessary to have a pharmacy licence for storing and dispensing medications in the hospital.

9. HR Management


HR Management, however goes beyond the statues and requires a satisfied, motivated, continuously trained and developed work force. The hospital must ensure that the performance of HR department is
up to the required standards and there is a programme of continuous performance appraisal and quality improvement

10. Right of the patients
Law of consents requires that the consent (implied, expressed or qualified) of a patient is a must at various stages of treatment. Under RTI it is obligatory for the service providers to provide all the info/ records to the patient on demand about his treatment. Similarly, the hospitals (e.g. under the local laws as in Delhi) are required to display the registration certificate and the services along with the schedule of charges. Quality management means full information and education of the patient about the illness and discussion about the courses open & their risks/benefits, with the patient at every stage and initiating the treatment/ procedure with the full, willing and informed consent of the patient /family.

Mandatory licences for Accreditation:
a. Registration under the Clinical Establishment Act/Local/state/ corporation registration
b. Pollution control board consent for air, water and sound
c. Biomedical waste segregation and disposable – MOU with approved agency
d. Fire NOC – for fire safety
e. B scan registration under PCPNDT act
f. ESI – PF registration as per requirements
g. MOUs and Agreement forms for outsourced services

Summary
Statutory regulations prescribe the basic minimum standards of infrastructure required to be followed and if a hospital/ nursing home satisfies those requirements, the license is issued to operate the facility. However, a lot depends on the degree of (seriousness/ laxity) with which the laws are implemented/ enforced. Further the regulatory approach has a limitation to that it does not address the process aspect. The process used for utilization of resources and delivery of services is crucial to quality. Therefore, for improvement of quality, the regulatory approach had to be supplemented by a programme of quality management. which is a voluntary approach driven by the provides quest for excellence.
Management of Medication standards are predominantly to ensure that the right patient gets the right medication with right strength & dosage and duration at the right time as per right instructions. They also ensure that medications are acquired & stored in the right environment and dispensed as per statutory requirement. In NABH Eye Care Organization standards Management of Medication is the 3rd Chapter with 6 Standards & 29 Elements.

Laws & Regulations that are mandatory are

a. Drugs & Cosmetics Act-1940 License
b. Narcotic Drugs & Psychotropic Substances Act-1985
c. Pharmacy Act-1948
d. Drugs & Magic Remedies (Objectionable Advertisement) Act-1954

Pharmacy license Retail or Bulk as applicable should be available with Pharmacist name endorsed in it. Number of pharmacists available should be as per timing at one per 8 hours. Pharmacy License must be displayed.

By definition Medication includes drugs, implants & prosthesis, blood & blood products that are given to patient and gases.

Management of Medications are ideally managed completely by the Pharmacy & Therapeutic committee with development of a proper Pharmacy Manual

A Formulary of drugs to suit the needs of the organization should be developed

List of available drugs should be known to all Doctors.

Procurement of drugs should be standardised as per protocols from approved list of vendors. Availability of drugs should be there and proper guidelines to order (ROL - Re Order List) depending on usage
(slow moving and fast moving) making sure there is no zero balance at any point of time to avoid local purchase

**Storage** of drugs should be as per manufacturer specification in dust free environment not only in the pharmacy but also at wards, operation theatre or any other storage area.

It is essential to following storage requirement

a. Alphabetical Order
b. FIFO – First in First Out
c. LASA – Look Alike and Sound Alike. List of LASA Medicines to be maintained
d. High risk medication as required by organization (List to be prepared) under lock and key separately stored for safety
e. Pharmacy should be air conditioned with a temperature of 24 degrees c
f. Medication in fridge temperature as per manufacturer recommendation
g. Monitoring of Room temperature and fridge temperature at least once in 12 hours should be done with proper alternative power available.

**Checking of Expiry:** It is essential to check medications as per following guidelines

a. Regular medications at the end of the month to remove medications with expiry date (pre-determined – ideally 3 months expiry) so that they can be returned for exchange of newer medication.

b. High risk and emergency medication should be checked every day and always replenished as when they are used or whenever expiry is in 3 months.

**Drug Prescriptions** are as per Medical Council of India requirement y Registered Doctors only

a. Should have all patient details – name, age, sex, MRD no & date
b. Name of the drugs written legibly in capital letters. Preferably generic name as per requirement of MCI
c. Strength, dosage & duration to be clearly written
d. Full signature of doctor with name, medical council registration number
e. Important to have general instructions and details to contact in emergency
f. Ideal to avoid abbreviations and no overwriting
g. If EMR is used Unique login should capture all details of Doctor and medicines as desired.
h. In records of in patients the orders are written in uniform location

Dispensing of medication to dispense Right Medication to the Right patient
a. Correct name, strength and dosage of medicines to be verified
b. Expiry date should be verified before dispensing and also make sure that the correct batch number and expiry date is reflected in the bill which will help in Recalling medication of that particular batch in case the drug is either contaminated or expired
c. Prior to dispensing High risk medication the pharmacist should verify with the Doctor regarding the identity of patient name and dosage of drug and enter in the relevant register. Double checks are done prior to dispensing. Can use colour labels and automatic alerts

Administering Drugs
a. Medications should be administered by people who are permitted by law
b. Patient should be correctly identified
c. Medication name, dosage, route of administration and time should be identified and then administered and making sure to document it properly in records with respect to name strength and amount and time of administering.
d. If medications are prepared are loaded it is essential to label before preparing a second one
e. There should be written protocols for using multi-dose vials to maintain sterility and following manufacturer recommendations

Own Medication
a. Patients are permitted to take their own oral medication but it must be mentioned in the case records
b. Parenteral medication should only be administered only by hospital staff
Emergency Medications be it in pharmacy, OT, ward or crash cart
a. List prepared based on the need and prepared
b. List should be checked daily signed and usage is documented
c. When used it should be replenished immediately
d. No other drug should be stored along with them
e. They should be kept securely with lock and key with easy access when needed
f. Crash cart arrangement should be as per standardised requirement with proper labelling and should also be checked daily and signed and usage is documented with replenished immediately whenever used

Narcotic Medicines
a. Narcotic license is essential for using these drugs
b. License to be displayed
c. Should be under lock and key
d. Records showing usage of Narcotics with respect to patient, dosage, time of use

Verbal orders are allowed as per following guidelines
a. Doctor can dictate orders to a paramedical person
b. The paramedical person should repeat (Read Back) the complete orders including the identity of patient
c. Doctor should confirm
d. The orders are entered in the case sheet and order carried out
e. The Doctor should sign in the case sheet within 12 hrs

Adverse Drug Events include Adverse drug reactions, medication errors, overdoses & allergic reactions
a. Adverse events with respect to medications used in the institution have to be defined
b. Adverse drug events should be documented and reported within a time frame which is ideally within 24 hours, analysed to avoid or reduce the same in future
c. Ideal Root Cause Analysis and Corrective and Preventive actions should be taken
Usage of Implants & Prosthesis

a. Implants & Prosthesis usage should be scientific as per various national & international guidelines approving their usage approved and selected by a multi-disciplinary committee.

b. Procurement should be standardised like other medications

c. Storage and Expiry date should clearly as per Manufacturer’s recommendation

d. Patients and family should be educated about it and consent to be taken.

e. List of Implants to be used and Implants register to be maintained.

f. It is mandatory to maintain all the details of the Implant or Prosthesis in the case records and should also be provided in the discharge summary.

Usage of Gases

a. It can be in centralise pipelines as per standard colour coding or as only cylinders

b. Procurement, transport, storage, replenishment and ideal back up for standby as per requirement should be as per protocols

c. Records for usage should be complete
Consent and Communications

Dr. Gagan Dudeja, Dr. Nirmal Fredrick

An Informed consent is a process for getting permission before conducting a healthcare intervention on a person, or for disclosing personal information. A health care provider may ask a patient to consent to receive therapy before providing it, or a clinical researcher may ask a research participant before enrolling that person into a clinical trial. Informed consent is collected according to guidelines from the fields of medical ethics and research ethics.

To give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts.

NABH Eye Care Standards COP 4b, COP 5d, COP 8e, COP 9b, COP 11c, PRE 3 define various requirement of consent for NABH accreditation

The ECO needs to define and obtain General Consent from all patients coming for treatment. The organization needs to list and document situations where informed consent is required such as surgical interventions, diagnostic and treatment procedures, anaesthesia, clinical or research trial, blood transfusion etc. The process of obtaining consent should be defined for all patients including policy in case of children (parents or legal guardians), patient incapable of giving consent (surrogate consent). The informed consent for surgery should be bilingual and should have information regarding procedure, risks, benefits and alternatives. The consent form should also state who will perform the procedure.

SOP on informed consent

SOP on Patients Consent

1  Consent in non-emergency situations – General Procedures

1.1  Take consent only of the patient in a non-emergency situation if the patient is adult (also refer to - Clause 6.1), competent (also refer to - Clause 6.5), and oriented.
In appropriate cases, especially high risk (also refer to - Clause 1.17), a confirmation from the next of kin may be taken or they may be asked to sign as witnesses. (Advisable)

1.2 Take ‘proxy’ consent from competent adults responsible for incompetent patients. (Minors/Incompetent/Emergency patients – Proxy Consent’). In appropriate cases, signature of witness/as may also be taken. (Advisable)

1.3 Do not take consent of spouse, children or parents in case of an adult, competent and oriented patient. However, they may be asked to sign as witnesses, especially in high risk cases. (Advisable)

1.4 Take patient’s written consent rather than not taking one. (Advisable)

1.5 Take written consent only for those investigations/diagnostic and therapeutic procedures that require invasive intervention. Take written consent (advisable not mandatory) for certain non-invasive therapeutic measures such as diathermy, lithotripsy, nuclear scan, and high risk cases (also refer to - Clause 1.17).

1.6 No written consent is required:
   i. For routine investigations such as drawing of blood.
   ii. From OPD patients on routine visits.
   iii. For non-invasive diagnostic/therapeutic procedures such as ECG, A scan, keratometry etc.

1.7 Do not reduce consent to a mechanical/routine act. Consent is a process and not merely an act of signing the consent form. It involves giving relevant information about the proposed treatment/intervention and discussing with the patient, arriving at a mutual agreement and then filling and signing the consent.

1.8 Do not deviate from what has been consented and agreed, except in life-threatening conditions, for bonafide reasons, and only in the patient’s interest

1.9 Take consent only after complete disclosures and proper explanation, neither by unduly scaring nor falsely alluring the patient into acceptance.
1.10 Explain and counsel in the language/dialect understood by the patient. In case services of a translator/interpreter have been taken, especially in case of international patients, the translator/interpreter must also sign the consent as witness and record specifically that he/she has explained in the language understood by the patient and only thereafter the patient has signed the consent.

1.11 Explain and counsel in simple non-medical terms. Informative booklets about the interventions/therapies could be provided to the patient, especially for high risk therapies/interventions (also refer to - Clause 1.17). (Advisable)

1.12 Explain and counsel the various aspects of the proposed treatment/intervention to the patient by handwritten notes/diagrams/figures/images/models/posters of organs/systems/diseases and only if the same are easily available. Annex these with the consent. Thereafter follow the protocol, as far as applicable, prescribed in Clause 3.13. (Advisable)

1.13 Disclose to the patient and duly record in the consent:
   i. Medically approved name of the treatment/surgery/procedure
   ii. Nature and purpose (intended benefits) of the treatment/surgery/procedure and the trouble/disease/complication for which the same is advised
   iii. Likely prognosis
   iv. Risks involved
   v. Commonly occurring life threatening and non-life-threatening complications/consequences - Even complications/consequences that are rare but likely to affect vision, bleeding (Advisable)
   vi. Available alternatives – The relative advantages and disadvantages of each of the available alternatives and the preferred one with reason/s.
   vii. Adverse consequences of refusal by the patient.
   viii. The fact that the surgeon may come across unexpected situations during the course of surgery and it may require additional/alternative/extension other than what has been consented and that the patient consents for the same.
1.14 Give the patient reasonably enough time, depending on the situation, to take decision for giving consent after counselling except in emergency situations.

If the clinical condition of the patient changes during this period of patients contemplation, initiate the process for taking fresh consent.

1.15 Video-record the pre-consent counselling session, especially in high risk cases (also refer to - Clause 1.17), only if the requisite facilities are easily available. Ensure that the CCTV signage is present in the counselling room and the patient is specifically informed of this fact. (Advisable)

1.16 Multi-stage treatment - Take single and comprehensive consent explaining the different stages one after the other even if the different stages are contemplated to be performed on different dates. Enumerate each stage specifically and separately in the consent. Eg. Releasable suture, AG surgery,

1.17 High-risk Consent: Inform the patient specifically; duly record the same in the medical records and take an elaborate ‘high-risk’ consent if:

i. Unusual requests are made by patient/attendants, abnormal/ suspicious circumstances, and such other conditions

ii. The treatment/recovery is expected to take a very long time.

iii. The rate of failure is high.

iv. The technique/procedure/drug/protocol is relatively new/ critical/complicated.

v. Relapse is common.

vi. Presence of any co-morbid condition that may interfere with the surgery/procedure/treatment.

vii. The patient is in a critical state or is even otherwise at high risk.

viii. Removal of any organ/limb is a possibility.

ix. You are proceeding with a surgery/procedure/treatment despite abnormal parameters.

x. The patient has potential for creating trouble.
1.18 Independent witness

i. Take patient’s consent in the presence of minimum one independent witness in case of high-risk consent

ii. (Ideally the witness should not be connected/employed/related to the doctor, hospital or patient. A patients relative knowing English could be a good choice as an independent witness.

iii. The witness must write in his/her handwriting on the consent form that the patient was explained the content of the consent form in the language/dialect known and spoken by the patient; the patient has consented to the same; and thereafter the patient has put his/her signature/thumb impression on the consent form in front of the witness. The witness must then sign the consent form, write his/her name, relation with the patient and contact co-ordinates. A copy of identity proof of such a witness must be taken for the purpose of traceability and preserved with the consent form.

iv. Translator/interpreter whose services have been used could be an independent witness for that particular patient (also refer to - Clause 1.10).

1.19 Record specifically in the consent form if a consultant/surgeon has agreed to manage the patient only for a specific period or only to perform a surgery/procedure and that thereafter the patient will be managed by other/another designated/assistant doctor. This clause will not apply to public hospitals/group practice’.

1.20 Prepare and provide the patients with a brochure, preferably in the local language/s, describing the therapy, risks, prognosis, and advantages of the commonly performed treatment/interventions especially in case of rare/new/complicated/risky - treatments/surgeries/procedures. Take acknowledgment of receipt from the patient and duly preserve this acknowledgment with the consent. (Advisable)

1.21 Check specifically whether the patient’s signature on the consent form is in English or not. If the signature is not in English, follow the protocol, as far as applicable, prescribed in Clause 1.22.
1.22 Taking consent of a patient not conversant with English/illiterate/semiliterate
   i. Exercise greater caution.
   ii. Give the requisite information in the language/dialect known to the patient.
   iii. If the doctor cannot speak the dialect, the patient must be asked to bring someone who can understand, translate and explain to the patient. If the patient expresses inability to bring anyone, staff members or someone known to the doctor can be involved; but only as a last resort. Record this fact in the consent specifically. (Advisable)
   iv. Take thumb impression (left hand for males and right hand for females) or signature of the patient.
   v. Take signature of an independent witness (also refer to Clause 1.18.). (Advisable)
   vi. Specifically record the fact that consent was taken after counselling in the patient’s language.
   vii. Ensure that the patient does not write anything on the consent that cannot be understood by the doctor/hospital staff.

1.23 Take thumb impression (left hand for males and right hand for females) on the consent of a literate patient who is unable to sign due to any reason. Record specifically the reason for taking thumb impression and also take suitable endorsement from the patient’s relatives/friends/attendants on the consent, if possible. Follow the protocol, as far as applicable, prescribed in Clause 1.22.

2 Consent Form

2.1 Printed consent forms in English can also have its printed translated version in the local language appended as a separate leaflet or printed on the reverse side. (Advisable)

2.2 Printed consent forms must have enough blank spaces for filling complete and additional information.

2.3 Consent forms can have suitable columns/spaces for the patient to indicate the names of relatives/attendants whose directions should be followed in case the patient is not in a position to give further
directions. Patients can fill this column/space with full name, address and telephone numbers of such relatives/friends and also indicate the order of preference amongst them. (Advisable)

3 **Filling the Consent Form**

3.1 Consent form can be filled in the local language or the language understood by the patient. (Advisable)

3.2 Consent form can be filled by a doctor/nurse.

3.3 Fill the consent form in one sitting even though counselling the patient may take more than one sitting. (Advisable)

3.4 Avoid changing the pen or the person who is filling the consent form midway. Maintain uniformity in filling the consent form. (Advisable)

3.5 Make entries in the designated spaces only. Mention specifically that appendices have been annexed if the designated space is inadequate

3.6 Fill the consent form completely. Do not leave any space blank in a printed consent form. Write ‘Not Applicable’ or ‘NA’ in spaces where nothing has to be written. (Advisable)

3.7 Try to avoid alteration, addition, overwriting or erasure while filling the consent form. In case any change has to be made, encircle the wrong portion, cancel with a single stroke and write the correct entry besides it with counter signatures rather than erasing or putting white ink. Filling a fresh leaflet of consent form would be a better option. (Advisable)

3.8 Take the patient’s signature/initials on every page of the consent form. (Advisable)

3.9 Doctor-in-charge of the patient/consultant /Principal surgeon/ principal anaesthetist should also sign the consent form.

3.10 Record specifically the name of the doctor/nurse who has obtained patient’s signature on the consent form. (Advisable)

3.11 Fill the consent form in legible handwriting. Avoid using abbreviations.
3.12 Writing a new sentence on a printed consent form below the space designated for the patient’s signature - Take patient’s signature with date and time below this newly added sentence.

3.13 Additional page/document attached with a consent form:
   i. Annex all these papers after the printed consent form.
   ii. Number them serially. The printed consent form must be numbered one.
   iii. Take patient’s signature on each page.

4 Risk Information

4.1 Explain and record the most commonly occurring risks in the consent.

4.2 All risks having probability of 10% or more must be specifically spelt out to the patient and duly enlisted in the consent. The exact percentage of the risk as stated/accepted by medical science need not be specifically mentioned in the consent.

4.3 Answer questions raised by patients about a specific risk and record the same in the consent.

4.4 During pre-surgery/procedure/treatment counselling, disclose to the patient and duly record in the consent:
   i. If the failure rate is higher, or relapse or recurrence is a known possibility.

   ii. Risk involving loss/diminution of life, vision, mental function, serious bleeding even though the risk may be rare. (Advisable)

4.5 Avoid disclosing risks that are remote or will frighten or confuse the patient. (Advisable)

5 Emergencies

5.1 Do not wait for consent in emergencies if waiting could be detrimental to the patient.

5.2 Emergency patient incompetent to give consent; unaccompanied/unconscious patient; or patient brought by unrelated person/s:
i. Proceed with lifesaving treatment/surgery by taking oral consent of the patient and in appropriate cases even without consent.

ii. Take proxy consent if the relatives/attendants are present at that point in time or even from another doctor/Medical Superintendent/Head of the hospital, only if possible and without much effort.

iii. Duly inform the hospital authorities.

iv. Record specifically in the patient’s medical records and/or the consent form the life threatening emergency as well as the reason/s for not obtaining consent or for obtaining proxy consent. This exercise can even be done once the emergency is over.

6 Minor/Incompetent/Emergency patient – Proxy Consent

6.1 Consent and Age

i. Child patient below 12 years - Take consent of the parents/guardian only.

ii. Child patient between 12 to 18 years - Take consent of the patient as well as the parents/guardian.

iii. Adult patient above 18 years - Take consent of the patient only.

7 Surgery/Procedure/Intervention

7.1 Do not take ‘blanket’ consent, general in nature, at the time of admitting a patient for surgery/procedure.

7.2 Try to take consent closer to the day of the surgery/procedure. (Advisable)

7.3 Disclose to the patient during pre-surgery counselling and record specifically in the consent if:

i. Any decision may have to be taken on the operation table after opening the patient - Even if it is the choice of not proceeding further after opening such as in the cases of advanced cancer or tuberculosis.

ii. Damage/removal of important organs is a possibility.
iii. Any other alternative/s may have to be adopted after opening the patient. Record specifically all such alternatives.

iv. The surgery/procedure may require multiple stages/sessions/sittings

v. Corrective surgery/procedure may be required to deal with known post-surgery complication/s.

vi. Re-operation/second intervention may be needed.

vii. Relapse/recurrence/failure is a known possibility for that particular surgery/procedure/disease.

7.4 Record the date fixed for performing a scheduled, non-emergency elective surgery/procedure in the consent.

7.5 No fresh consent is required if the surgery/procedure is rescheduled but without any change to whatever was originally consented by the patient. However, if the surgery is postponed by more than 48 hours, contemplate of taking a fresh consent. (Advisable)

7.6 Take composite consent for both the surgery/procedure and re-exploration, if foreseeable and anticipated.

7.7 Take separate consent for each procedure/surgery if two or more surgeries/procedures are to be performed together either by the same surgeon or by different ones.

7.8 Take separate and specific consent for each and every foreseeable and anticipated alternative surgery/procedure. Consent for a difficult/complicated surgery/procedure does not automatically operate as consent for a comparatively easier/simpler alternative. Additional/alternative/extension that may have to be performed during the course of a surgery/procedure is not intended to be covered by this clause (also refer to – Clause 8.3).

7.9 Take ‘high-risk consent’ (also refer to - Clause 1.17) in appropriate cases. Inform the patient/attendents accordingly and record the said fact specifically in the medical records also.

7.10 Anaesthesia:

i. Take separate specific consent for anaesthesia.

ii. Duly record the type of anaesthesia - general/local/epidural/
spinal/nerve block or any other in consent.

iii. Take advance consent for each option if multiple anaesthesia options are contemplated in alternative.

7.11 Record specifically name of the principal surgeon and the principal anaesthetist in the consent.

7.12 Take a fresh consent if the doctor scheduled to perform a surgery/procedure for whom the patient had specifically consented is changed.

7.13 Non-availability of the surgeon for post-surgery care especially when the surgeon has agreed only to perform the surgery/procedure and thereafter the day-to-day management would be the responsibility of others or of another designated doctor or a team of doctors:

i. Inform the patient in advance of the aforesaid, and record it specifically in the consent. Emergencies are exceptions as far as informing the patient is concerned.

ii. Provide proper substitute even in an emergency not anticipated by the surgeon.

iii. This clause will not apply to public hospitals.

7.14 Confirm before starting every surgery/procedure whether the OT nurse has personally checked the consent form/s in the patient’s medical records, it is signed by the patient and complete in all respect.

7.15 In case of an accidental injury/mishap/ complication during a surgery/procedure follow the protocol.

7.16 Do not take separate consent for sending any part/tissue/fluid/organ removed from the patient’s body for usual cytological or histopathological examination. But sending it for research purpose requires separate specific consent as per ICMR guidelines.

8 Additional/Alternative/Extension During a Planned Surgery/Procedure (same anaesthesia period)

8.1 Discuss, explain and take specific consent beforehand for any additional/alternative/extension that may have to be performed
during a planned surgery/procedure when the patient would be unable to take an informed decision.

8.2 Record specifically the name/s of each of the anticipated and foreseeable additional/alternative/extension in the consent.

8.3 Additional/alternative/extension during the course of a surgery/procedure without the patient’s specific consent

i. Do not proceed without specific consent only because it would be beneficial to the patient, or would save considerable time and expense of the patient, or relieve the patient from pain and suffering in future.

ii. Proceed only if it is “necessary in order to save the life, limb or organ or preserve the health of the patient and it would be unreasonable to delay.”

iii. Take written consent, if possible, from the patient’s attendants. (Advisable)

iv. Record specifically and elaborately the reason/s for the additional/alternative/extension in the intra surgery notes and in the written consent taken from the patients attendants.

9 Consent for HIV Test

8.1 Take written consent of the patient after proper counselling.

Reference:

2. NABH Accreditation standards for Eye Care Organisations 1st Edition
Intent of the Standards

The standards guide the provision of a safe and secure environment for patients, their families, staff and visitors. To ensure this, the organization complies with the relevant rules and regulations, laws and byelaws and requisite facility inspection requirements.

The organization plans for emergencies within the facilities and the community. The organisation plans for limiting smoking within the facility and safe management of hazardous materials. The organization provided for safe water, electricity, medical gases and vacuum systems. The organization has a program for clinical and support service equipment management.

Facility and Engineering Systems

Structure

Structural design is often taken for granted. However, a healthcare facility, aside of being a public institution facility, also sees deployment of some rather heavy equipment – loads that are not accounted for in regular structural design. This equipment may call for uniformly distributed load of 500 kg/m² and above.

Heating, Ventilation and Air Conditioning Systems

Temperature and indoor air quality controls are intrinsic to the heating, ventilation and air conditioning (HVAC) systems. Where temperature is maintained too hot or too maintained, the occupants develop fatigue, reduced alertness and communication breakdown thereby affecting quality of care on part of the caregiver and the healthcare outcomes on
part of the patient. Inadequate safety measures during construction to contain dust and debris, especially in renovations, quickly degenerate the indoor air quality. Such conditions lead to poor staff attendance, human errors and precede the adverse events that lead to many a death and disabilities.

All spaces, especially clinical, require infusion or fresh air to dilute the contaminants and to maintain the natural composition of air. Therefore, air-conditioning units such as splits and windows are not admissible. Spaces with lower air changes per hour such as inpatient accommodation units may make do with natural cross ventilation aided by some mechanical support. However, critical clinical spaces such as intensive care, surgical suite, etc. do not merely require air changes per hour but also require filtration and this is afforded only by central air-conditioning. HVAC in healthcare is not only about comfort conditioning but is more so about infection control.

Commissioning of HVAC systems entails ascertaining conformance to the established design parameters. These include temperature, relative humidity, etc. But of critical importance are air changes per hour, particle counts and pressure gradients. Pressure differentials are mandated with the very specific objective of maintaining asepsis and therefore it is mandatory to institute systems to monitor these on a continuing basis.

**Plumbing**

Plumbing encompasses domestic water supply, hot water systems and the drainage systems. Water treatments are based on water test reports. Water is tested periodically as a standard monitoring protocol. This becomes a challenge when one source of water falls short of requirement. In such instances, it may be prudent to have a separate tank for raw, untreated water and which may be used for flushing and other non-domestic applications.

Stagnant water leads to proliferation of organisms and therefore, even though fire tank water requirement is static, the water is received in the fire tank and the overflow into raw water tanks helps ensure there is no static storage. The reverse osmosis product must conform to standards prescribed by Association for the Advancement of Medical
Instrumentation or EN standard, which is more stringent.

**Power**

Load estimation is important in healthcare as there tends to be a very significant difference between the connected load and the demand load most of the time. This is largely attributable to imaging equipment, which witness momentarily high inrush currents thereby skewing the load pattern.

Power is a critical application and as with all things critical, provision of stand-by and back-up is mandated. While most facilities are equipped with such provision, at least for the critical load, the locations can leave much to be desired. Power plants, panels, DG sets, etc. must be located above flood level.

Safety is particularly important design criteria as patients can be very vulnerable to electrical shock hazard because of their weakened condition, because of drugs or anaesthesia administered, and/or because of their unconscious state. Electrical shocks that would not severely affect a healthy person could be fatal to a patient.

**Circuit breakers** are safety devices that allow power to trip in case of overload or short-circuit. But, life support equipment such as heart pumps, medical vacuum pumps, dialysis machines, and ventilators demand continuous power and loss of power can be fatal. Therefore, earth leakage circuit breakers are not recommended for critical patient applications. UPS does provide relatively clean, uninterrupted power, but will yet trip in case of fault.

Medical grade isolation transformers come equipped with panels that indicate the status of insulation and earth leakages; these emit an alarm on the occurrence of first fault. These are especially recommended for operating rooms. However, unless the system is monitored, the provision may not serve the purpose.

**Lighting**

Lighting has both psychological and physiological impact. Natural lighting allows the patients relate to the diurnal cycle and helps maintain a near normal circadian rhythm. In other words, the patient is rooted and does not lose time – orientation. Patients in spaces bereft of natural light are known to be prone to depression.
Artificial lighting becomes inevitable and generally, indirect lighting is preferred. Daylight lamps that allow colour temperature of 6400 K are preferred as these afford artificial lighting akin to day light at noon. Colour rendering index of 84 is considered optimal as it is neither too yellow, nor too blue and helps discern pallor.

**Electronic Safety**

Electronic safety encompasses patient data and information systems, but also building automation management systems. Patient records are increasingly being maintained in the electronic format. Inadequate protection of such data can significantly impair delivery of care. It’s better to have the patient records housed in fire-safe enclosures. Fire-walls help check unauthorized intrusions. There should be real – time data backup that is possible on a mirror server.

**Closed-Circuit Televisions (CCTVs)** offer a significant value in deterrence, aside of monitoring human movements, authorized or otherwise. Assaults, rapes and homicides figure high in the list of preventable adverse events and a central monitoring facility that allows observation of all critical and vulnerable spaces can help check and control this to a fair degree.

Smoke detection systems interfaced with HVAC can ensure an immediate closing of the dampers to check spread of smoke while simultaneously activating the exhaust mode to ease smoke evacuation.

The maintenance of pressure gradients, a key element of infection control in HVAC systems, is best afforded by interfacing with building automation management.

**Fire Safety**

Fire safety encompasses both prevention and extinguishing. Smoke and heat detection systems, sprinklers, hydrants and fire extinguishers comprise the fire safety systems. In addition, there are gas-based suppression systems can be deployed where water, foam, carbon dioxide and dry chemical powders cannot be used, viz. in operating rooms, server rooms, etc.

It is necessary to understand that vulnerable and high-risk patients cannot evacuate themselves, so the building design must be conducive to enable the rescuers/staff to move the patients to safety. Specified
distances between two fire staircases, can help the ambulatory patients, bed-ridden patients can at best be moved through ramps and/or fire lifts (designated lifts operated by fire men in instance of a fire).

**Disaster Management Plan**

- Must incorporate essential elements of
  - Alert code
  - Information and communication
  - Action cards for each of the staff
  - Availability and earmarking of resources
  - Establishment of command nucleus
  - Training
  - Mock drills

**Hazardous Materials**

- The hazardous materials could be identified as per part II of manufacture, Storage and Import of Hazardous Chemical (Amendment) Rules, 2000

In addition, biological materials like blood, body fluids and microbiological cultures; mercury; nuclear isotopes; medical gases; LPG gas; steam; ETO etc are some of the other common hazardous materials.

**Operation Theatres**

Operating theatres were so-called in the United Kingdom because they traditionally consisted of semi-circular amphitheatres to allow students to observe the medical procedures. An operation theatre complex is the “heart” of any major surgical hospital. An operating theatre, operating room, surgery suite or a surgery centre is a room within a hospital within which surgical and other operations are carried out. The patient is the centre point of a functioning OT complex. He/she is in isolation for varying times, away from his near and dear ones and is physically sick. Efforts should be directed to maintain vital functions, prevent infections/promote healing with safety, comfort and economy.

The establishment and working of the operation theatre (O.T.) needs specialised planning and execution and is not a simple civil engineering
work. A “civil-mechanical-electrical-electronic- bio medical” combo effort driven and coordinated by the needs, preferences and safety of the medical/ surgical team forms the basis for starting and maintaining an operation theatre.

The standards guide the provision of an effective infection control program in the organization. The program is documented and aims at reducing/elimination infection risks to patients, visitors and providers of care.

The organization measures and acts to prevent or reduce the risk of Hospital Associated Infection (HAI) in patients and employees. The organization provided proper facilities and adequate resources to support the Infection Control Program.

The program includes an action plan to control outbreaks of infection, disinfection/sterilization activities, Bio-medical Waste (BMW) management, training of staff and employee health.

High risk areas & procedures
- Areas: OT
- Post –operative ward
- CSSD

**Procedures**

*Standard Precaution*

- Standard Precautions combine the major features of Universal Precautions (UP) and Body Substance Isolation (BSI) and are based on the principle that all blood, body fluids, secretions, excretions except sweat, non-intact skin, and mucous membranes may contain transmissible infectious agents.

*Universal Precautions*

- Universal precautions, as defined by CDC, are a set of precautions designed to prevent transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens when providing first aid or health care.
- Under universal precautions blood and certain body fluids of all patients are considered potentially infectious for HIV, HBV and other blood borne pathogens.
Standard Precautions...

- Standard precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered.
- These include:
  - Hand hygiene,
  - Use of gloves,
  - Gown,
  - Mask,
  - Eye protection, or face shield, depending on the anticipated exposure; and
  - Safe injection practices.

Standard Precautions...

- Standard Precautions are also intended to protect patients by ensuring that healthcare personnel do not carry infectious agents to patients on their hands or via equipment used during patient care.

Basics of Engineering Controls...

- Some HAI are caused by airborne pathogens and appropriate ventilation is necessary. Circulation of fresh filtered air dilutes and removes airborne bacterial contamination, in addition to removing odour.
- All hospital areas and the high-risk areas, should be well ventilated as far as possible. Ventilation systems should be designed and maintained to minimize microbial contamination.
- The air conditioning filtering should be cleaned periodically and fans that can spread airborne pathogens should be avoided in high-risk areas.
- Good housekeeping should ensure that unnecessary items like empty boxes do not clutter and impede ventilation in high-risk areas.
- Positive air pressure is recommended for high-risk areas that must be kept clean.
- Negative air pressure vented to the air is recommended for
contaminated areas and is required also for isolation of patients with infections spread by the airborne route.

- Filtration systems (air handling units) designed to provide clean air should have HEPA filters in high-risk areas
- Unidirectional laminar airflow systems should be available in appropriate areas in the hospital construction.

The principles of maintaining Heating, Ventilation and Air conditioning in Eye Operation Theatres is an intensely debated subject the air conditioning requirements for Operation Theatre in a Hospital have been deliberated at length with manufacturers, engineers, technical committee members and other stake holders and the following guidelines have been finalized by NABH. Given below are the guidelines as released by NABH

**Air Conditioning in OT – Revised Guidelines by NABH**

A. The air conditioning requirements for Operation Theatre in a HCO have been deliberated at length with manufacturers, engineers, technical committee members and other stake holders and the following guidelines have been finalized.

B. For this purpose, operation theatres have been divided into groups:

1. **Super specialty OT:** Super specialty OT means operation theatres for Neurosciences, Orthopaedics (Joint Replacement), Cardiothoracic and Transplant Surgery (Renal, Liver etc).
2. **General OT:** This includes operation theatres for Ophthalmology, District hospital OTs, FRU OT and all other basic surgical disciplines.

   **Day-care centre:** Day surgery is the admission of selected patients to hospital for a planned surgical procedure, returning home on the same day, would fall under the category of general OT.

C. The following basic assumptions have been kept in view:

- Occupancy: Standard occupancy of 5-8 persons at any given point of time inside the OT is considered.
• Equipment Load: Standard equipment load of 5-7 kW considered per OT
• Ambient temperature & humidity at each location to be considered while designing the system.

**OT Construction:**
a) Paint- antibacterial, anti-fungal
b) OT door – automatic/ Hermetically Sealed/Touch free (preferable)
c) General Lights – Clean room lights
d) Provision of safety against static charge.
e) Separate power circuit for equipment like Phaco machine, monitors and microscopes
f) Flooring – seamless, including skirting, should not be of porous stone as it absorbs moisture and could be a source of bio-burden.

**Requirements**

**General OT standards - applicable for Ophthalmic Theatres**

1. **Air Change Per Hour:**
   • Minimum total air changes should be 20 based on international guidelines although the same will vary with biological load and the location.
   • The fresh air component of the air change is required to be minimum 4 air changes (i.e. 16%) out of total minimum 20 air changes.

2. **Air Velocity:** should be same as per previous guide.

3. **Positive Pressure:** There is a requirement to maintain positive pressure differential between OT and adjoining areas to prevent outside air entry into OT. The minimum positive pressure recommended is 15 Pascal (0.05 inches of water).

4. **Air handling/Filtration:** should be same as previous. *When not possible, the OTs should be well ventilated with 2 filtrations (pre and microvee filters should be in position at the AHU).*

5. Temperature and Humidity: The temperature should be maintained
at 21C +/- 3 Deg C inside the OT all the time with corresponding relative humidity between 40 to 60%. Appropriate devices to monitor and display these conditions inside the OT may be installed.

**Design considerations for Planning New Operation Theatres**

- The AHU of each OT should be dedicated one and should not be linked to air conditioning of any other area for all OT constructed.
- During the non-functional hours AHU blower will be operational round the clock (may be without temperature control). Variable frequency devices (VFD) may be used to conserve energy.
- Window & split A/c should not be used in any type of OT because they are pure re circulating units and have convenient pockets for microbial growth which cannot be sealed.
- The flooring, walls and ceiling should be non-porous, smooth, seamless without corners (coving) and should be easily cleanable repeatedly. The material should be chosen accordingly. Hermetic sealing of the doors is recommended.
- Validation of system to be done as per ISO 14664 standards and should include:
  - Temperature and Humidity check
  - Air particulate count
  - Air Change Rate Calculation
  - Air velocity at outlet of terminal filtration unit /filters
  - Pressure Differential levels of the OT wrt ambient/adjoining areas
  - Validation of HEPA Filters by appropriate tests like DOP etc; repeat after 6month in case HEPA found healthy.
- Maintenance of the system: It is recommended that periodic preventive maintenance be carried out in terms of cleaning of pre-filters at the interval of 15 days. Preventive maintenance of all the parts is carried out as per manufacturer recommendations.
References


Introduction

Hospital acquired infection (HAI) contribute to about 20% of admissions in the developing world. Hospitals should exercise great care in proper maintenance of the Operating room (OR) environment, HVAC system, medical and non-medical equipments inside the OR. Personnel involved in disinfection and sterilization process should follow aseptic protocols.

Sterilization means complete eradication of micro-organisms from the operating environment. The sources of bacteriological contamination can be from air, water, medical, paramedical staff, Patients, articles brought in to the sterile environment, clothing, instruments, infected body fluids, electronic gadgets and personal items like wallets, mobile phones and jewellery.

Aseptic protocols means following safe and disciplined procedures to minimize or eradicate the microbiological load in the environment and in the instrument brought into the sterile field during the surgery.

Requirements to maintain the sterilisation in the Operation rooms or Theatre complex.

Infrastructure and Engineering Controls:
1. Proper Architecture and planning of hospital and OR complex.
2. Zoning Inside the Operation theatre complex.
3. HVAC system (Air quality, Cooling, Pressure, Particulate count to maintain ISO class 5 clean room standards).

Managerial Controls:
4. Disinfection process of the OR and equipments.
5. Sterilization process of Instruments.
6. Validation of Sterilization process

**Proper Architecture and planning of OR complex:**

In the present era of evidence based medicine, it is imperative to give maximum importance in planning an operation theatre complex. Within the limitation of finance and space, maximum benefit can be obtained by proper planning in the initial stages.

LOCATION: The OR should be preferably located where the movements of patients are limited. It is best to avoid an Operation Room in the ground floor, where maximum traffic of personals is located in most hospitals. The materials used for the construction of the OR needs to be long lasting, easy to maintain and resistant to growth of microorganisms.

**Zoning Inside the OR**

The four zones are planned depending on the Layout and the available space in an OR. They are

**Protective Zone:** This consists of the Change rooms, Transfer bay, Staff rooms, Stores & Records, Recovery Beds.

**Clean Zone:** This intermediate zone is located between the Protective and the sterile zone. This houses the sterilization area, Induction area and sterile disposables storing area

**Sterile Zone:** The main operating area along with the scrub zones forms the sterile area.

**Disposal Zone:** All unsterile items from the OR should come out through a separate exit which leads to the disposal area directly. Sterile and Unsterile items should not use the same entrance.

Proper planning is essential to incorporate the standards as laid down by the local bodies and NABH.
Table 1: Minimum standards required for EYE OT

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum space</td>
<td>Minimum 260 sq feet of space (as per NPCB norms, however IPHS norms - 400 sq. feet)</td>
</tr>
<tr>
<td>Height</td>
<td>Height -10 feet (depends on the laminar hood size and height)</td>
</tr>
<tr>
<td>Number of persons</td>
<td>5-8 persons at any point in time (standards take into account the minimum personnel required to perform a surgery)</td>
</tr>
<tr>
<td>Humidity</td>
<td>Humidity 20-60%</td>
</tr>
<tr>
<td>Temperature</td>
<td>Temperature- 21C +/- 3 Deg</td>
</tr>
<tr>
<td>Air Handling Unit</td>
<td>AHU/Filtration- 2 sets of pre filters &amp; 1 terminal HEPA filters</td>
</tr>
<tr>
<td>Air Velocity</td>
<td>Air Velocity 25-35 FPM</td>
</tr>
<tr>
<td>Air Changes</td>
<td>Air changes-20/hr, 10-20 % fresh air change /hr.</td>
</tr>
<tr>
<td>Positive pressure</td>
<td>Positive pressure 2.5 Psi</td>
</tr>
<tr>
<td>Equipment load</td>
<td>Equipment load-5-7KW</td>
</tr>
<tr>
<td>Heating Ventilation and Air Conditioning system (HVAC)</td>
<td></td>
</tr>
</tbody>
</table>
A proper HVAC system brings the entire personal inside the hospital under the umbrella of protection as it eliminates the pathogen at source. The quality of air inside an OR is maintained by a HVAC system which regulates the quality of air on the following parameters to achieve Clean room standards as per ISO class 6,3,4&5 Namely

- Temperature & humidity
- Pressure gradient between zones
- Particulate count

The HVAC system consists of the Air Handling Unit (AHU), Inflow and Outflow ducts, Air conditioning compressor, Air Blower, Pre-HEPA filters, (3 and 5 micron filters) and Laminar Air Flow (LAF) Plenum with terminal 0.3micron HEPA filter.

Plan of HVAC system with AHU and LAF plenum
The size of the AHU and HEPA filters are in accordance to the volume of air inside the operation room. The number of the Pre-HEPA filters in the AHU can be altered depending on the volume and pressure of air that is to enter the Main operating room. Approximately the volume of air entering the OR should be equal to or greater than the volume of air in the OR. It is easier to attain the required air quality standards with less strain on the HVAC system, when the AHU and the Terminal LAF plenum are placed close to each other, as this would reduce the length of the inflow air ducts. Reduced inflow duct length would translate as less strain on the compressor to produce air cooling and less strain on the air
blower to achieve the required air pressure and air changes/hour. All this has to be taken into consideration for planning the OT and zoning.

The AHU has three chambers the first chamber has provision for Fresh air inlet and Return air inlet. The air passes through a set of 5 micron filters into the 2nd chamber where it is cooled by the condenser coils and blown by an air blower at a desired pressure through a set of 3 micron filters into the 3rd chamber. The cooled filtered air now passes through a thermo-insulated aluminium air ducts into the terminal Laminar Air Flow plenum inside the OR, which houses a 0.3 micron filter. The Pressure, temperature and humidity are continuously monitored.

The AHU should be operational throughout the clock to maintain the quality of air. To reduce the electrical load consumption, a variable flow device can be installed which regulates the air-exchanges in the operating room without the cooling effect. The Pre-filters installed in the AHU needs to be cleaned regularly, at 3 monthly intervals and can be re-used. The terminal 0.3micron terminal filter needs to be changed, when the required standards of particulate count monitoring are not met or the air qualities are not up to the required standards.

Managerial Controls:

Operating Room Disinfection and Cleaning:
In operating room with a HVAC system, proper surface disinfection is crucial to maintain an infection free environment. Disinfection means cleaning an instrument/item to make it completely or partly free of any infection causing micro-organisms. An ideal disinfectant must kill all micro-organisms and at the same time not cause any harm to humans. Unfortunately no such disinfectant exists.

Some of the commonly used disinfectants are: Table:2

<table>
<thead>
<tr>
<th>Disinfection Levels</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Bactericidal, Fungicidal, Viricidal, Parasiticidal &amp; even Mycobacterium. E.g.: Glutaraldehyde</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Kills most viruses, bacteria, fungus.</td>
</tr>
<tr>
<td>Low</td>
<td>Kills vegetative bacteria, fungi &amp; few viruses.</td>
</tr>
</tbody>
</table>
Formaldehyde, Glutaraldehyde are not recommended for Disinfecting operating rooms as they are Carcinogenic in the concentration used to disinfect. Hence they have a limited role as a disinfectant.

Fumigation can be done initially during a start-up of a theatre or after an overhaul cleaning process.

Formaldehyde 6%, Glutaraldehyde 6% and Benzalkonium chloride 5% can be used using adequate Personal Protective Devices. E.g. For 4000 cft, 325 aldekol in 350 ml of water is sprayed for 30 minutes. OT must be Closed for 2 hrs.

**Bacillocid:** It is a Formaldehyde-free disinfectant cleaner with low use concentration. Ingredients are Glutaral 100 mg/g, benzyl-C12-18-alkyldimethylammoniumchlorides 60 mg/g, didecyldimethylammonium chloride 60 mg/g. This provides complete asepsis within 30 to 60 minutes. Cleaning with detergent or carbolic acid is not required.

**Bacillol** - Ethanol, 2-propanol, 1-propanol can be used as spray for surface disinfection, and does not act on spores. It is used for instant disinfection.

UV irradiation as a form of disinfection is not standardized and not recommended as a routine disinfection technique. However it is used inside Ducting of HVAC system, Pass-boxes to disinfect the air.

**Microbiological monitoring:**

With the development of Fumigation free theatres and HVAC systems, routine microbiological monitoring are not advised. Unlike in western countries, no standard exists in India on the frequency of microbiological surveillance. At present in the Indian scenario, microbiological surveillance is done based on the individual knowledge, availability of resources, funds, access to microbiologist/laboratory, amount of surgical load, occurrence of SSI and the maintenance of air quality inside the OT.

Ideally microbiological surveillance is done by

- Air sampling (bacterial counts)
- Swabs- Preferably peptide water swabs
- Settle plate method (Duration of exposure should be equal to the time taken for the shortest surgery)
Settle plate should be placed 12 inches above the operating table. Minimum CFU should be 10, but depends on the bacteria isolated. Cultures incubated at 37 degree for 48hrs. Aerobic and anaerobic bacteria culture media need to be used.

In HVAC systems Microbiological monitoring is replaced by particulate count monitoring of 0.3 & 0.5microns size and other parameters as shown in Table 4. The frequency of operation theatre Validation depends on the surgical volume. Ideally it should be done twice a year.

### Table 4: Swab’s to be taken from

<table>
<thead>
<tr>
<th>OT table head end</th>
<th>Crash cart</th>
<th>Terminal HEPA filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phaco tray</td>
<td>Refrigerator</td>
<td>Scrub basin</td>
</tr>
<tr>
<td>Mayo trolley</td>
<td>Surgeon &amp; nurse gloves</td>
<td>Microscope handles</td>
</tr>
<tr>
<td>Boyle’s</td>
<td>Door handles/walls</td>
<td>Light Pendant handles</td>
</tr>
</tbody>
</table>

Cleaning Process:

Adequate cleaning with a proper disinfectant is important as it removes all dust, bacterial flora, organic matter and other contaminants. The disinfectant used should non-carcinogenic, easily available and safe to be used by the hospital staff. Most disinfectant removes almost 90-95% of the infectious microbes except spores. Keeping the operating complex dry would make microbes and even spores unviable.

Only wet mopping of walls, floor should be employed inside the operating room complex. Use the three bucket system to mop the OT.
The first 2 buckets contains RP purified water and the third bucket contains the disinfectant diluted with RO water. A clean and dry mop is immersed sequentially into the buckets before the figure of eight method of cleaning is used. The walls also cleaned with a lint free cloth using the 3 bucket system taking care to mop from clean to unclean area.

Table 5: Cleaning Protocol

<table>
<thead>
<tr>
<th>Area</th>
<th>Disinfectant</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roof</td>
<td>2% Bacillocid</td>
<td>Once in 3 months</td>
</tr>
<tr>
<td>Walls</td>
<td>2% Bacillocid</td>
<td>Daily twice</td>
</tr>
<tr>
<td>Floor</td>
<td>2% Bacillocid</td>
<td>Daily twice</td>
</tr>
<tr>
<td>Refrigerator</td>
<td>Defrost &amp; Clean with Soap and water</td>
<td>Weekly once</td>
</tr>
<tr>
<td>Sink</td>
<td>Soap, Water/Sodium Hypochlorite</td>
<td>Daily once</td>
</tr>
<tr>
<td>OT furniture</td>
<td>Alcohol based spray</td>
<td>Daily once</td>
</tr>
<tr>
<td>AHU &amp; Pre-filters</td>
<td>Water</td>
<td>Once in 3 months</td>
</tr>
</tbody>
</table>

**Instruments processing for Sterilization**

The American Operating Room Nursing (AORN) Recommended Practices Committee has provided guidelines for the care and cleaning of surgical instruments.

1. The cleaning process includes separation of sharp and blunt instruments. The instruments are initially rinsed using distilled water.

2. After ensuring that the instruments are removed of dirt and organic matter, they are processed in an Ultrasonic cleaner using Cetrimide 15% & Chlorhexidine gluconate 3% for 10 to 20 minutes. The Ultrasonic cleaner generates sound waves at frequency of 100,000 Hz in liquid and generate sub microscopic bubbles which later implode and create minute vacuum that separates particles from instruments 2.

3. The next process of cleaning involves the three bin technique in which Mechanical scrubbing is done sequentially using a soft bristle brush and care is taken not to damage the fine tips of the
ophthalmic instruments. Hollow instruments are thoroughly flushed with distilled water to ensure no residual organic matter is present.

4. The washed, cleaned and scrubbed instruments are air dried using a high flow jet air gun. This removes the moisture from them instantaneously.

5. The cleaned and air dried instruments should be packed or wrapped for sterilization to prevent dust accumulation. Alternatively the instruments can be stored in a UV irradiated chamber before sterilization.

6. Packing is done using woven or non-woven fabrics. Peal pouches can also be used when the visibility of instruments is crucial. Heat resistant Stainless steel 304 grade bins are used for surgical instruments sterilization.

7. Every item that is packed for autoclave must have a date and time. Steam sterilized items must be used within 48 hours. Once the sterile pack is opened, the contents become unsterile even if they are not used. Have a separate storage area for sterile goods.

**Sterilization:**

Sterilization is a process in which all micro-organisms including bacterial spores are destroyed completely. The common methods of sterilization are as follows.

<table>
<thead>
<tr>
<th>Method</th>
<th>Time</th>
<th>Advantage</th>
<th>Disadvantage</th>
<th>Suitable Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam under pressure-Autoclave</td>
<td>125*C, 25 min</td>
<td>Lethal to all bacteria, Viruses &amp; Spores</td>
<td>Items need to be heat &amp; Moisture resistant</td>
<td>All Linen, metallic instruments</td>
</tr>
<tr>
<td>Dry Heat (Ethylene oxide gas)</td>
<td>5psi-12 hrs, 10psi-6 hrs</td>
<td>Low temperature</td>
<td>Toxic to humans and explosive. Needs standoff time of 24 hrs</td>
<td>Heat labile instruments, tubing’s, Phaco, Vitrectomy, cryo probes.</td>
</tr>
<tr>
<td>Dry heat (Plasma-Activated hydrogen peroxide gas)</td>
<td>90 minutes</td>
<td>Low temperature, items can be used immediately</td>
<td>Specific packing and expensive</td>
<td>Heat labile instruments, tubing’s, Phaco, Vitrectomy, cryo probes.</td>
</tr>
</tbody>
</table>
Flash autoclaves and Glutaraldehyde forms of sterilization are not applicable and safe for ophthalmic instruments. However if used must be done with caution.

### Table 7: Autoclave types

<table>
<thead>
<tr>
<th></th>
<th>Class N</th>
<th>Class B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principal</strong></td>
<td>Gravity air displacement</td>
<td>Vacuum air removal.</td>
</tr>
<tr>
<td><strong>Pre-Vacuum Cold air removal</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Pre-Vacuum Hot air removal</strong></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Drying effect</strong></td>
<td>Present</td>
<td>Best</td>
</tr>
<tr>
<td><strong>Specific use</strong></td>
<td>Solid Unpacked instruments only</td>
<td>Solid, porous, non-porous &amp; hollow packed &amp; unpacked instruments</td>
</tr>
<tr>
<td><strong>Time</strong></td>
<td>More</td>
<td>Less</td>
</tr>
<tr>
<td><strong>Steam penetration</strong></td>
<td>Not Effective</td>
<td>Effective removal with pulses of steam-vacuumed cycles</td>
</tr>
</tbody>
</table>

Ethylene Oxide (ETO) Sterilization – was first reported in 1859. The sterilization cycle consists of 5 stages – gas introduction, evacuation with humidification, exposure, evacuation, and air washes, taking about 2 1/2 hours. Mechanical aeration takes between 8 to 12 hours at +50 to +60°C, and on completion of aeration, the sterilized objects are removed. Ethylene Oxide (ETO) Sterilization is suited for objects which can’t sustain the high temperature and moisture necessary for steam such as with autoclave sterilization.

**Plasma Sterilizer**

1. Hydrogen Peroxide Sterilization – Hydrogen peroxide was discovered by LJ Thenard in 1818 and is a popular alternative to ethylene oxide. It is known for its use in the pharmaceutical industry and can be used in 2 ways – hydrogen peroxide plasma sterilization and vaporized hydrogen peroxide sterilization.

2. Vaporized Hydrogen Peroxide (VHP) sterilization is made up of 3 stages – conditioning including vacuum generation, aeration and...
H2O2 injection, taking about 60 minutes, including aeration time. VHP sterilization is suited for objects that can’t sustain the high temperature and moisture necessary for autoclave sterilization, and its low temperatures – +25°C to +50°C make it suited for medical devices which may have electronics.

**Autoclave indicators:**

<table>
<thead>
<tr>
<th>Indicator class</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1 chemical indicator (ISO11140-1:2005)</td>
<td>Process indicators. Eg. Indicator tape, Differentiates processed from unprocessed loads</td>
</tr>
<tr>
<td>Class 2 Indicator Specialty indicators</td>
<td>Intended to check a specific test procedure as defined by relevant sterilization standards. Eg. Bowie dick test strip/paper. It tests steam penetration with dynamic air removal in class B autoclaves. Used in an empty cycle at 134°C for 3.5 minutes or 125°C for 15 minutes.</td>
</tr>
<tr>
<td>Class 3 Indicator Single Variable Indicators</td>
<td>These indicators react to one of the critical process parameters of the sterilization. Critical parameters chosen for steam sterilization are time and temperature. Temperature tube where a pellet melts at a specific temperature. Used to determine that a specific temperature was achieved. Used in ETO.</td>
</tr>
<tr>
<td>Class 4 Indicator Multi-Variable Indicators</td>
<td>Designed to react to two or more of the critical variables and is intended to indicate exposure process at the stated value of the chosen variables. Eg. Time and temperature are the chosen variables in steam sterilization and time and concentration of ethylene oxide are chosen for ETO</td>
</tr>
<tr>
<td>Class 5 Chemical Integrators</td>
<td>Integrating integrators designed to react to all critical variables. The Stated values are generated to be equivalent to, or exceeds the performance requirements given in ISO 11138 series for Biological Indicators. Indicates 3 autoclave parameter of Steam quality, Temperature and Time and correlates with Biological indicator.</td>
</tr>
<tr>
<td>Class 6 Indicator Emulating Indicator</td>
<td>Cycle verification indicators which shall be designed to react to all critical variables for specific sterilization cycles. Eg “Process challenge device” (PCD)/Helix test denotes steam ability to penetrate hollow instruments. Does not correlate with Biological indicator.</td>
</tr>
</tbody>
</table>
The chemical indicators are classified into six groups.\textsuperscript{6,7,8} The indicators within each group are further sub-divided by the sterilization process for which they are intended to be used. The classification has no hierarchical significance. The appropriate chemical indicator should be used to obtain the information needed to determine the effectiveness of the sterilization process.

**Table: 8: Autoclave Indicators**

**Biological Indicator:**

This is the only indicator that confirms the sterility of the autoclaved load. It is also used to validate the Sterilization process. This consists of a sealed vial with two chambers. The inner chamber contains the Broth and outer chamber has the spores of the most heat resistant bacteria Bacillus thermophilus. For every load one vial is packed and placed in the most challenging part of the load intended to be sterilized. After the sterilization process the processed vial and a unprocessed control vial are crushed so that the inner chamber breaks mixing the broth and the spores. These crushed vials are then incubated at 57°F for 48 hours in a Biological indicator incubator.\textsuperscript{10,11} The vials are inspected and findings documented at 12 hrs, 18 hrs and finally at 48 hrs.

In a successful sterilization cycle the processed vial does not change colour and remains violet, while the unprocessed vial shows colour change from violet to yellow indication growth of bacteria in the vial. The BI should be ideally used in every load of the autoclave cycle.

**Bio-Medical Waste management (BMW):**

A proper biomedical waste management process is needed for the proper functioning of any healthcare facility. “Bio Medical waste” is any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining to or in the production or testing of biological and categories.
Table 8: Categories of Biomedical waste

<table>
<thead>
<tr>
<th>Hazardous (10-25%)</th>
<th>Non-Hazardous (75-90%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infectious:</strong></td>
<td></td>
</tr>
<tr>
<td>1. Sharps</td>
<td></td>
</tr>
<tr>
<td>2. Non-Sharps</td>
<td></td>
</tr>
<tr>
<td>3. Plastics</td>
<td></td>
</tr>
<tr>
<td>4. Liquid waste</td>
<td></td>
</tr>
<tr>
<td><strong>Others:</strong></td>
<td></td>
</tr>
<tr>
<td>1. Radioactive waste</td>
<td></td>
</tr>
<tr>
<td>2. Discarded glasses</td>
<td></td>
</tr>
<tr>
<td>3. Expired medicines</td>
<td></td>
</tr>
<tr>
<td>4. Pressurized containers</td>
<td></td>
</tr>
<tr>
<td>5. Cytotoxic waste</td>
<td></td>
</tr>
<tr>
<td>6. Incinerator ash</td>
<td></td>
</tr>
<tr>
<td>7. Chemical waste</td>
<td></td>
</tr>
</tbody>
</table>

Table 9: Colour Coding of BMW disposal:

<table>
<thead>
<tr>
<th>Yellow – Anatomical Waste</th>
<th>Red – Solid Waste</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Placenta</td>
<td>1. Soiled cotton</td>
</tr>
<tr>
<td>2. Human body parts</td>
<td>2. Dressings</td>
</tr>
<tr>
<td>4. Items saturated with blood</td>
<td>4. Diapers</td>
</tr>
<tr>
<td>5. Microbiological waste</td>
<td>5. Swabs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blue – Non-Biodegradable Waste</th>
<th>Black – Discarded Drugs/Chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Plastic bottles</td>
<td>1. Discarded Medicines</td>
</tr>
<tr>
<td>2. Tubing’s</td>
<td>2. Outdated Medicines</td>
</tr>
<tr>
<td>3. Dialysis kits</td>
<td>3. Cytotoxic drugs</td>
</tr>
<tr>
<td>5. Urine bags</td>
<td>5. Lab chemicals</td>
</tr>
<tr>
<td>6. Catheters</td>
<td>6. Disinfectants</td>
</tr>
<tr>
<td>7. Disposable Syringes</td>
<td></td>
</tr>
<tr>
<td>8. Gloves</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Green – Biodegradable Waste</th>
<th>White – Waste Sharps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Office waste</td>
<td>1. Broken bottles</td>
</tr>
<tr>
<td>2. Wrapping paper</td>
<td>2. Broken ampoules</td>
</tr>
<tr>
<td>3. Food waste</td>
<td>3. Needles</td>
</tr>
<tr>
<td>5. Paper cups</td>
<td>5. Slides</td>
</tr>
</tbody>
</table>
Proper Disposal of Sharps: To Prevent Needle Stick Injuries

- Used disposable needles and syringes and other sharps shall be placed in the sharps container (HUB cutters) containing 1% Sodium Hypochlorite, designated for this purpose.
- HUB cutters shall be placed throughout the Hospital in locations, which facilitate their immediate use. These locations shall be such that they exclude injury to patients, visitors and staff.
- Lancets and other sharps shall be placed in sharps container (HUB cutters) unless used in areas with special procedures, such as the operating room.
- When sharps containers securely removed and disposed daily.
- Used syringes shall be placed in blue bins and removed from unit.
- Recapping of needles should be avoided where at all possible. When it is ABSOLUTELY NECESSARY (e.g. because there is no sharps container available for disposal, etc.) needles are recapped using the scoop method, as follows:
  a) Place the cap on a flat surface.
  b) Without holding the cap, use the needle to scoop the cap onto the needle.
  c) Shake the cap down over the needle.
  d) Press the cap firmly into place.

Blades shall be removed by an appropriate tool and discarded by the use of a tool. Sharps shall never be left “lying around”. Loose needles shall never be placed or left in the patients’ linen.

BMW water treatment:

All the water used in the Operation theatre complex and Laboratories should be treated in a water chamber, with 5% sodium hypochlorite for 30 minutes in a ratio of 1:3 (part of 5% sodium hypochlorite for 3 parts of waste water) before let out into the main sewer.

Proper personal protection devices like gloves, cap, mask, aprons and shoes should be used by the personals while handling the biomedical
waste. Segregation of biomedical waste at source and proper transportation to the site of disposal is important.

**Financial & competing interest disclosure**

The authors do not have any competing interests in any product/ procedure mentioned in this study. The authors do not have any financial interests in any product / procedure mentioned.

**References**


Introduction

The standards encourage an environment of continuous quality improvement. The quality program should be documented and involve all areas of the organization and all staff members. The organization should collect data on structures, processes and outcomes, especially in areas of high risk situations. The collected data should be collated, analysed and used for further improvements. The improvements should be sustained. The quality program of the diagnostic services should be integrated into the organization’s quality plan. Infection control and patient safety plans should also be integrated into the organization’s quality plan. The organization should define its sentinel events and intensively investigate when such events occur.

Hospitals are accountable for the quality and safety of the delivered care to the patients. Despite of various measures taken for the same, hospitals still face difficulties in overseeing safety risks. To overcome such predicaments, hospitals need tools and methods that assist in monitoring information to mitigate or prevent adverse events.1

Internal audit is one of the tools for gathering information that assist the healthcare organizations in monitoring patient safety. The internal audit is an ‘objective assurance and consulting system for detecting patients’ risks of adverse events early’, which ‘should encourage the continuous improvement of patient safety’.2 An audit is a “systematic, independent and documented process for obtaining audit evidence [records, statements of fact or other information which are relevant and verifiable] and evaluating it objectively to determine the extent to which the audit criteria [set of policies, procedures or requirements] are fulfilled.”3
Internal audits are performed by an audit team consisting of internal peers (i.e., employees of a hospital who audit colleagues of other departments).

Internal audits evaluate following aspects of patient care:

- **Structure of care** – For example, availability of fire extinguishers in a hospital.

- **Process of care** – For example, auditing the process of patient transfer from ward to Operation theatre as per the standard guidelines.

- **The outcome of care** – For example, Number of endophthalmitis cases documented in a month.

Clinical Audits and System Audits should be conducted periodically to identify gaps and levels of performance, and implement changes for improvement. Internal audits are important events in monitoring continuous quality improvement in a hospital.

Internal Assessment is a (as per section 3.1 of ISO 19011:2002) – systematic, independent and documented process for obtaining Assessment evidence and evaluating it objectively to determine the extent to which Assessment criteria are fulfilled.

Internal assessments, sometimes called first party audits, are conducted by, or on behalf of, the organization itself for management review and other internal purposes and may form the basis for an organization’s self-declaration of conformity.

External assessments include what are generally termed second- or third-party assessments. Second-party assessments are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third party assessments are conducted by external independent organizations, such as those providing registration or accreditation of conformity to the specified requirements.

**Principles of Assessment**

Assessment is characterized by reliance on a number of principles. These make the assessment an effective and reliable tool in support of management policies and controls, providing information on which an organization can act to improve its performance. Adherence to these
principles is a prerequisite for providing assessment conclusions that are relevant and sufficient and for enabling assessors working independently from one another to reach similar conclusions in similar circumstances.

**Why internal assessment?**

Internal assessment is an assessment on self. It is conducted at planned intervals to:

a) determine whether the system conforms to the planned arrangements and to the requirements of the applicable NABH Standards and has been properly implemented and maintained and

b) provide information on the results of assessment to management

The internal assessment is an effective and reliable tool in support of management policies and controls, providing information on which the management of the organization can act in respect of the weaknesses of the system and thus enabling it to correct them and further improve its performance.

**How to conduct internal assessment?**

Each ECO opting for adoption of NABH Standards should have a procedure to give necessary guidance in internal audit. In an assessment
programme, the status and importance of the processes and areas to be assessed shall be given due consideration along with the results of the previous assessments.

The ECO’s internal assessment schedule shall be based on (indicative and not exhaustive):

a) importance of individual departments,

b) specializations being offered by the ECO,

c) evaluation of performance in health care by ECO itself,

d) ECO’s own infrastructural conditions,

e) performance of support services,

f) community demands and services being provided,

g) compliance of legal requirements (including governmental directives),

h) other related activities,

i) identification of training needs,

j) improvement need to be effected

k) provision of resources

l) the results of previous assessments.

The scope of the assessment shall be the scope of the system as adopted by the department / organization. Selection of assessors and conduct of the assessment shall ensure objectivity and impartiality of the assessment process. General rule is Assessors shall not assess their own work.

As stated above, internal assessment is an exercise of finding the maladies of a system so that these could be removed. Assessors and assesses are all from the same organization. It is not the intention to harm any colleague. The assessors shall be fair, hardworking, reasonable, objective, polite and respectful to the dignity of the assessed. This way only they can contribute in the long term towards the improvement in the organization to which they belong.

**Audit cycle**

The audit process is composed of a vicious cycle with crucial stages (Figure 1)
1. Identify the Audit topic

The topic of the audit can be structure, process or outcome based depending upon the requirements assessed through the identification of problem/gap. It should be of high priority for the hospital and may involve areas in which there is a high volume of work, high risks or huge investment in care or an area critical for patients. Audit team has to be identified before beginning the audit. The team must have one person from Quality department of the organization and other person from a different department depending upon the skills and knowledge required to perform the audit.

2. Set the standard

Once the topic of the audit is identified along with the selection of team, the next step is to set the standards, which the current practices will be compared to.

The choice of criteria and standards is one of the most crucial steps in the design of an audit and it requires team effort. Since, the outcome of the audit i.e. the quality of care provided will be evaluated based on a comparison with these standard parameters.

The sources where criteria and standards can be drawn from may be: international guidelines, scientific literature, expert consensus, data obtained by other health care facilities and personal case studies.4
3. **Collect the data**
Data collection can be retrospective or Prospective.

Data collection tools like interviews, questionnaires or surveys can be used to collect the data OR it can be collected through computerized records or patient files.

4. **Analyze the data**
The data is analyzed by the audit team and compared with the selected standards or criterion. If the findings are not synergistic with the standards, then it has to be assessed whether or not there is a possibility of real improvement. Afterwards, audit methodology requires that the audit team plan intervention strategies and recommendations, according to the results. The recommendations need to be clear and explicit.

Subsequently, all the findings of the audit along with the results and intervention strategies planned should be reported and distributed to all the members who participated in the audit along with key stakeholders.

5. **Implement the change**
The recommendations once approved by the authority are then implemented in an effective manner.

These five stages constitute an audit cycle but the audit cycle also needs an auditing mechanism. A tool should be designed to monitor the effects of the changes introduced to the audited process. Using a data collection method and strategy similar to that used for the previous analysis is advisable for the monitoring process so that the results are effectively comparable.

If it is analyzed, the objectives have not been achieved and the intervention strategies were not effective, it could be necessary to make changes to planned strategies. If the objectives have been achieved, then also a monitoring plan is required to maintain its success.

**The Internal audit process**
The Quality department of the hospital takes the responsibility of planning and facilitating the internal audits. The audits are Structure, process and outcome based depending upon the scope of services
(Identification of the topic). The audit team is identified as per skills and knowledge required to audit a process or a department. The Standard operating procedures (SOPs) of the concerned departments which were prepared according to NABH (National accreditation board for hospitals and healthcare providers) standards are considered as baseline for these internal audits (Set criteria).

Before beginning the Audit, An audit calendar is prepared which states the name of the departments to be audited, Audit date and time, Name of the auditee and auditor (Figure 2).

<table>
<thead>
<tr>
<th>S.No</th>
<th>Department/Activity</th>
<th>Auditee</th>
<th>Date of Audit</th>
<th>Time of Audit</th>
<th>Auditors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laboratory</td>
<td></td>
<td>22/3/17</td>
<td>10.30 AM</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Safety</td>
<td></td>
<td>21/3/17</td>
<td>10:30AM</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>ENT</td>
<td></td>
<td>30/3/17</td>
<td>10:30 AM</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Medical Education</td>
<td></td>
<td>27/3/17</td>
<td>3.00 PM</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Paediatrics Ophthalmology</td>
<td></td>
<td>29/3/17</td>
<td>10:30 AM</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Hospital Infection Control</td>
<td></td>
<td>23/3/17</td>
<td>10:30 AM</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>IT</td>
<td></td>
<td>29/3/17</td>
<td>3:00 PM</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Purchase &amp; Store</td>
<td></td>
<td>25/3/17</td>
<td>3:00 PM</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Outsourced Services Canteen, HK, Laundry &amp; Security</td>
<td></td>
<td>28/3/17</td>
<td>10:30AM</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>OPD Optometry</td>
<td></td>
<td>31/3/17</td>
<td>3.00 PM</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Maintenance</td>
<td></td>
<td>23/3/17</td>
<td>3:00 PM</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Human Resource</td>
<td></td>
<td>21/3/17</td>
<td>3.00 PM</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Medical Record Department</td>
<td></td>
<td>27/3/17</td>
<td>10:30AM</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>OPD Non Clinical</td>
<td></td>
<td>24/3/17</td>
<td>10:30AM</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>Counselling</td>
<td></td>
<td>31/3/17</td>
<td>10:30 AM</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Operation Theatre</td>
<td></td>
<td>24/3/17</td>
<td>3.00 PM</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>Wards</td>
<td></td>
<td>28/3/17</td>
<td>3.00 PM</td>
<td></td>
</tr>
</tbody>
</table>

**Figure 2: Audit calendar**

After the preparation of audit calendar, the audit calendar along with a circular of acceptance is circulated to all the auditors and auditees for signatures. The auditors prepare checklist for the concerned department
Continuous Quality Improvement & Internal Audits - Patient Safety

keeping the standard operating procedures as standard guidelines. Figure 3 refers to sample audit checklist prepared for the audit of Help desk at OPD of the hospital.

Figure 3: Sample Audit checklist for Helpdesk (OPD) audit.

The audit checklist has the following contents-

a) Audit checkpoints
b) Audit findings
c) Grade of compliance-Compliance, No compliance and Partial compliance
d) Action taken report
e) Re-audit/closure report

The first three contents are under the ambit of auditors. The auditors visit the department at the planned time period to perform the audit. Once the audit is completed, the audit checklist is signed by the auditee taking his/her acceptance and then it is handed over to the auditee to complete the ATR (Action taken Report) and closure report. Afterwards, within a stipulated period of time the auditee submits the ATR and Closure report in the Quality department (Data collection).
### Figure 4: Data analysis of the audit reports

Once all the reports get submitted, the data is analyzed owing to the number of Compliances, Partial compliances and Non compliances mentioned in the report (Figure 4).

The percentage compliances of all the audit reports are calculated and average compliance is determined for the entire internal audit process (Data analysis). The results are thus sent to the key stakeholders and it is compared with previous results. The necessary recommendations are discussed amongst the Quality Steering Committee members and proposed to implement (Implement change). The recommendations are then implemented with the necessary support.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Department/Activity</th>
<th>Total No. of observations</th>
<th>Compliances</th>
<th>Non-Compliances</th>
<th>Partial Compliances</th>
<th>Percentage Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laboratory</td>
<td>12</td>
<td>10</td>
<td>0</td>
<td>2</td>
<td>83</td>
</tr>
<tr>
<td>3</td>
<td>Safety</td>
<td>26</td>
<td>24</td>
<td>1</td>
<td>1</td>
<td>92</td>
</tr>
<tr>
<td>4</td>
<td>ENT</td>
<td>15</td>
<td>15</td>
<td>0</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>5</td>
<td>Medical Education</td>
<td>18</td>
<td>14</td>
<td>2</td>
<td>2</td>
<td>78</td>
</tr>
<tr>
<td>6</td>
<td>Paediatrics Ophthalmology</td>
<td>14</td>
<td>13</td>
<td>1</td>
<td>0</td>
<td>93</td>
</tr>
<tr>
<td>7</td>
<td>Hospital Infection Control</td>
<td>30</td>
<td>26</td>
<td>0</td>
<td>4</td>
<td>87</td>
</tr>
<tr>
<td>8</td>
<td>IT</td>
<td>23</td>
<td>20</td>
<td>2</td>
<td>1</td>
<td>87</td>
</tr>
<tr>
<td>9</td>
<td>Purchase &amp; Store</td>
<td>19</td>
<td>16</td>
<td>2</td>
<td>1</td>
<td>84</td>
</tr>
<tr>
<td>10</td>
<td>Outsourced Services Canteen, HK, Laundry &amp; Security</td>
<td>33</td>
<td>23</td>
<td>8</td>
<td>2</td>
<td>70</td>
</tr>
<tr>
<td>11</td>
<td>OPD Optometry</td>
<td>18</td>
<td>8</td>
<td>2</td>
<td>8</td>
<td>44</td>
</tr>
<tr>
<td>12</td>
<td>Maintenance</td>
<td>18</td>
<td>13</td>
<td>3</td>
<td>2</td>
<td>72</td>
</tr>
<tr>
<td>13</td>
<td>Human Resource</td>
<td>25</td>
<td>21</td>
<td>1</td>
<td>3</td>
<td>84</td>
</tr>
<tr>
<td>14</td>
<td>Medical Record Department</td>
<td>19</td>
<td>14</td>
<td>1</td>
<td>4</td>
<td>74</td>
</tr>
<tr>
<td>15</td>
<td>OPD Non Clinical</td>
<td>69</td>
<td>62</td>
<td>5</td>
<td>2</td>
<td>90</td>
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<tr>
<td>16</td>
<td>Counselling</td>
<td>21</td>
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<td>0</td>
<td>1</td>
<td>95</td>
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<tr>
<td>17</td>
<td>Operation Theatre</td>
<td>17</td>
<td>9</td>
<td>3</td>
<td>5</td>
<td>53</td>
</tr>
<tr>
<td>18</td>
<td>Wards</td>
<td>28</td>
<td>25</td>
<td>1</td>
<td>2</td>
<td>89</td>
</tr>
<tr>
<td>19</td>
<td>Pre Surgical Co-ordinator</td>
<td>19</td>
<td>17</td>
<td>0</td>
<td>2</td>
<td>89</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>398</strong></td>
<td><strong>328</strong></td>
<td><strong>37</strong></td>
<td><strong>33</strong></td>
<td><strong>82</strong></td>
</tr>
</tbody>
</table>
Hence, this shows a glimpse of the way to carry out internal audit of various departments or processes in a hospital.

**Conclusion**

Internal audits are excellent tools to monitor and control patient safety in a healthcare setup. The internal audit results give a precise and legible status of quality improvements made by departments. Monitoring and frequently discussing audit results and improvement plans contribute to the feeling of being in control. Audit results can prove to be an incentive for the top management to adjust hospital policies and culture.

Once carried out in an effective manner, the internal audits provide a clear picture of the systems and functions of departments.

**References**


Public and professional belief in the crucial quality of clinical care got flustered in recent years which need immense attention through planned interventions by experts. Different tools like incident analysis, assessment of health technology and clinical audit have been developed in this regard.

What is Clinical audit?

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.

Clinical audit is at the heart of clinical governance:

- It provides the mechanisms for reviewing the quality of everyday clinical care provided to the patients.
- It analyses the history of doctors, nurses and other healthcare professionals.
• Reviewing case notes and finding ways to serve their patients in a better way.
• It addresses issues pertaining to Quality in a systematic and explicit manner, providing reliable and concise information.
• It can highlight the need for improvement by confirming the quality of clinical services.³

Conducting clinical audit is a challenge for healthcare management team because of barriers in clinicians’ engagement in quality prospects in an organization. This can be sorted through different actions:
1. Increase the culture of Quality among clinicians through sensitizing them and training them frequently
2. Involving them in the process
3. Formation and Monitoring of Clinical audit committee.
4. Making them accountable for the audit results.
5. Developing their interest through implementing interventions and seeking improvements.

From a methodological point of view, clinical audit consists of a “quality loop” (Figure 1): once chosen a topic and set shared and measurable criteria and standards, current clinical practice is evaluated, especially in terms of process or outcome, and suggestions for improvement are developed and applied, and then the cycle can begin again.⁴

![Figure 1](image-url)
Principles of Clinical Audit

6. Preparation of Audit
For the success of clinical audit, good preparation is necessary.

The key elements to design worthwhile clinical audits are: choosing the topic, defining a clear purpose and providing the audit staff and resources.

a) **Choosing the topic:** The topic of the audit can be process or outcome based depending upon the adequacy of care process or the results. It would be a good choice to pick up problems that implicate clinicians in terms of (a) High volumes of work; (b) High costs in terms of health and/or economic; (c) High risk; (d) High variability; (e) High complexity; and (f) High innovation.⁴

b) **Defining a clear purpose:** After selection of the topic of the audit, the purpose should be defined in order to frame a proper audit methodology. The purpose/aim of the audit can include the improvement of current processes or implementation of newer processes.⁵

c) **Provision of staff and resources:** Before beginning a clinical audit, the resources and audit team should be clearly identified based on the requirements. Regarding the audit project team, it is advisable that it be customized for the specific audit project, with team members providing many of the skills needed.⁶

7. Selection of indicators, criteria and standards and definition of intervention strategies
Once the topic of the audit is identified along with defining its purpose and selection of team, the next step is to set the standards, which the current clinical practice will be compared to.

The choice of criteria and standards is one of the most crucial steps in the design of a clinical audit and it requires team effort. Since, the outcome of the audit i.e. the quality of care provided will be evaluated based on a comparison with these standard parameters.

The sources where criteria and standards can be drawn from may be: international guidelines, scientific literature, expert consensus, data obtained by other health care facilities and personal case studies.⁷
The audit team should also frame the intervention strategies to be implemented in case of significant discrepancies between standards and actual practices.

8. Data collection
In clinical audit, data is collected in two ways-Prospectively and retrospectively.

Retrospective method is faster taking into account the past clinical documentation, but the quality of collected data/information is not optimal.

Prospective method takes more time, but they offer a more transparent description of current clinical practices. Before data collection, the variables have to be identified and type of analysis which will be done must be stated.

Data collection tools like interviews, questionnaires or surveys can be used to collect the data. Medical records serve as good data sources for any clinical audit.

9. Comparison of collected data with the standards and development of corrective actions
The audit team after collection of data analyses it and compares it with the selected standards or criterion. If the findings are not synergistic with the standards, then it has to be assessed whether or not there is a possibility of real improvement. Afterwards, audit methodology requires that the audit team plan intervention strategies and recommendations, according to the results. The recommendations need to be clear and explicit.

Subsequently, all the findings of the audit along with the results and intervention strategies planned should be reported and distributed to all the members who participated in the audit along with key stakeholders.

10. Check and maintenance of improvements
The audit cycle is completed with the final stage of monitoring and control of implemented strategies.

A tool should be designed to monitor the effects of the changes introduced to the audited process. Using a data collection method and strategy similar to that used for the previous analysis is advisable for the
monitoring process so that the results are effectively comparable.

If it is analyzed the objectives have not been achieved and the intervention strategies were not effective, it could be necessary to make changes to planned strategies.

Moreover, in case of success, Maintenance of it is required through a monitoring plan.

Clinical audit can be conducted successfully if all the above steps of an audit cycle are followed religiously and thus can impact the clinical processes and Quality of services provided to patients. Owing to its momentous nature, it is essential for continuous quality improvement in an organization by continuously doing analysis of clinical processes and outcomes followed by implementation of intervention strategies and recommendations as determined by the audit team.

An example to highlight the effect of clinical audit in the process of continuous quality improvement is cited below.

**Referral Patient Tracking Process-Clinical audit performed at a Super specialty eye care hospital, North India**

A clinical audit on referral tracking process was performed at a NABH accredited hospital in north India which has a Clinical audit committee under its Quality steering committee.

**Background and aim:** The identified problem was that the record of all referral patients was not entered in the Hospital Management Information system. This led to gap in continuity of care medical management with referral doctor. Secondly it affects bonding between referral clinician and the hospital.

The audit was carried out keeping the defined policies and processes of the hospital as baseline standards.

The audit was carried out for 4 months where first two months were designated for audit, next two months for intervention and last two months for post intervention audit (Re-audit).

**Criteria and Methodology:** Retrospective methodology was used for the audit. A questionnaire form was designed to be used as data collection tool and was aimed to interview the registration staff, Medical
Clinical Audit - A step Towards Continuous Quality Improvement

record department technician and secretarial staff, Process owner and attending clinician. 30 Referral patients’ files were selected through random sampling method.

**Inclusion criteria:**
- Patient reported in the hospital for consultation/medical management/second opinion/expert opinion/diagnostic test or procedure.

**Exclusion criteria:**
- Cross internal referrals were excluded.
- Physician referral.

**Audit Team:** The audit team was composed of Chairperson-Clinical audit committee, Chairperson-Quality Assurance, Manager-Patient care, Manager-Quality Assurance and Optometrist.

![Figure 2: It depicts the referral process in the hospital.](image)

**Results:**
- During interview with the registration staff most of the Registration staff were aware of the process through their experience although there is no documentation of the process.
• Manual register is kept at the Private counter only, it’s not there at the other OPD areas

• There are four counters in the hospital for registration-Private, General, Semi private OPD counters. Only at the private registration counter, a register is maintained to document the referrals. During the interview with the secretaries there is no clarity to keep the final copy of thanks letter in the patient record file.

• There is no single document to show the total number of Referrals captured.

• In 47% of patient files scrutinized, The photocopy of Referral note was not enclosed.

Figure 3: It shows the findings of the referral files audited as per the process guidelines.

**Recommendations:**

1. There was a need to document the process to make it streamlined and train the registration staff accordingly and frequently (every three months).

2. It was suggested that a Register / e-register needs to be maintained at all the registration counter to track referrals and back communication.

3. All the documents/letters should be enclosed in the referral patient file as per the policies and processes.
Post-intervention phase

Post intervention, a re-audit was done, and the collected data was analysed. With the proper process document in place, there was a remarkable improvement when the analysis was compared with the previous analysis. The registration staff was well aware of the referral process now. The whole process was documented. 30 referral files based on random sampling method were again audited (Figure 4)

![Figure 4: Post intervention result of the Re-audit.](image)

Conclusion

Clinical audit is a significant tool which acts as a screw driver for continuous quality improvement in order to improve and streamline clinical processes and outcomes. Though clinicians face many barriers in the entire process of doing clinical audit like lack of time due to increased workload, behavioural problems compelling clinicians to perceive audits as professional threat and an impedance in clinical freedom, Lack of adequate resources and other organizational impediments(8), yet it is the effort of top management to create a culture of positive attitude amongst the clinicians and highlight the quantified success of the clinical audits in front of the key stakeholders giving recognition and motivation to the performing team.

Clinical audits through their vicious cycle lead to improved patient care and satisfaction which is the ultimate goal of any healthcare organization catering to patient needs. Thus, every healthcare organization must foster an environment for performing clinical audits to lend best quality patient care and services.
References


Introduction

It is important to healthcare providers, regulators and consumers to be able to measure quality against a set of agreed standards. This is crucial to assess because it reflects the improvement in quality of care and continuity of care. As Darzi wrote:

“We can only be sure to improve what we can actually measure.” ¹

Quality indicators aim to assess sub-optimal care in structure, process or outcome, and can be used as a tool to guide the process of quality improvement in health care.

What are Quality Indicators?

“Quality Indicators (QIs) are standardized, evidence-based measures of health care quality that can be used with readily available hospital inpatient administrative data to measure and track clinical performance and outcomes.”²

Or

“Established measures used to determine how well an organization meets needs and operational and performance expectations.”³

Indicators provide a quantitative basis for evaluation of Quality improvement to clinicians, planners and other stakeholders of the hospital.

Monitoring and measuring of Indicators make it possible to:

- Document the quality of care provided
- Benchmark (making comparisons) over a time period
- Set priorities and make judgments
- Embark accountability, regulation, and accreditation
• Facilitate quality improvement
• Enhance Quality of patient care
• Monitor the performance of the hospital.

Types of Quality Indicators

Indicators can be related to structure, process, or outcome of health care. (Figure 1)

*Figure 1*

Structural Indicators

Structural indicators illustrate the type and quantity of resources used by healthcare setup to deliver the services. This includes the attributes of material resources (such as facilities, equipment, and financing), of human resources (such as the number and qualifications of personnel), and of organizational structure (such as medical staff, organization, methods of peer review, and methods of reimbursement) (5).

Examples of Structural indicators are mentioned in Table 1.

Process indicators

Process indicators determine the efficiency of processes of delivery of services in a healthcare organization. Processes are a series of interrelated activities undertaken to achieve objectives. Process indicators measure the activities and tasks in patient episodes of care (6).

Examples of process indicators are mentioned in Table 1.
**Outcome indicators**

Outcome indicators determine the effect or consequences of care processes on the health of patients. Outcomes can be expressed as ‘The five Ds’(7):

(i) death: a bad outcome if untimely
(ii) disease: symptoms, physical signs, and laboratory abnormalities
(iii) discomfort: symptoms such as pain, nausea, or dyspnoea
(iv) disability: impaired ability connected to usual activities at home, work, or in recreation and

| Table 1 |
|———|———|———|
| Structural Indicators | Process Indicators | Outcome Indicators |
| • Proportion of doctors to nurses | • Proportion of patients assessed by a doctor within 24 hours of referral. | • Patient satisfaction rate |
| • Number of optometrists assigned at a specific unit | • Proportion of patients treated as per clinical guidelines. | • Number of complaints received in a day. |
| • Ratio of number of beds to nurses in the ward. | • Compliance percentage of OT starting time. | • Mortality rate |
| | | • Infection rates |

Examples of outcome indicators are mentioned in Table 1.

NABH (National accreditation board for hospitals) lists down some of the Quality indicators which need to be monitored for Continuous Quality Improvement. Examples of those indicators include- Time for initial assessment of emergency patients, Average number of admissions per day, Percentage of medication errors, Surgical site infection rate, Bed occupancy rate etc.

**Characteristics of an ideal indicator**

**Specific:** An indicator should be expressed in a precise way. It should target a specific area of improvement.
**Measurable:** Indicators should be related to structures/processes/outcomes that can be measured in an unambiguous manner.

**Achievable:** Indicators should be achievable i.e. possible to accomplish.

**Replicable:** The measurements should come out to be the same when made by different people using the same method.

**Timebound:** There should be a time limit within which changes are expected and measured

**Criteria for selection of Quality Indicators**

The Quality indicators should be selected on the basis of following factors.

**A. Importance of what is being measured**

The measure shall point out the areas which are at high risk and significant for best patient care. There has to be a scope for improvement in the gaps present in that area or process.

**B. Scientific soundness of the measure**

- **Validity:** The indicator should capture crucial aspects of quality of care. It should make a logical and clinical sense.

- **Reliability:** The indicator should be reliable i.e. it should be able to replicate consistent results when repeated in the same settings and populations, when assessed by different personnel at different times.

- **Explicitness of the evidence base:**
  The measure has to be evidence based. There should be a clearly documented scientific foundation for the measure in literature.

**C. Feasibility of obtaining internationally comparable data for the measure**

- **Existence of prototypes:** If the measure developed is being used at the national level, or for sub-national groups of populations.

- **Availability of internationally-comparable data across countries:** internationally-comparable information needed for the measure can be collected

- **Cost or burden of measurement:** cost to collect the data needed
for the measure should be estimated and it should be affordable in the ambit of the development and monitoring of the indicator.

**Development and Measuring Quality Indicators - A team effort**

It requires a team effort for development, measuring and monitoring the Quality indicators. A hospital can form Measuring and Monitoring committee for the same. The indicators once developed needs statistical analysis, tabulations and presentations to prepare it in a report format. The report has to be shared with the key stakeholders for the following purposes:

- To have feedback with self, external, or standard comparisons.
- To analyse and discuss Quality indicators with a low score.
- To analyse the barriers and facilitators in the provision of optimal care.
- To design the improvement and implementation strategy and executing it.
- To analyse the process (was the improvement process carried out as agreed?).

**Quality indicators for an Ophthalmology Centre**

Clinical Key Performance Indicators:

1. **KPIs to assess Surgical outcomes:**
   1. No of Patients who had Best Corrected Visual Acuity of 6/9 or more on Day 1 Post-OP This data will be collected by Optom team at the time of Post-Op review of patients on day 1. This will measure the outcome of cataract surgery and will be presented by the Surgeons/team

   \[
   \text{No of patients having } \frac{6/9 \text{ vision on day 1}}{\text{No of cataract surgeries in a month}} \times 100
   \]

   2. No of Times Patient had to Return to OT Unplanned. This data will be collected by OT staff team and this indicator will show the number of errors or complications occurred after surgery. This indicator will be presented by surgery team and CAPA will have to done to find
and implement Corrective Actions and Preventive Actions to reduce these incidences.

\[
\frac{\text{No of surgeries didn’t result in Unplanned return to OT}}{\text{Total surgeries per year}} \times 100
\]

**II. KPIs to Measure Patient Assessment: CQI 2, CQI 3b**

3. No Of Patients Having Satisfactory Refraction. This is a very important indicator for pre-assessment. This data will be captured by the consultants/doctors. This will highlight the errors of refraction and will provide opportunity to rectify and train the Optom team. This indicator directly results in satisfaction of the patient with his/her glass prescription. This KPI will be presented by OPtom Team

\[
\frac{\text{No of Refraction without any errors}}{\text{No of patients refracted in a month}} \times 100
\]

**III. KPIs to measure Safety and Infection Control:**

4. No of times the C/S of OT showed Nil Growth/Acetable growth. The Culture swab sensitivity test will be done every month. The swabs are sent to laboratory for analysing the growth of microorganisms. This indicator validates the cleaning protocol of Operation theatre. This data will be presented by the OT staff team during HIC meeting every month.

\[
\frac{\text{No of time OT culture swab howed Nil growth, Acceptable growth}}{12} \times 100
\]

5. No of Sentinel Events After Surgery Including SSI, TASS, Wrong Procedure, Wrong Eye, Wrong IOL. Sentinel Events have to defined and tracked thoroughly. The adverse events should be immediately recorded and classified as Sentinel event, No Harm and near miss. The person who notices the incident first will record the incident. The incident is presented by the respective department and CAPA has to be done immediately.

\[
\frac{\text{No of surgeries didn’t result in sentinel events}}{\text{No of surgeries in a month}} \times 100
\]

**IV. KPIs to assess Efficiency (Managerial KPIs)**
6. **OT Utilization Rate.** This performance indicator measures the utilization of Operation theatre. The number of resource days/hours is the number of days that the surgery can be performed, that is Surgeons available, OT staff available and Equipment’s in working conditions. No. of days utilized is the actual number of days the OT was used for surgeries. This KPI helps in measuring the effective days of utilization of OT

\[
\frac{\text{No of hours OT is utilized}}{\text{OT Resource hours}} \times 100
\]

7. **No of Surgery Patients Rescheduled.** This performance indicator will help in finding reasons for re-scheduling of surgery and reduce cancellation/postponement at the last minute. The data of the number of surgeries rescheduled will be collected and presented by patient coordinator or counselling team.

\[
\frac{\text{No of surgeries performed as scheduled}}{\text{Total no of surgeries done in a month}} \times 100
\]

8. **Documentation-Medical Records:** This indicator keeps track of completeness of medical record. The following are required for completeness of medical record Patient care plan complete (Pre-surgery)
   a. Consent form complete with Patients’ and Surgeons Signature
   b. Pre-Open Anaesthesia evaluation complete with Anaesthesiologists signature
   c. Counselling and Acceptance slip complete with signatures
   d. Surgical Safety checklist complete with OT staff and Anaesthesiologists signature
   e. Operative Note complete and signed by Surgeon
   f. Post-Op Vital recorded and signed by Anaesthesiologists
   g. Discharge summary signed by Surgeon
   h. IOL sticker stuck on Discharge summary
   i. Biometry readings enclosed

\[
\frac{\text{No. of incomplete records}}{\text{Total Surgeries in the month}} \times 100
\]
9. Time Tracking: This is an indicator at OPD and bears direct relationship to the satisfaction of the patient. The time taken by the appointment patient undergoing Pre-Assessment check-up by the Optom team within the pre-determined standard.

\[
\frac{\text{No of times Appt patient have waiting time less than 30 mins before meeting the Dr}}{\text{No of patients in a month}} \times 100
\]

10. KPIs to measure Patient Satisfaction

a. OP Satisfaction Index. The patients should be requested to rate the performance for OPD services for various parameters. This will help in understanding the gaps and also help in taking corrective action and improve patient satisfaction. A sample size of 10 to 20% of patients should be considered.

\[
\frac{\text{Score achieved}}{\text{Maximum possible score}} \times 100
\]

b. Surgery Satisfaction Index(M) All surgery patients should be requested to rate the various aspects of services including billing, counselling, insurance processing and comfort level after surgery. Patient feedback will serve as areas for improvement and also motivation for job well done. The sample size of this indicator should be 75% to 100%.

\[
\frac{\text{Score achieved}}{\text{Maximum possible score}} \times 100
\]

11. Critical Equipment Downtime. Equipment’s are classified as critical and non-critical. The turnaround time for critical equipment’s should be defined. At the time of breakdown of an equipment, the same should be reported/documentated and the Safety Officer/Medical Engineer should be intimated. The time taken from the time of reporting to the time when the repair was done should be noted.

\[
\frac{\text{Critical downtime of instrument < 24 hours}}{\text{No of instruments non - functioning in a month}} \times 100
\]
Conclusion

Healthcare Quality indicators provide an important tool for measuring the quality of care. Indicators are based on evidence of “best practices” in healthcare that have been proven to lead to improvements in health status and thus can be used to assess, track and monitor provider performance (9).

In order to embed Continuous Quality Improvement in the system, development, measuring and monitoring of Quality indicators is crucial which will not only enhance the performance of the organization in the long term but also patient satisfaction with the best care possible.

References

3. Quality Indicators: Past and Present Michael A Noble MD FRCPC Professor Medical Microbiology and Infection Control, Vancouver Coastal Health
Introduction

Sentinel events are an unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of health care services.

“NABH auditing in many hospitals revealed that 10% of the deficiencies revealed by auditing are matters for incorporation in the Medical Education and 90% of deficiencies have little or no bearing on the doctor’s knowledge or lack of it, but are due to failures of hospital management or organisation, Hospital staff and systems failures, or to poor performance or the genuine human error of simply forgetting to do something. Analysis also point to deficiencies in resources, expertise or adequate documentation.”

Common areas where Sentinel events occur or related to:

1. Surgical events
   a) Surgery performed on the wrong body part
   b) Surgery performed on the wrong patient
   c) Wrong surgical procedure performed on the wrong patient
   d) Retained instruments in patient discovered after surgery/procedure
   e) Patient death during or immediately post-surgical procedure
   f) Anaesthesia related event

2. Device or product events: Patient death or serious disability associated with:
   a) The use of contaminated drugs, devices, products supplied by the organization
b) The use or function of a device in a manner other than the device’s intended use

c) The failure or breakdown of a device or medical equipment

3. **Patient protection events**

a) Discharge of an infant to the wrong person

b) Patient death or serious disability associated with elopement from the health care facility

c) Patient suicide, attempted suicide, or deliberate self-harm resulting in serious disability

d) Intentional injury to a patient by a staff member, another patient, visitor, or other

e) Any incident in which a line designated for oxygen or other came to be delivered to a patient and contains the wrong gas or is contaminated by toxic substances

f) Nosocomial infection or disease causing patient death or serious disability

4. **Environmental events**

Patient death or serious disability while being cared for in a health care facility associated with:

a) A burn incurred from any source

b) A slip, trip, or fall

c) An electric shock

d) The use of restraints or bedrails

5. **Care management events**

a) Patient death or serious disability associated with a haemolytic reaction due to the administration of ABO-incompatible blood or blood products.

b) Medication error leading to the death or serious disability of patient due to incorrect administration of drugs, for example:

   i. omission error

   ii. Dosage error

   iii. Dose preparation error
iv. Wrong time error
v. Wrong rate of administration error
vi. Wrong administrative technique error
vii. Wrong patient error

c) Patient death or serious disability associated with an avoidable delay in treatment or response to abnormal test results

6. Criminal events
a) Any instance of care ordered by or provided by an individual impersonating a clinical member of staff
b) Abduction of a patient
c) Sexual assault on a patient within or on the grounds of the health care facility
d) Death or significant injury of a patient or staff member resulting from a physical assault or other crime that occurs within or on the grounds of the health care facility.

10 Most often reported sentinel events in Hospitals are:
1. Operative/Postoperative complication:
2. Wrong-site surgery
3. Medication error
4. Delay in treatment
5. Patient fall
6. Patient suicide:
7. Patient death or injury in restraints
8. Assault, rape, or homicide
9. Transfusion error
10. Perinatal death/loss of function

10 most commonly identified root causes for sentinel events

These were analysed and reported in a group of accredited hospitals. Most events have more than one root cause. Root cause analysis revealed the following:
1) Human factors — the human factors category relates to staffing
levels and mix, Education, experience, expertise and other staff-related factors, such as fatigue and complacency.

2) Communication error - This refers to communication among any of the following groups: staff, physicians, administration, patients and patients’ families.

3) Leadership — Organizational planning, culture and leadership are included in this category.

4) Assessment — Assessment includes patient assessment and care decisions.

5) Information management — Information management includes data definitions, security, availability and medical records.

6) Physical environment — Physical environment includes Hospital safety and equipment management.

7) Care planning — Care planning includes long term planning, outsourcing and/or collaboration.

8) Continuum of care — Continuum of care includes access to care, continuity, and discharge and patient transfers.

9) Medication use — Medication use includes medication storage and control, ordering, administering and other medication-related tasks.

10) Operative care — Operative care includes surgical planning, blood use and/or patient monitoring.

If the top 10 root cause are tackled effectively, 90 percentages of Sentinel events can be managed effectively.

Protocol for Sentinel / Near miss events.
Every Hospital should have a Sentinel Event Policy:

- To define the process for identification,
- Reporting,
- Investigation and
- Management of sentinel events that occur in a hospital.

Line of Responsibility: Should be fixed among all health care personnel, administrative staff and Patient safety committee
Near Miss Events
A Near miss is defined as an act of commission or act of omission that could have harmed the patient but did not do so as a result only by the virtue of good luck, skilful management and/or prompt evasive action.

As a Hospital Administrator or Consultant, How do I approach the near miss or sentinel event?

Drilling down to the cause of medical mistakes, making errors more transparent and empowering staff to plan and implement corrective actions are necessary steps in creating a sustained culture of safety. All Serious Clinical Events should be managed, documented, appropriately communicated and investigated promptly in a consistent and non-accusatory manner.

Quality Improvement processes such as Root Cause Analysis should be applied to identify the underlying causes and the opportunities for improvements to the systems and processes that will reduce the probability of such an event recurring.

- In case a sentinel event is reported Consultant / safety committee must do root cause analysis and decide upon corrective and preventive actions to be initiated.
- Corrective and preventive actions decided must be initiated within 24 working hours by the concerned personnel. In case a near miss event occurs the same is to be reported within 8 working hours to Safety committee.

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Abstract

Medical records are the document that explains all detail about the patient’s history, clinical findings, diagnostic test results, pre and postoperative care, patient’s progress and medication. If written correctly, it will support the doctor about the correctness of treatment. Inspite of knowing the importance of proper record keeping in India, it is still in the initial stages. Medical records are the one of the most important aspect on which practically almost every medico-legal battle is won or lost. This article discusses the various aspect of record maintenance.

Introduction

A good medical record serves the interest of the medical practitioner as well as his patients. It is very important for the treating doctor to properly document the management of the patient under his care. Medical record keeping has evolved into a science. The key to dispensability of most of the medical negligence claim rest with the quality of the medical records. Record maintenance is the only way for the doctor to prove that the treatment was carried out properly. Medical records are often the only source of the truth. They are likely to be far more reliable than memory.

Intent of the Standards

Information is an important resource for effective and efficient delivery of health care. Provision of health care and its continued improvement is dependent to a large extent on the information generated, stored and utilized appropriately by the organisations.

The goal of information management is a hospital is to ensure that the
required inputs are available to the right personnel. This is provided in an authenticated, secure and accurate manner at the right time and place. This helps to achieve the ultimate organizational goal of a satisfied and improved provider and recipient of health care.

An effective information management system is based on the information needs of the organization. The system is able to capture, transmit, store, analyse, utilize and retrieve information as and when required for improving clinical outcomes as well as individual and overall organizational performance.

Although a digital based information system improves efficiency, the basic principles of a good information management system apply equally to a manual/paper based system.

**Prevailing laws and regulations**

- IT Act 2000 for computer based records
- PNDT Act for relevant details of all patients undergoing ultrasound
- MTP act
- Code of Medical Ethics, 2002
- RTI Act 2005, etc
- Relevant state legislation e.g. Maintenance of Clinical Records Act (MOCRA) in Maharashtra.

Patients are well informed of the services that an organization can and cannot provide. This will facilitate in appropriately matching patients with the organization’s resources. Only those patients who can be cared for by the organization are admitted to the organization. Emergency patients receive the stabilizing treatment and are then either admitted (if resources are available) or transferred appropriately to an organization that has the resources to take care of such patients. Out-patients who do not match the organization’s resources are similarly referred to organizations that have the matching resources.

Patients that match the organizations resources are admitted using a defined process that include patient and family education.

Patient cared for by the organization undergo an established initial assessment and periodic and regular reassessments.
Assessments include laboratory and imaging services. The laboratory and imaging services are provided by competent staff in a safe environment for both patients and staff.

These assessments result in formulation of a definite plan of care.

Patient care is multidisciplinary in nature and encourages continuity of care through well-defined transfer and discharge protocols. These protocols include transfer of adequate information with the patient.

**Objectives of maintaining medical records**

1. Monitoring of the actual patient
2. Medical research
3. Medical/dental or paramedical education
4. For insurance cases, personal injury suits, workmen’s compensation case, criminal cases, and will cases
5. For malpractice suits
6. For medical audit and statistical studies

**Altering medical records**

1. While writing the medical notes, as far as possible do not overwrite. If the change is needed, strike the whole sentence. Do not leave ambiguity. Make a habit of signing if change is made. Preferably put the date and time below the signature. Attempting to obliterate the erroneous entry by applying the whitener or scratching through the entry in such a way that the person cannot determine what was written originally written raises the suspicion of someone looking for negligent or inappropriate care [1,2]

2. Do not alter the notes retrospectively. If something written was inaccurate, misleading or incomplete then insert an additional note as a correction [3https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR2]

3. Entries in a medical record should be made on every line. Skipping lines leave the room for tampering with the records [1https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR1].

4. Amend on electric record by striking through rather than deleting and overwriting the original entry. After inserting the new note, add
date, time and doctor name [4https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR3].

5. Correction of the personal identification data of the patient like name, age, father/husband name, and address should only be made on the basis of affidavit attested by notary or 1st class magistrate [4https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR3].

Who has access to medical records?

1. Medical records are the property of the hospital or patient’s medical practitioner. It is a confidential communication of the patient and cannot be released without his permission [1https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR1].

2. All patients have right to access their records and obtain copy of those records [1https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR1].

3. Patient’s legal representative has the right to those records as long as patient has signed a release of records to accompany any request from the legal representative [5https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR4].

4. Other health care providers have the right to the records of the patient, if they are directly involved in the care and treatment of the patient [5https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR4].

5. Parents of a minor also have access to patient’s medical records [5https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR4].

6. Medical records are usually summoned in a court of law in certain cases like-road traffic accident, medical negligence, insurance claim etc. [3https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR2].

7. The impersonal documents have been used for research purposes as the identity of the patient is not revealed. Though the identity is not revealed, the research team is privy to patient records and a cause of concern about the confidentiality of the information. Recently a need has been felt to regulate the need of medical research, effectively restricting the manner in which this type of research is conducting. An ethical review is required for using the patient’s data [4https://
Release of records

1. Request for medical records by patient or authorized attendant should be acknowledged and documents should be issued within 72 hours [4https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR3].

2. Maintain the register of certificates with the detail of medical records issued with at least one identification mark of the patient and his signature [6https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR5].

3. Certain document must be given to the patient as a matter of right. Discharge summary, referral notes, or death summary are important document for the patient. Therefore, these documents must be given without any charge for all including patients who discharge themselves against medical advice [4https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR3].

4. A subpoena to produce clinical records is a form of court order. Failure to comply is in contempt of court and may be punished. Medical records which are subpoenaed are to be made over to the court and not to the solicitor who sought the subpoena [7https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/- CR6].

Care while issuing certain medical records:

Prescription

The prescription should be preferably on the OPD slip of the institution or on the letter pad of the doctor. Drug company or chemist prescription pad should never be used. Prescription must contain—patient’s name, age, sex, address and institution/hospital name. Prescribed drug should be preferably in capital letter or else clearly visible. One should mention its strength (especially in pediatric age group), its dose frequency, duration in days, and total quantity (number of tablets and capsules). Below the main drug, also mention other instructions of precautions and what to avoid. If any investigation is advised, do not forget to mention it on the prescription slip and call the patient after the investigation. If patient fails to keep follow up date and if then some complication occurs, then patient is also considered negligent (contributory negligence)
Reports
All reports i.e. lab investigation, X-ray reports, ultrasound reports, computed tomography (CT-scan)/magnetic imaging resonance (MRI) reports, and his to-pathological reports should be issued by a qualified person. Biopsy report should preferably be issued in duplicate so that the referring doctor/hospital can keep the original copy. If the pathologist does not give a duplicate copy the referring doctor should get it copied and should be handed over to the patient.

Referral notes
Always keep the carbon copy of referral note especially in case of critically ill patient. Referral note should mention the date and time of writing the note. Also write the treatment given.

Discharge card
Consultant in-charge should himself fill or supervise the discharge card. Condition of the patient on the admission, investigation done, the treatment given and detail advice on discharge should be written on discharge card. Operation notes if mentioned have to be correct otherwise just mention the name of the operation and give separate note in detail if asked for. If any complication is expected after discharge ask the patient to report immediately. Instructions while discharge must be very clear and elaborative. Keep in mind that abbreviations may not be understood by others. Also do not use code messages, sarcasm or poor opinion to the patient.

Certificates
A medical certificate is defined as a document of written evidence vouching for the truth of a fact as determined by the doctor issuing such a document. If medical certificate is admitted in a court of law as evidence and is proved to be false, the issuing doctor is liable for punishment. While issuing a medical certificate following things should be kept in mind,

1. Medical certificate should be on institution/doctor letter pad.
2. Date, time, and place should be mentioned.
3. Issue it only for legitimate purpose and only when necessary.
4. It has to be true and clear without any ambiguity.
5. There should be an identification mark of the patient, preferably a thumb impression.
6. Period of illness should be clearly mentioned.
7. Diagnosis disclosure of the diagnosis should be only after the patient’s express consent, unless required by the law.
8. Doctor should maintain the duplicate copy of every certificate.

How long to maintain the records
1. Ideally records of adult patient are maintained for 3 year.
2. 21 year for neonatal patient (3 + 18 year).
3. For children 18 year of age + 3 year.
4. For mentally retarded patient forever till hospital/institution is working.
5. From income tax point of view for 7 years.

How to destroy the records
1. Public notice of destroying the records in English newspaper and in one vernacular paper mentioning the specific date up to which destruction will be sought [2https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR1].
2. Give a time limit of 1 month for taking away records for those who want the records with written consent [2https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR1].
3. After 1 month destroy the records up to date specified except for following
   a. Where litigation is going on.
   b. Where future trouble is expected.
   c. Mentally ill or retarded patient.
   d. Pre-litigation process of notice exchange is going on.

Hard copy
Computers are now widely used in institution/hospitals for electronic patient records but still hard copy is required for following documents [2https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR1]
1. Consent need to be on hard copy.
2. Referral to doctor need hard copy.
4. Certificate of fitness should be on hard copy.

**Preservation of medical records**

- Collect all the records and classify them according to the different section [8](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR7].
- Protect the records from insect attack. Spray insecticide or place naphthalene balls over shelves to preserve the records.
- Plan a periodical checking for the records [4](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3238553/ - CR3].
- Proper care should be observed while handling the records. Fire extinguisher should be available in record room. Protect all records from dampness, water, and from hot and dry climate [9]. Records should be kept in dust free area. Windows and ventilators should be properly covered with frames as safeguard against sabotage. Destroy the records as per the regulation established for retention of records.

**Conclusion**

Medical records form an important part of a patient management. It is important for the doctor and medical establishment to properly maintain the records of the patient for two important reasons. First one is that it helps in proper evaluation of the patient and to plan treatment protocol. Second is that the legal system relies mainly on documentary evidence in cases of medical negligence. Therefore, medical records should be properly written and preserved to serve the interest of doctor as well as his patient.

**References**


First Step is making the decision about getting accreditation for your hospital from NABH, and announcing it to the team. Make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation, who is familiar with existing hospital quality assurance system.

Next step would be to procure a copy of standards and guide book from the NABH Secretariat. Understanding the NABH standards, their intent and implementation guidelines by attending Program on Implementation or reading the guidebook.

- After Understanding the standards- and training needs, Interact / educate the end users regarding the same- including doctors. Identify and address all infrastructure, statutory and legal requirements.
- A good idea would be to visit a friend’s hospital which has been Accredited.
- Download the application form and self-assessment tool kit for NABH accreditation from the website. Identify gaps from the existing practices in relation to the NABH standards.
- Conduct Self-assessment for NABH standards at least 3 months before submission of application and must ensure that it complies with NABH standards at least 50% for entry level pre-accreditation and 70% for complete accreditation.
- Assemble a team and have a common goal and strategy to improve Quality with involvement of senior management
- Committee Formation: First Committee to be formed is a multidisciplinary Quality team which will be the Steering committee for NABH , which in turn will form various other committees for
Broad Guidelines for Implementation of NABH Standards in an Eye Hospital

Infection control, Safety, Pharmacy, Medical, Records, Internal complaints etc.

- Functioning of Committees will be governed by a strict protocol consisting of Objective Quorum required, Agenda points, Minutes of the meeting.
- Framing your policies and protocol based on your workflow and established guidelines. Reference guidelines for your policies is a paramount importance. Following is the list of references you can refer, while making your policies and protocols

Some of the references that will help you formulate your hospital policies are:

- NABH entry level guidebook ,CAHO guidebook
- Medical Records manual(WHO)
- National infection control guidelines 2017
- National building code 2017
- CDC , Centre for disease control and prevention guidelines
- National program for control of blindness
- ESCRS Guidelines for management of endophthalmitis 2015
- American academy guidelines for preferred practice patterns in ophthalmology
- American society for cataract and refractive surgery guidelines for preferred practice patterns in cataract surgery 2017

Infrastructure reference:

- NABH revised OT guidelines for general OT
- National Building Commission guidelines 2017

Documentation Guidelines: Standard Operating Procedure (SOP)

“A soul searching exercise for any organization.”

The first step in your quality journey is making SOP manuals for your organisation, it will be a fact finding exercise which will improve quality at grass root level. A copy paste job done here, will defeat the very
purpose of one’s quality improvement journey.

An SOP manual is the hallmark of any successful organisation, because it is the most effective way of streamlining its operations. Moreover it is the best way to create a great first impression about your organisation.

When a department assigns staff to write SOP for each task, that itself is a huge fact finding exercise which will help improve quality at grass root level. A copy paste job done here, will defeat the very purpose of one’s quality improvement journey.

Standard Operating Procedure

What is an SOP?
A standard operating procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organisation.

Philosophy of SOP
Human beings make mistakes because the systems and processes with which they work are poorly designed, well thought of systems and operating procedures reduces the chance of error.

Where does it belong?
Current copies of the SOPs should be readily accessible for reference in the work areas of those individuals actually performing the activity.

Documentation of communication is vital to make any strategy work.

The information is divided into two types.
1. Unretainable information which is in the minds of staff, and cannot be retained.
2. Documented information is further divided into
   A. Maintained Documentation - What I Need - SOP Manual
   B. Retained Documentation - What I have done - Records, reports

Purpose of SOP
• To detail the regularly recurring work processes
• Assist that organization to maintain their quality control and quality assurance processes and ensure compliance.
Benefits of SOP

- Minimises variation and promotes quality through consistent implementation of a process, even if there are temporary or permanent personnel changes.
- Reduces work effort, easier to pursue people to follow the steps of a task meticulously.
- Improves Comparability, Credibility and Legal defensibility

‘The process of writing down meticulously, gives structure to your thoughts’ Even better if it is a result of group brainstorming, which will help reduce Muda’s (Japanese word for unnecessary steps) from your

Author

- Written by individuals knowledgeable with the activity and the organization’s internal structure, either individually or as a group brainstorming
- Experts who actually perform the work or use the process.

Who is your target end user of SOP?

Any Staff who has requisite qualifications for performing an activity and is knowledgeable with the general concept, but with limited experience with the procedure. This staff should be able to read the SOP, and perform the given task without supervision. This is the hallmark of a well written SOP.

Content of SOP

- A set of instructions of how to complete an activity.
- Time taken before drafting to focus on exactly what information is to be conveyed to the user.

Writing Styles keeping in mind your end user

- Written in concise, step-by-step, and easy-to read format.
- Unambiguous
- Simple
- Clearly worded so as to be readily understandable by a person,
- Sufficient detail to carry out the procedure without supervision
Drafting tips for SOPs:

1. Use short, concise sentences.
2. Present one idea at a time whenever possible.
3. Use active voice verbs, read and do the task now.
4. Avoid jargon.
5. Use position titles (personal names of individuals).
6. Avoid gender nouns and pronouns whenever possible.
7. Use acronyms only when these are included in the terms and definitions section.
8. For Mandatory activity, the SOP shall use highly prescriptive language.
9. Few examples of well written SOP
10. Kindly observe the detailing of SOP in each of them.

Examples of a well written SOP: SOP for Registration according to ISO 9001-2015 Guidelines

process

   a) Patient approaches Reception staff to avail consultation.
   b) Reception staff - check with patient whether it is patient’s first visit or subsequent visit.
   c) If it his/her first visit, enter Patient’s information in HMS and generate the UHID.
   d) If it is not first visit, find out from patient his or her UHID
   e) If patient does not have registration number, track the number in HMS with the help of patient’s name or phone number.
   f) If you cannot find the UHID, give a new UHID to the Patient.
   g) Direct the patient to the cashier for collection of fees

• SOP can be tested by getting it implemented before sending for approval.
SOP Approval

- Head of department or organisation can approve each SOP
- Signature approval indicates that an SOP has been both reviewed and approved by management. This will be the date of implementation of SOP

SOP General Format for Details

- Title
- Purpose
- Qualification and experience of end user
- Abbreviations
- References
- SOP identification (ID) number.
- Version number
- Name of the place where it belongs
- Date of issue, revision and date of expiry
- Scope-Names of holders/Users of SOP
- Name and signatures of people who authored, reviewed and approved and released the SOP

Frequency of Revisions and Reviews

1. A valid SOP should be reviewed once in 2 years.
2. SOPs need to remain current to be useful. So changed if procedures are changed.
3. Review date should be added to each SOP that has been reviewed.
4. If SOP describes a process that is no longer followed or found faulty, should be withdrawn from the current file and archived by the Quality department.

Role of Quality Department

- Release
- Filing and administration
- Monitoring implementation
Role of quality department-SOP release
• To generate 3 Copies of SOP; the historical, back-up file, third copy will be in the place where it will be used.
• The proper distribution of the SOP, inform potential users that a new SOP has been written.

Role of Quality department- filling and administration
• Filing of the original and further copies
• Electronic access can be limited to a read-only format, thereby protecting against unauthorised changes made to the document.
• Follow correct protocol for withdrawing SOP across organisation when required.
• Superseded versions should be collected and destroyed (except the copy for the historical file) to avoid confusion and unauthorised use.
• To ensure that only officially issued copies may be used, only then the use of the proper instruction is guaranteed.

Role of Quality department – Implementation
• Monitoring implementation of the SOP
• Well written SOP is of no use, if it is not used correctly or its implementation is not ensured

Conclusion
If following things are kept in mind, in the beginning of your SOP journey, it would make your ride less bumpy.

• Philosophy of a step-by-step approach should be adopted
• Kept as simple as possible
• Must grow by trial and error with increasing experience, by group discussion and with changing perceptions
• Start with Basic operational SOPs
• Filling gaps as practice reveals missing links in the chain of Quality assurance
Example of a **SOP format**

**Ref.: Entry level guidebook available on NABH website**

<table>
<thead>
<tr>
<th>Sl.No</th>
<th>Standard Operating Procedure (SOP)</th>
<th>Responsibility</th>
<th>Supporting Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Do the OPD registration of first-come, first-served basis.</td>
<td>Registration Staff</td>
<td>HMS Software</td>
</tr>
<tr>
<td>2.</td>
<td>Enter the following details of the patient from the patient or relative in the hospital management system (HMS) Name, Sex, Marital status, Address, Phone no (Mobile/ Landline), Occupation, Drug allergies, E-mail ID.</td>
<td>Registration Staff</td>
<td>Registration form, General Consent slip</td>
</tr>
<tr>
<td>3.</td>
<td>Check for referral slip if any and enter in the HMS.</td>
<td>Registration Staff</td>
<td>Referral Slip</td>
</tr>
<tr>
<td>4.</td>
<td>If it is his/her first visit, enter patient’s information in HMS and generate a new UHID, If it is not first visit, find out from patient his or her UHID.</td>
<td>Registration Staff</td>
<td>HMS Software</td>
</tr>
<tr>
<td>5.</td>
<td>If you cannot find the UHID, give a new UHID to the patient.</td>
<td>Registration Staff</td>
<td>HMS Software</td>
</tr>
<tr>
<td>6.</td>
<td>The details of the name are manually written on the patient’s file. For example Mr. Naresh Chandra Dr. Vijay</td>
<td>Registration Staff</td>
<td>Patient’s file</td>
</tr>
</tbody>
</table>

**References**

1. NABH Website -Laxmi memorial hospital documents NABH entry level guidebook
2. ISO 9001-2015 guidelines
3. United States environmental protection Agency guidance for preparing Standard Operating Procedures (SOPs)
Annexure I

Tentative List of documents to be prepared for NABH Eye Care standards (may vary depending on the size and scope of the ECO)

1. Hospital Manual
2. Department Manual
   a. Hospital infection control and CSSD Manual
   b. Emergency Manual
   c. FMS – safety manual
   d. Medical Records / IMS manual
   e. HR Manual
   f. Pharmacy and Medication Manual
3. System Procedures – for each procedures
5. Process Approach - Standard Operating Procedures (SOPs)
6. Name of departments (for Eye care hospitals – may vary depending on the size and scope of services)
   I. AAC 8 sops
   II. COP 14
   III. CQI
   IV. General 25 sops
   V. MOM 15 sops
   VI. PRE 05
7. System Formats / records
8. Hospital Committee
9. A. NABH Audit checklist
   B. NABH requirement wise documents list: Hospital manual

Access, Assessment and Continuity of Care (AAC)
- Scope of services
- Registration
• Policy for Admission
• Filling the admission form
• Procedure during non-availability of beds
• Laboratory safe practices
• Imaging services
• Admission of patient
• Assessment Policy
• Discharge Procedure
• Patient Education on expected cost

Care of Patients (COP)
• Uniform care of patient
• Administration of Anaesthesia
• Ambulance services
• Care of patient under Surgical Procedure
• Care of Vulnerable Patient
• Cardiac Pulmonary Resuscitation
• Emergency care
• Handling of Medical Legal Cases
• Nutritional Assessment of Patient
• Pain Management
• Prevention on Adverse Event in Surgical Patient
• Quality Assurance Programme- Surgical Services
• Rationale use of Blood & Blood Products
• Sedation

Management of Medications
• Pharmacy Services
• Hospital Formulary
• Acquisition of medicines
• Storage of medication
• Use of medical gases
• Verbal order of medication
• List of high risk medication
• Dispensing of medication
• Use of Implantable Prosthesis
• Medication administration
• Use of Narcotics and Psychotropic Substances

**Patient Rights and Education (PRE)**

- Patient Rights
- Informed Consent
- Protection of patient rights
- List of condition required informed consent
- Patient Charter–Display Copy

**Hospital Infection Control (HIC)**

- Infection control manual
- Personal Hygiene
- Hand Washing
- Receipt of used material for Processing
- Proper Method of cleaning
- Preliminary checking of supplies
- Inspection and Assembling
- Packaging of Instruments set/ Labelling / Method of wrapping sets
- Procedure for sterilizing linen
- Steam Sterilization - Preparation and loading of autoclave
- Bowie and dick test for pre vacuum sterilizer
- Principles of Ethylene Oxide sterilization / Maintenance and Operation of ETO sterilizer
- Checks for proper functioning of sterilizer
- Procedure for outdated items
- Sharp disposal and needle stick policy
• Indexing of records
• Physical separation of sterile and non-sterile area
• Maintenance of sterile storage

**Continuous Quality Improvement (CQI)**
• Indicator Monitoring system
• Sentinel events

**Responsibility of Management (ROM)**
• Hospital committee manual

**Facility Management and Safety (FMS)**
• Emergency preparedness manual
• Bio Medical manual

**Human Resource Management (HRM)**
• Human Resource Manual

**Information Management System (IMS)**
• Medical records manual

**Reference docs**

**Casualty**

**System Procedure**
• Management Review
• Document And Data Control
• Corrective And Preventive Action
• Control Of Quality Records
• Internal Quality Audit
• Control Of Monitoring And Measuring Equipment
• Training
• Control Of Non–Conforming Products / Services
• Hazards Identification And Risk Assessment
• Identification Of Legal And Other Requirements
• Objectives and targets
• Emergency Preparedness And Response
• Performance Monitoring And Measurement
• Incident Investigation, Non–Conformity, Corrective Action And Preventive Action

Process Approach
• Engineering
• HR
• Laboratory
• Purchase
• Store
• Utility
• Formats For Housekeeping
• Sanitation audit report
• Pest control report
• Fumigation report
• Operation theatre readiness form
• Toilet Cleaning record
• Daily Equipment Cleaning record

Formats For HRD
Credentialing And Privileging Of Nursing Staff
Credentialing And Privileging Of Medical Professionals
Check list for Employee personal record file

Formats For business development / Marketing
• Suggestion Card
• Patient Complaint Report
• Inquiry Monitoring record
Formats For safety Analysis
- Near Miss Report
- Investigation Report
- Safety Inspection Check List
- Firefighting checklist
- PPE Preventive Maintenance check points
- Location List of fire extinguisher
- Fire hydrant checklist
- Ambulance review checklist
- Earthing pit test report

Formats For Operation
- Sterilization report
- DG Set monitoring report
- Preventive maintenance schedule
- Breakdown History card
- Request for microbiological testing
- Room Check list
- Anti-termite treatment/ Rodent Treatment/ Cockroach Treatment

Formats For Purchase
- Purchase Order
- Indent cum incoming inspection report
- Supplier Registration form
- Approved Vendor list

Formats For Store
- Daily stock statement
- Gate pass
- Preservation assessment Report
Formats For System

- Master list cum distribution list of documents
- Change Note
- Calibration status of instruments
- Master list of records
- Quality Objectives
- Audit schedule/plan
- Internal audit non conformity report
- Clause wise document wise audit review report
- Continual Improvement Plan
- Corrective Action report
- Preventive Action report

Formats For Training

- Training calendar
- Training need cum record sheet
- Induction training report
- Job description and specification

Formats For Admin

- Admission Check list
- Discharge Check list
- Audit questions Self-assessment tool kit
- Audit questions department / area / Clause wise audit questions
Standard wise operation theatre checklist
Operation Theatre

- Anaesth assessment and plan
- Adverse anaesth events
- Prevention of wrong site, etc
- Blood transfusion
- Medical gas
- Compressed air purity
- Engineering controls
- Infection control
- Hand hygiene
- Sterilisation
- Re-use policy
- Quality assurance
- Credentialing & privileging
- Consents
- Vulnerable patients
- Medication management
- Medication orders
- Narcotics
- Adequate equipment
- Equipment/furniture maint’ance
- BMW
- Hazmat
- Patients’ rights
- Case records – documentation
- Fire safety

| COP 6 a-g | • Documented policies and procedures for Nursing Services in OT
|          | • Assignment of patient care. Nursing Plan of Care documented
|          | • Provision of adequate equipment
|          | • Empowerment for nursing related decisions
| COP 14 a-k | • Administration of anaesthesia – Policy and procedure
|           | • Pre-anaesth assessment. Anaesthesia plan. Immediate pre-op assessment
|           | • Informed consent for anaesthesia obtained by the anaesthesiologist
|           | • Monitoring during & post anaesthesia
|           | • Criteria for transfer / discharge from recovery area
|           | • Adherence to infection control guidelines
<p>|           | • Monitoring and recording of adverse anaesthesia events |</p>
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
</table>
| COP 15 a-k | • Surgical procedures - Policy and procedure  
• Preop assessment & provisional diagnosis documented  
• Informed consent for surgery obtained by a surgeon  
• Documented policies and procedures to prevent adverse events  
• Qualified surgeon to perform. Operating notes & post-operative plan of care  
• Infection control practices  
• Availability of appropriate facilities & equipment in OT  
• Quality assurance programme. Engineering controls  
• Surveillance of OT environment. Monitoring of SSI |
| MOM 3 a, b-g | • Medication storage, inventory, expiry dates, storage conditions, emergency crash carts, LASA, high risk medications |
| MOM 9 a-d | • Narcotic drugs procedure  
• Storage; handling; documentation |
| MOM 12 a-d | • Procedure for procuring, storage / stocking, usage of implants  
• Counselling of patient and/or family for the usage of implants  
• Entry of batch & serial no in patient’s case file and master log book |
| PRE 4 a, d-h | • Informed consent |
| HIC 2a-i, k, l | • Policies to prevent infection. Overall adherence to infection control  
• Re-use policy.  
• Hand hygiene. Instructions for hand washing displayed  
• Adherence to safe injection and infusion practices  
• Equipment cleaning and disinfection  
• Antibiotic policy. Linen management. Housekeeping. Engineering controls. Safe injection practices |
| HIC 5 a-d | • Hand hygiene facilities, instructions for proper hand hygiene  
• Check Isolation / Barrier nursing facility available  
• Check adequate soap, masks, gloves and disinfectants are available  
• Pre- & post exposure prophylaxis |
| HIC 7 a-f | • Sterilisation disinfection activities; validation  
• Storage of sterilised items  
• Re-use of instruments and equipment’s. Recall procedure |
| HIC 8 b, e | • Segregation of bio-medical waste. Use of PPE |
| FMS 2 b-g | • Floor plans; Fire Escape routes; Signages  
• Layout of OT (no mix of sterile and unsterile)  
• Availability of potable water and electricity round the clock  
• Alternate sources for electricity & water as backup for any failure  
• Access control for outsiders |
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>FMS 2 k</td>
<td>• Facility &amp; furniture maintenance</td>
</tr>
</tbody>
</table>
| FMS 3 c-f, FMS 4 c-f | • All equipment is inventoried and log maintained / calibrated  
• PM labels on Equipment/calibration records/Refrigerator |
| FMS 4 g | • Procedure for equipment replacement & disposal |
| FMS 5 a-f | • Colour coding of gas pipelines  
• Medical gases handling, storage and usage safely  
• Storage of oxygen cylinders/Condition of Humidifiers  
• Compressed air purity  
• Alt. sources for gases, vacuum & compressed air. Operational & main. plan |
| FMS 6 | • Documented plan for handling fire and non-fire emergencies  
• Safe exit plan. Signage pertaining to fire exits  
• Open and easily accessible fire exits without any obstruction  
• Smoke detectors, fire alarms, fire alarm control panel etc. Fire exit, fire extinguishers, no smoking signs etc. |
| FMS 7 a,b,d,e | • Identification of hazmat. Sorting, labelling, handling, storage, disposal Spills management plan of hazardous materials. Staff awareness |
| HRM 9 a-f, HRM 10 a-f | • Credentialing and privileging of doctors and nurses |
| IMS 3 a, c, d | • Medical record unique identification no. / Named, signed, dated and timed entry / author are clear, up-to-date and chronological |
| IMS 4 c | • Operation notes documented in case records  
• Patient interview  
• Staff interview |

**Data collection for quality indicators in operation theatres:**
- CQI 3 c (ii): Percentage of admissions with ADRs
- CQI 3 d (i): Modification of anaesthesia plan
- CQI 3 d (ii): Unplanned ventilation following anaesthesia
• CQI 3 d (iii): Adverse anaesthesia events
• CQI 3 (iv): Anaesthesia related mortality rate
• CQI 3 e (i): Unplanned return to OT
• CQI 3 e (iii): Re-scheduling of surgeries
• CQI 3 e (iii): Percentage of cases – prevent adverse events like wrong site, patient, surgery
• CQI 3 e (iv): Percentage of cases – prophylactic antibiotics within specified time
• CQI 3 e (iv): Re exploration
• CQI 3 j (ii): Incidence of patient identification errors
• CQI 3 j (iii): Compliance to hand hygiene
• CQI 3 j (iv): Compliance to medication prescription in capitals
• CQI 4 c (ii): OT utilisation rate
• CQI 4 c (iii): Critical equipment down time
• CQI 4 c (iv): Nurse-patient ratio
• CQI 4 f (i): Sentinel events
• CQI 4 f (ii): Near misses
• CQI 4 f (iv): Needle stick injuries

**Checklist for operation theatre – individual patients**

*Date: ________________________________*

Patient Name: _____________________________________________

Age/Gender: _________________ MRD:________________________

Wheel Chair/ Differently Abled: Yes □ No □

If Yes, Indicate Kind of Disability: __________________________

Eye to be operated: Right Eye □ Left eye □

One-Eyed Patient: Yes □ No □

Name of Surgery: __________________________________________

Total Amount to be paid: ____________________________________
TPA : Yes □ No □
Fully Settled : Yes □ No □
Advance : ________________________________________________
Balance : _________________________________________________
Payment Mode : Card □ Cash □ Cheque □
Consent Forms Signed: Yes □ No □
Patient/Guardian, Attender, Doctor
All Investigation Reports/Fitness forms brought: Yes □ No □
Special Instruction to OT nurse:
Anesthetist Informed Yes □ No □
Is the eye dilated: Yes □ No □
Name & Signature:

OT Entry Check
To check all the previous entry
Face wash:
Shoes
Jewellery Removed: Yes □ No □

Check Consent Forms/ Fitness forms
Has the patient stopped blood thinners/DM medications? Yes □ No □
Has the patient taken HTN/Thyroid Medications? Yes □ No □
Test dose/Drug Allergy Checked: Yes □ No □
If No, Reason: _______________________________________________
Allergic Drugs: __________________________________________

Verify and Label the Eye to be operated on: Yes □ No □

Any Eye Congestion/Pustules: Yes □ No □

If Yes, Action taken________________________________________

Eye Lash trimmed Yes □ No □

Is the Eye Dilated Yes □ No □

Before surgery BP: PR:

Has the procedure been explained to the patient: Yes □ No □

Monofocal IOL / Toric IOL / Multifocal IOL

Company Name:__________________________________________

Power:__________________________________________________

Cartridge:_______________________________________________

Surgery Notes/anesthetist notes completed: Yes □ No □

Patient data entered in Register: Yes □ No □

After Surgery BP: PR:

HPE to be sent: Yes □ No □

If yes, has HPE form filled: Yes □ No □

Patient Comfortable: Yes □ No □

Post operative instructions given: Yes □ No □

(Medicines/Diet/Review)

Name & Signature:____________________
Sample CHECKLIST FOR INTERNAL AUDIT AND SELF ASSESSMENT

Out Patient Department - Standard requirements

- Initial assessment
- Priority access in clinical needs/Triage
- Patients’ rights displayed
- Case records –documentation
- Complaint redressal, feedback
- Vulnerable patients
- Infection control
- Display of scope IN OPD
- Admission process
- Drug reconciliation in admissions
- Medication management
- CAPITAL letters – prescription
- Fire safety
- BMW
- Equipment/furniture maintenance

| AAC 2 a-e | Patient admission from OPD. Managing non availability of beds  
| AAC 2 f | Access prioritised according to clinical needs  
| AAC 3 b-e | Referral of patients  
| AAC 4 a, b, c, f, g, h, i | Predefined initial assessment  
| | Time frame for doing and documenting initial assessment  
| | Initial assessment to include screening for nutritional needs.  
| | Documented plan of care including preventive aspects of the care  
| AAC 5b | Out-patients are informed of their next follow up where appropriate  
| COP 10 c, d | Care of vulnerable patients - Policy and procedure, safe and secure environment, informed consent from the appropriate legal representative  
| COP 12 b, e, f, h | Care of paediatric patients: display the scope, provisions for special care of children, detailed nutritional, growth, psychosocial and immunization assessment, parent education on nutrition, immunization and safe parenting and documentation of the same |
| MOM 4 a-h | • Prescription of medicines. Medication orders  
          • Prescriptions in CAPITAL letters  
          • High risk medications defined |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PRE 1 a, d</td>
<td>• Patients’ rights displayed, staff awareness</td>
</tr>
</tbody>
</table>
| PRE 4 b, c | • General consent for treatment  
          • Patient and/or his family members interview for the scope of general consent |
| PRE 6 a, b | • Uniform pricing policy. Availability of tariff list to patients |
| PRE 7 a-c | • Documented complaint redressal procedure  
          • Patient and/or family members interview for awareness of the procedure for lodging complaints |
| HIC 2 c-f | • Instructions for hand washing displayed near every hand washing area  
          • Adherence to safe injection and infusion practices  
          • Sterilized sets: expiry dates, storage conditions |
| HIC 5 a, b | • Availability of hand hygiene facilities  
          • Availability of PPEs, soaps and disinfectants; and their correct usage |
| HIC 8 b, e | • Segregation of bio-medical waste  
          • Use of PPE |
| FMS 2 k | • Facility & furniture maintenance |
| FMS 6 | • Documented plan for handling fire and non-fire emergencies  
          • Safe exit plan. Signage pertaining to fire exits  
          • Open and easily accessible fire exits without any obstruction  
          • Smoke detectors, fire alarms, fire alarm control panel etc. Fire exit, fire extinguishers, no smoking signs etc. |
| PRE 6 b, c, f | • Communication with patients & relatives  
                      • Staff awareness on above policies and procedures  
                      • Patient interview  
                      • Staff Interview – Care of Patients  
                      • Staff interview – HR  
                      • Staff Interview – Safety |

**Data collection for quality indicators to be verified:**
- CQI 3 j (iv) : Compliance to medication prescription in capitals
- CQI 4 d (i): Out-patient satisfaction index.
- CQI 4 d (iii): Waiting time for out-patient consultation
HVAC Protocol for Operating Rooms Installation

1. **AHU Panels**
   - Check for the location of the AHU panel – it should be easily accessible and operable.
   - Check for the earth connection.

2. **AHU**
   - Check for the AHU parameters as per tender checklist
   - Check for the mounts and balancing
   - Check whether the surface is clean and maintainable
   - Check adequacy of gradient for the drain
   - Check for protection from weather elements
   - Check for cleanliness of chambers
   - Check for air-seals
   - Check for probe orifices for PDMs
   - Check for calibration certificate of PDMs being installed.

3. **Ducting + insulation**
   - Check for the distance between FA intake and exhaust—this shall not be <8m.
   - Check for the MOC of ducting—it shall be aluminium and not GI.
   - The ducts shall be transported and fabricated in a clean manner. These shall be worked upon on a surface covered with clean polythene, with no dust generating activity allowed in the vicinity.
   - The duct ends shall be sealed before being transported to the location of installation.
   - The location of installation too shall be free of dust.
   - Thermal insulation shall be carried out in a clean manner without affecting the insides of the ducting.
• Acoustic insulation, where required, shall be neatly covered with aluminium foil of approved gauge and the interfaces neatly sealed with aluminium tape.
• Approved aluminium scaffolds shall be deployed.
• The flange joints shall be inspected for alignment and air leakages, before these are insulated.
• The installed and insulated ducts shall be enveloped in clean polythene pending testing of the system.

4. Plenum
• The plenum shall be free of grease with the joints neatly finished.
• Check for probe orifices
• Specified anchor fasteners shall be used for mounting.
• Insulate before mounting
• Check for balancing
• Insulate the joints neatly
• Deploy the copper tubing
• Check for accessibility of damper(s).

5. Filters
• Check for physical damage
• Microvee and HEPA filters should be in intact factory packs with a certificate of quality conformance in the pack.
• Installation of Microvee and HEPA shall be done in clean environment using sterile gloves.

Commissioning
1. Check the power to the AHU panel
2. Check for installation of PDMs.
3. Ensure the environment around the AHU and in the OR is wet-mopped and clean.
4. Undertake dry run of the AHU for one hour with the FA at 10% and EA dampers closed, with a neat muslin cloth mounted in the return path in the AHU.
5. Undertake cleaning of the AHU as specified in the maintenance section.

6. Install the coarse filters and run the AHU for six hours with the FA at 20% and EA dampers closed. Ensure the OR is closed and wet mopping is carried out at intervals of two hours.

7. Take a shutdown to install the HEPA filters.

8. Mark the boxes relating to the grid where these are to be installed on the plenum drawing.

9. Use fresh, sterile gloves before opening the pack.

10. Check for the filter ref and mark it on the respective grid.

11. Ensure the filter media is NOT touched while affixing the filter.

12. Validate by way of following:
   a. Velocity at 150 mm below the filters—to take readings starting at 150mm from the outer edge of the filter and then at intervals of 300 mm—the standard deviation should not exceed 20%
   b. Particle count under the plenum at 1 meter level.
   c. Particle count under beyond the plenum at 1 meter level
   d. CFM measurements—ACPH.
   e. Record the pressure drop against filters and communicate the data to the maintenance department.

**Maintenance**

1. The temperature set-point is to e normally set at _̊C and the RH would be maintained at <_%.

2. The AHUs pertaining to the Operating Theatres and the Sterile Corridor will not be shut down except for fumigation or planned maintenance with notice and concurrence of the OT-I/C (Extn. __) and the Engineering Office (Extn. __).

3. Fumigation protocol:
   - Clean the area with clean water.
   - Clean the area with mild dilute detergent using lint-free material.
   - Clean the area again with clean water, using a different, clean mop.
• Clean the area with disinfectant___ using lint-free material. The dilatation of the concentrate should be carried out under an able authority assigned the responsibility specifically.

• Periodically, the disinfectant employed should be changed by rotation—to employ board-spectrum high-level disinfectants in consultation with Infection Control Committee.

• Fumigate with formaldehyde – weekends:
  - Activate the vaporizers __:__ hours.
  - Seal the apertures / frames.
  - Switch off the AHU at 10 minutes
  - Activate the exhaust at __:__ hours the next morning.
  - Switch to normal mode at __:__ hours.

• Fumigate with _____________ (to check and validate the efficacy)—mid-week.

4. Periodically, the following tests/checks/cleaning should be carried out.

• Daily:
  - Temperature – set – point and observed.
  - Humidity –set – point and observed.
  - Pressure differential (if the same is mounted).
  - Cleaning of service floor(above OTs)

• Weekly (to be by – passed in case of an outbreak)
  - Air load—separately under plenum and beyond.
  - Microbiological surveillance—floor, wall, ceiling, filter, lamp – heads, light-handles, table, cabinets—both inside and outside, and the equipment.

• Monthly:
  - Pressure drop against HEPA filters.
  - Particle count at operating level under the plenum at four corners and centre.
  - Particle count at operating level beyond the plenum.
- Check for leakages from the AHU components on the service floor.

- Change the AHU components as per hospital’s infection control guidelines.

  • Quarterly: Cleaning of the pre – filters.
  
  • Half – yearly: Cleaning of the Micro vee filters (to be preceded by cleaning of pre-filters)—a frequency of quarterly cleaning for the first six months is suggested.

• Yearly:
  
  - Calibrate pressure differential manometers (if these are mounted).
  
  - Calibrate the temperature and humidity sensor readings on Siemens panel.
Key performance indicators for Eye hospitals

1. Waiting Time for Initial Assessment OPD
2. Percentage of cases desired outcome is documented in care plan
3. Patient Satisfaction OPD/IPD – Sample Size
4. Waiting Time
5. Reporting Errors per 1000 Investigations – Lab/Biometry
6. Percentage of Reports matching Clinical Diagnosis B-Scan, OCT, Histopathology
7. Safety Precautions in Diagnostics – Lab
8. Medication Error – Prescription/Administration/Combinations Minimize
9. Adverse Drug Reactions
10. Percentage Medication Charts with Error Prone Abbreviation
11. Adverse Anaesthesia Events
12. Percentage of unplanned return to OT - Cataract and speciality wise (Glaucoma, Retina, Cornea etc.)
13. Percentage of Rescheduling of Surgeries – 4 hrs GA
14. Percentage of cases prophylactic antibiotic – Antibiotic Policy - Guidelines
15. Percentage of Change in Planned Surgery Per Operatively
16. Percentage of Resurgery within 2 weeks
17. SSI Endophthalmitis Rate 30 Days
18. Percentage of Stock Outs for emergency drugs
19. Percentage of Variations from the procurement Process
20. No of Variations in Mock Drills – Once a year
21. Incidence of Falls
22. Percentage of Staff provided Pre Exposure of Prophylaxis
23. Critical Equipment Downtime
24. Satisfaction Index OP / IP
25. Waiting Time for Services Diagnostics
26. Employee Satisfaction
27. Employee Attrition
28. Employee Absenteeism
29. No of Sentinel Events
30. Percentage of Near Miss
31. Needle Stick Injuries
32. Medical Records not having Discharge Summary
33. Medical Records without Proper Consent
34. Percentage of Missing Records – IP
35. Missing ID Errors
36. Hand Hygiene compliance
37. Medical Prescription in Capitals
38. Wrong Prescription/Spectacle
ANNEXURE VI

Sample Consent Form

- I, ---------------------------------------- aged …… yrs. Wife/Son/Daughter of ------------------------------------residing at -------------------
  ------------------------------------------------ state that I am admitting/submitting myself to the above Nursing Home/Hospital/Clinic, for all necessary treatment, under the care and supervision of Dr.------------------
  ------------------------------------------------------------------, voluntarily without any coercion, misrepresentation, mistake, fraud or undue influence.

- I hereby consent and agree to the administration of all necessary drugs, medications, intravenous fluids, blood, blood products, etc. and also to subject myself to all necessary investigations and references as my attending Doctors may deem necessary.

- I am not allergic to any drug/I am allergic to ---------------------------
  ----------------------------------- drugs.

- I hereby consent and agree to the administration of General/Regional/Local Anaesthesia and or Sedation by Dr.-------------------
  ------------------------------------------ for the performance of Surgical Operations, Delivery, Diagnostic or Therapeutic procedures, Investigations, etc., and also to be supplemented with any other mode of anaesthesia if necessary. I say that I have been explained the risks of consuming solids/liquids including water eight hours prior to the induction of anaesthesia.

- I hereby also consent and agree to the performance of ----------------
  -----------------------------------upon myself by Dr.------------------- I also further consent to such further or alternative operative measures as may be deemed necessary, to be performed upon myself, during or subsequent to the course of the above operation and also to the administration of anaesthesia for its purpose. I say that I have also obtained the consent of my spouse/relatives for the said operations, procedures and treatment.

- I further say, that I have been explained the status of general
condition with reference to _____________________________

its complications systemically and the Posterior segment or Vitreo Retinal complication that has been there in both eyes.

- I am aware that my eye would require multiple surgical treatment and procedures for my ocular condition and all questions regarding my illness/treatment and the same have been satisfactorily answered by the attending Doctors.

- Other alternative methods of treatment have also been discussed. No warranty or guarantee has been given to me with respect to the results of the treatment by my attending Doctors, the Hospital/Nursing Home/Clinic or its Staff.

- I also hereby consent to and permit my attending Doctor to use assistants such as the Hospital/Nursing Home/Clinic Residents, Other Doctors, Nurses, Staff, etc. as he deems necessary.

- I further consent and agree to the disposal by the Hospital Authority of any tissues or parts that may be removed in the course of my treatment at this Hospital/Nursing Home/Clinic.

- I further consent and agree to the publication of my treatment for medical, scientific or educational purposes provided the pictures or the descriptive texts accompanying them do not reveal my identity.

- I further consent and agree to being transferred to any other Hospital/Nursing Home/Clinic, as considered fit by my Doctor, during any time of the treatment, if my Doctors feel that it is beneficial for my recovery.

- I further say that I have informed the Doctor of all my previous illnesses, allergies, drug reactions, surgical procedures and all other facts relevant to my treatment. I shall not hold the Hospital or the Doctor responsible for the consequences, which may arise for the non-disclosure of the same.

- I hereby release the Hospital/Nursing Home, its personals, attending Doctors, Anaesthetists, Pathologists, Radiologists and all other person participating in my care from any liability whatsoever for any untoward of unfavourable consequences or results that may arise
out of, or during my treatment (including surgery and anaesthesia) at this Hospital/Nursing Home/Clinic.

- I have seen the schedule of all charges and the same are acceptable to me and I undertake not to leave the Nursing Home/Hospital/Clinic until full and final settlement of all dues has been made by me. I also undertake to pay the clinic/Hospital/Nursing Home bills immediately/within twenty four hours of its presentation.

- I have fully understood the rules & regulations of the Nursing Home/Hospital/Clinic and I agree to abide by the same. / The above has been explained to me and I have fully understood the same and I am signing this consent cum undertaking by my own free will and in a fully alert state of mind.

- I declare that I am more than 18 years of age.

- I have been informed that there are inherent risks involved in the treatment/procedure.

- I have signed this consent voluntarily out of my free will without any pressure and in my full senses.

Patient Signature  Name:

Place:  Date:  Time:

Address:

Witness Signature/Name

Doctors Signature/Name/Seal
1.0 Index Sheet

2.0 Amendment Sheet 2016 – 2017

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Section no/page no</th>
<th>Details of amendment</th>
<th>Reasons</th>
<th>Signature of department head</th>
<th>Approval (HOD-Quality)</th>
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</table>

<table>
<thead>
<tr>
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<th>Page no.</th>
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<tr>
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<td>Index sheet</td>
<td></td>
</tr>
<tr>
<td>2.0</td>
<td>Amendment sheet</td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td>Vision/Mission statements</td>
<td></td>
</tr>
<tr>
<td>4.0</td>
<td>Department Profile</td>
<td></td>
</tr>
<tr>
<td>5.0</td>
<td>Resource management</td>
<td></td>
</tr>
<tr>
<td>6.0</td>
<td>Work flow/Instructions/Standard Operating Protocols</td>
<td></td>
</tr>
<tr>
<td>7.0</td>
<td>List of records</td>
<td></td>
</tr>
<tr>
<td>8.0</td>
<td>Information Management</td>
<td></td>
</tr>
<tr>
<td>9.0</td>
<td>Policies &amp; Procedure</td>
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</tbody>
</table>

3.0 Vision / Mission:

Vision
Our Vision is Restoring Sight and Hope.

Mission
To be a centre of excellence in eye care services, with a focus on extending affordable, advanced, and appropriate eye care services to all those who seek Eye care.

Quality Policy
Nirmals’ Eye hospital is committed to provide “Quality Eye Care” with the highest level of competence and concern, by adopting best practice standards and technologies, to fulfil patients’ needs to their satisfaction.
Quality Objectives
- To Continually enhance Performance by monitoring our adherence to the accepted standards in all areas of Activity.
- To Upgrade Patient Care System and Technology Continuously.
- To Motivate, Train and Develop Human resources.
- To conduct Community Eye Care, Outreach Services and Education Programmes.

Patients Safety Policy
- The Nirmals’ Eye Hospital is committed to providing and maintaining a safe and healthy work place and to provide suitable resources, information, training and supervision on health and safety to staff, patients, contractors and visitors.
- The Nirmals’ Eye Hospital aims to do all that is reasonably practicable to manage non clinical risk.
- It is the policy of The Nirmals’ Eye Hospital to do all that is reasonably practicable to prevent personal injury and damage to property on the hospital premises.
- The overall objective of this policy is to ensure that there is a hospital wide approach to the development, management and implementation of health and safety policies and procedures that are communicated to and available to all staff.

Department Profile

<table>
<thead>
<tr>
<th>Hospital Manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front Office Supervisor</td>
</tr>
<tr>
<td>Front office staff</td>
</tr>
</tbody>
</table>

Resource Management

<table>
<thead>
<tr>
<th>S. No</th>
<th>Assets</th>
<th>Quantity</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Computer</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Printer with scanner</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Laptop</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Telephone</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td></td>
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</tr>
</tbody>
</table>
Key Performance Indicators
To monitor the outpatient satisfaction index

Introduction
The main goal of the front office department is to guide patients who require treatment to the eye related problems.

Objectives
- To help in smoothening the patient’s journey as they move through the healthcare delivery system by assisting and guiding them.
- To assist in the generation of the hospital registration number for the patients.
- To communicate effectively and to ensure the right information is passed on to the right person at the right time.
- To provide adequate information to the patient when needed

Scope:
- Enquiry, Registration, Admission, Raising bills

Location:
Near the entrance of the hospital.

Standard Operating Protocols For Reception Department:
1. Provide warm welcome to the patient.
2. Get preliminary filled from patient (collect basic information, socio demographic profile)
3. If new patient, entry should be made in HMS.
4. If the patient is old (i.e. already have MRD number), update the patient’s data
5. Enter the registration time in the preliminary.
6. Raise bills after entry is done, Give the bill along with preliminary to the patient
7. Give token to the patient
8. Get the preliminary from the patient after paying the bills.
9. Update the case sheet movement register if the old case sheet is removed from the MRD.
10. Transfer the entry to the refraction department
11. In case of emergency, inform the doctor before registration and send the preliminary to the doctor.
12. Maintain the incoming and outgoing letter register
13. Maintain the attendance register
14. Maintain the incoming and outgoing letter register
15. Maintaining customer complaint and suggestion register
16. Getting inpatient and outpatient feedback
17. Maintaining the reception area clean and pleasant
18. Giving the brochures and patient information leaflets to the patients.
19. Explaining and informing the hospital services to the patient.

List of Records:

<table>
<thead>
<tr>
<th>Format No.</th>
<th>Format Name</th>
<th>Location</th>
<th>Retrieval Time</th>
<th>Retention Period</th>
<th>Disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEC/CRP/F/07</td>
<td>Incident report form</td>
<td>Reception</td>
<td>3 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEC/CRP/F/07</td>
<td>Preliminary Questionnaire</td>
<td>Reception</td>
<td>2 mins</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>NEC/CRP/F/00</td>
<td>Case sheet movement register</td>
<td>Reception</td>
<td>3 mins</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>NEC/CRP/F/02</td>
<td>Patient complaint &amp; suggestion register</td>
<td>Reception</td>
<td>3 mins</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>NEC/CRP/F/01</td>
<td>Outpatient feedback form</td>
<td>Reception</td>
<td>3 mins</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>NEC/CRP/F/03</td>
<td>Registration form</td>
<td>Reception desk</td>
<td>3 mins</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>NEC/CRP/F/04</td>
<td>Incoming &amp; Outgoing call register</td>
<td>Reception (incoming register)</td>
<td>3 mins</td>
<td>3 years</td>
<td></td>
</tr>
<tr>
<td>Pharmacy (outgoing register)</td>
<td>3 mins</td>
<td>3 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEC/CRP/F/05</td>
<td>Incoming &amp; Outgoing letter register</td>
<td>Reception</td>
<td>3 mins</td>
<td>3 years</td>
<td></td>
</tr>
</tbody>
</table>
OP Registration Process Flowchart

1. Reception
2. Registration
3. Billing
4. Refraction Room
5. Reception (Waiting)
6. Consultation Room
7. Optica
8. Pharmacy
9. Investigations
10. Get the Feedback Form
11. Sending Patient with Thanks

Additional notes:
- Counselling for treatment/surgery/laser
- Annexure VII
NABH Internal Audit Format for Corrective Action and Preventive Action EG. Eye Operation Theatre

Department: OT
Auditor: __________________ Auditee: ________________________
Audit Cycle No: ___________________________________________
Date: _____________ Time In: ___________ Time Out: _________

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Chapter</th>
<th>Checks</th>
<th>N/C</th>
<th>Root Cause</th>
<th>Corrective Action Proposed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AAC</td>
<td>Whether they practice safe transportation of patient on wheel chair, trolley?</td>
<td></td>
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<tr>
<td></td>
<td>AAC</td>
<td>Whether they carry the samples to the lab safely.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AAC</td>
<td>What are the visiting hours of the hospital?</td>
<td></td>
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<tr>
<td></td>
<td>AAC</td>
<td>Whether identity of the patient is verified before carrying him for any procedure.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AAC</td>
<td>How information is exchanged and documented during each staffing shift, between shifts and during transfers between units/departments?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>The staff is well aware &quot;what to do&quot; if any person (patient/patient relative/ visitor) gets into a cardiac arrest situation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>What are the documents are checked before the patient is taken into the Operation room?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>The patient's pre-anaesthesia assessment is complete before the patient is taken into the Operation room. (Applicable for both planned and emergency cases).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sl. No.</td>
<td>Chapter</td>
<td>Checks</td>
<td>N/C</td>
<td>Root Cause</td>
<td>Corrective Action Proposed</td>
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<tr>
<td></td>
<td>COP</td>
<td>The anaesthesia plan is documented before the patient is taken into the Operation room</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>COP</td>
<td>The immediate preoperative re-evaluation is documented (done just before the patient is taken into the operating room)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>Surgical patients have preoperative assessment and a provisional diagnosis documented prior to surgery. (Applicable for both planned and emergency cases)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>COP</td>
<td>The patient site of surgery is marked before he is received in the OT complex. (If any other practice is also being followed to prevent the wrong site, wrong surgery and wrong patient, please note the same)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>The adverse anaesthesia events are recorded.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>The staff nurse is aware about the pain management system</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>What are the criteria for discharge from recovery room?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>How patients are monitored pre and intra operative?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>COP</td>
<td>How patients are monitored post anaesthesia?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MOM</td>
<td>Medicines are stored in a clean, well lit &amp; ventilated environment.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>MOM</td>
<td>There is no expired drug stored in the OT (check randomly the drugs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MOM</td>
<td>Look-alike and sound alike medicines are stored separately.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>MOM</td>
<td>Temperature of the refrigerator is monitored regularly</td>
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<tr>
<td></td>
<td>MOM</td>
<td>Prepared medicine is labelled prior to preparation of next</td>
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<tr>
<td>Sl. No.</td>
<td>Chapter</td>
<td>Checks</td>
<td>N/C</td>
<td>Root Cause</td>
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<tr>
<td>MOM</td>
<td></td>
<td>Narcotics are stored in double lock and proper records are maintained.</td>
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<tr>
<td>MOM</td>
<td></td>
<td>The staff is aware of the adverse drug reaction reporting forms. (to verify, -(I) check the availability of the forms, (ii) check if any case is there and form is filled)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOM</td>
<td></td>
<td>The implantable prosthesis is approved under the National (FDA) or International notification (US-FDA) and any register is maintained.</td>
<td></td>
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<td></td>
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<tr>
<td>MOM</td>
<td></td>
<td>The medical gas cylinders are marked properly (for empty/ filled).</td>
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<td></td>
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<tr>
<td>MOM</td>
<td></td>
<td>The outlets/pendants of the medical gas supply are in proper working condition. If any of them is under maintenance-it should be properly displayed at that place for the information of user.</td>
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<td></td>
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</tr>
<tr>
<td>MOM</td>
<td></td>
<td>The staff is well aware of the alarm system of the medical gas supply pipelines.</td>
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<tr>
<td>MOM</td>
<td></td>
<td>Before administrating the drug to patient she verifies - patient id, name of drug, dose, route &amp; time</td>
<td></td>
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<tr>
<td>MOM</td>
<td></td>
<td>Are aware of the sound-alike and look-alike list developed by the drug therapeutic committee.</td>
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<tr>
<td>MOM</td>
<td></td>
<td>Verbal orders are taken cautiously (minimizing the errors)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MOM</td>
<td></td>
<td>What are near miss, no harm, medication error, adverse drug reaction?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>MOM</td>
<td></td>
<td>The crash cart is maintained properly. (1. some mechanism should be there to ensure that the medicines in it are available in apt amount and are not expired, 2. Defib is checked regularly, 3. O2 Cylinder is checked regularly)</td>
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<tr>
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<tr>
<td>PRE</td>
<td></td>
<td>The consent form for blood transfusion is complete before the patient is wheeled into the OT complex.</td>
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<tr>
<td>PRE</td>
<td></td>
<td>The consent form for surgical procedure is complete before the patient is wheeled into the OT complex.</td>
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<tr>
<td>PRE</td>
<td></td>
<td>The consent form for the anaesthesia is complete before the patient is wheeled into the OT complex.</td>
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<tr>
<td>PRE</td>
<td></td>
<td>Patients are educated about pain management.</td>
<td></td>
<td></td>
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<tr>
<td>PRE</td>
<td></td>
<td>The staff is aware of the patient rights. (ALL STAFF)</td>
<td></td>
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<tr>
<td>PRE</td>
<td></td>
<td>The staff is aware of the patient responsibilities. (ALL STAFF)</td>
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<td></td>
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<tr>
<td>HIC</td>
<td></td>
<td>The surveillance activities of the OT complex environment include: monitoring the quality of air, rate of air exchange, cleaning &amp; disinfection process.</td>
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<td></td>
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<tr>
<td>HIC</td>
<td></td>
<td>What does the staff does if any medical record, that is blood soiled, comes to him. (prevent himself, make new record and discard older soiled record in correct colour waste bin)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HIC</td>
<td></td>
<td>Staff is aware about the colour codes of the biomedical waste management rules and is using that properly. (check the waste bins)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HIC</td>
<td></td>
<td>The staff properly follows the standard precautions (use of Personal Protective Equipment)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HIC</td>
<td></td>
<td>How disinfection is used in the OT before and in between the cases.</td>
<td></td>
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<tr>
<td>HIC</td>
<td></td>
<td>The air sampling records are verified (signed) by the microbiologist every week.</td>
<td></td>
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<tr>
<td>HIC</td>
<td></td>
<td>The records of the disinfection of OT are verified (signed) by the infection control nurse every week.</td>
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<td></td>
<td>HIC</td>
<td>Hand wash technique display is there at all hand wash facilities. Ask for the steps?</td>
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<tr>
<td></td>
<td>HIC</td>
<td>Demo for the blood spill management correctly done by staff.</td>
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<td></td>
<td>HIC</td>
<td>The proper record of the sterile supply (linen / surgery sets etc.) received is maintained.</td>
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<tr>
<td></td>
<td>HIC</td>
<td>They know what to do in case of needle stick injury</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>HIC</td>
<td>How equipment’s are cleaned and sterilized?</td>
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<tr>
<td></td>
<td>CQI</td>
<td>Staff is aware of the quality indicators of OT-</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>1. Surgical site infection rate</td>
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<td>2. Percentage of adverse anaesthesia events</td>
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<td></td>
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<td>3. Anaesthesia related mortality rate</td>
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<td>4. Percentage of re-scheduling of procedures</td>
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<td></td>
<td>CQI</td>
<td>Ask about vision. (ALL STAFF should know this)</td>
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<tr>
<td></td>
<td>CQI</td>
<td>Ask about mission. (ALL STAFF should know this)</td>
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<tr>
<td></td>
<td>CQI</td>
<td>Ask about quality policy and quality statement. (ALL STAFF should know this)</td>
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<tr>
<td></td>
<td>CQI</td>
<td>Ask about our core values. (ALL STAFF should know this)</td>
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<td></td>
<td>CQI</td>
<td>What are the sentinel events?</td>
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<td></td>
<td>CQI</td>
<td>What are the patient safety goals?</td>
<td></td>
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<tr>
<td></td>
<td>FMS</td>
<td>The biomedical equipment are properly maintained (preventive maintenance and the calibration)</td>
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<td></td>
<td>FMS</td>
<td>If any of the biomedical equipment is &quot;under repair&quot;, then either it is removed from the user site or if not possible to remove it is labelled properly to avoid confusion to the user.</td>
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<td></td>
<td>FMS</td>
<td>Check whether that staff knows correctly about &quot;what to do&quot; in the emergency situations (fire, bomb threat)? (ALL STAFF should know this)</td>
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<td></td>
<td>FMS</td>
<td>The staff knows what to do if any situation of violence occurs (not necessarily in/around the department but anywhere in the hospital)</td>
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<tr>
<td></td>
<td>FMS</td>
<td>Look for signage, fire exit are displayed. Fire exits are free from obstruction. Firefighting equipment’s are free from obstruction.</td>
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<td></td>
<td>HRM</td>
<td>The staff is aware of the grievance handling process correctly (as in written HR policy of the hospital). (ALL STAFF)</td>
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<tr>
<td></td>
<td>HRM</td>
<td>The staff is aware of the &quot;disciplinary actions policy/procedure&quot; of the hospital. (ALL STAFF)</td>
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<td></td>
<td>HRM</td>
<td>The staff is well aware of the appraisal system.</td>
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<td></td>
<td>HRM</td>
<td>Check whether the staff is aware of Employees rights. (Free health, leave etc.). (ALL STAFF)</td>
<td></td>
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<tr>
<td></td>
<td>HRM</td>
<td>Check employee grooming in the dept?</td>
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<tr>
<td></td>
<td>HRM</td>
<td>Check whether the staff is aware of their responsibilities? (ALL STAFF)</td>
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<tr>
<td></td>
<td>HRM</td>
<td>All job descriptions are available.</td>
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<td></td>
<td>HRM</td>
<td>Training records of staff /see the kind of training: safety, code blue, induction, orientation /fire emergency. (If the records are told to be available at a different place then go and check at that place)</td>
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<td></td>
<td>IMS</td>
<td>How do you maintain patient's confidentiality?</td>
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</table>
THE MOST WIDELY USED ANTI-INFECTION EYEDROPS IN INDIA*

Moxicicrop
Moxifloxacin 0.5% Eye Drops Livewire for infection control

No. 1 prescribed Moxifloxacin brand by ophthalmologists*

- Preservative-free, contributes to comfort and tolerability

- Offers 24x7 hour infection control


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DON’T TAKE CHANCES WITH OCULAR INFECTIONS

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Gatifloxacin 0.5%
EYE DROPS

THE FUTURE OF INFECTION CONTROL

Gatifloxacin 0.5% exhibits improved pharmacokinetics, efficacy and patient compliance\(^1,2\)

**Achieves 2/3\(^{rd}\) greater target tissue concentration than 0.3% formulation\(^3\)**

**Provides increased efficacy\(^1\)**

**Reduced resistance\(^2,3\)**

**Less frequent dosing regimen\(^*\) may ensure patient compliance\(^2\)**

\(^*\)Dosage: Day 1: one drop every 2 hrs (up to 6 times), Day 3 to 7: one drop 3-4 times daily

References:
1. Nish D. *Gatifloxacin* 0.5% ophthalmic suspension. Med Lett. Last accessed on 2nd January 2018
2. Shtul DB, Gruk B, Kogan AA, Gitler ME, Gafny N, Greenstein D, et al. CiplaGat® 0.5% administered twice daily for the treatment of acute bacterial conjunctivitis in infants one year of age or older. *Journal Of Ocular Pharmacology And Therapeutics* 2014; 1:3-8
3. Shtul DE. Assessing and maintaining the value of topical prophylaxis. *Topics In Ocular Health* 2011; issue 7, 1-8
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Flogel Ultra
Polyethylene Glycol 400 0.4%, Propylene Glycol 0.3% Smart working Gel

- Forms a protective gel matrix and restores ocular surface\(^1\)
- Greater lubricity compared to other artificial tears\(^2\)
- Extended relief in dry eye symptoms\(^3\)

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