



OPERATIONAL GUIDELINES FOR OPERATION THEATRE COMPLEX





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Ministry of Health & Family Welfare
Government of India



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Preface

Government of India is committed to achieve the highest standards of health and wellbeing for all its citizens. In order to fulfill this vision, under National Health Mission (NHM), several initiatives have been taken like Indian Public Health Standards (IPHS), National Quality Assurance Standards (NQAS), "Kayakalp", along with release of various technical and operational guidelines to ensure quality services.

Among the various specialty services which are designated to be provided under Indian Public Health Standards (IPHS), surgical services are quite critical and vital, as they are the major contributors in reducing out of pocket expenditure. Provision of safe surgical services minimizes the chances of post-operative infections. A well-functioning and equipped Operation Theatre is therefore crucial for safe surgical services.

To ensure quality surgical service standards at hospitals, Ministry of Health and Family Welfare, Government of India, formed an Expert Group to develop Guidelines on Operation Theatre Complex. After several rounds of deliberations, the Guidelines have been developed to give a wider perspective for planning and designing the OTs at secondary care facilities. The Guidelines also provide a comprehensive and holistic overview of OT design which complement the technical protocols. I take this opportunity to convey my thanks to all the experts, NHM Division of the Ministry and NHSRC who have made important contributions in preparation of these guidelines.

This document will guide the States in improving the quality of surgical services at public health facilities. The state and district programme officers will find it useful in planning and operationalizing surgical services in the district.

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FOREWORD

District Hospital (DH) is the backbone for delivering comprehensive secondary care services. Under the National Health Mission there is a special focus on strengthening district hospitals for providing assured quality care which is affordable and accessible to all. Among the various specialty services which are designated to be provided under IPHS, surgical services are amongst the most vital, as they are the major contributors to high out of pocket expenditure

Every district hospital must be sufficiently equipped to provide quality surgeries for General, Ortho, Eye, Obstetrics & Gynecology, ENT etc. Thus, the planning and layout of the OT complex should be such that it facilitates controlling infection, minimizes the risk of infection transmission and gives enabling environment for providing quality surgical services.

The guideline is a ready reckoner and provides a comprehensive and holistic overview of OT design which complements the technical protocols. Every effort has been taken to incorporate the existing best practices, emerging trends, technically correct protocols for infection prevention etc so that the safe surgeries can be conducted.

It is envisaged that the state and district program officers, Hospital planners & Architects, Surgeons anesthetists, nurses and hospital managers at the health facility will find it useful in augmenting and strengthening surgical services in a district hospital.

The effort undertaken by NHSRC team with support from National and State experts and Program divisions of the ministry is deeply appreciated. I believe the state and UTs, Principle Secretary and Mission Directors will find the guideline useful and utilize its provision for ensuring quality surgical services in a district hospital and other secondary health care facilities.

(Vandana Gurnani)

स्वच्छ भारत-स्वस्थ भारत

JS MESSAGE



ABBREVIATIONS

ABCDE	Airway, Breathing, Circulation, Disability, Exposure
AC	Air Conditioner
AED	Automated External Defibrillator
AHU	Air Handling Unit
AMC	Annual Maintenance Contract
BMW	Biomedical Waste
BMWM	Biomedical Waste Management
CCTV	Closed Circuit Television
CMC	Comprehensive Maintenance Contract
CME	Continuing Medical Education
CO₂	Carbon Dioxide
C-Section	Cesarean Section
CSSD	Central Sterile Services Department
CTG	Cardiotocography
DCP/LCDCP	Dynamic Compression Plate/Limited Contact Dynamic Compression Plate
DCS	Dynamic Condylar Screw
DH	District Hospital
DHS	Dynamic Hip Screw
DOP	Dispersed Oil Particulate
ECG	Electrocardiogram
ENT	Ear, Nose, Throat
ETT	Endotracheal Tube
FRU	First Referral Unit
GoI	Government of India
HAI	Hospital Acquired Infections
HDU	High Dependency Unit
HEPA	High Efficiency Particulate Air

HICC	Hospital Infection Control Committee
HR	Human Resource
HVAC	Heat Ventilation and Air Conditioning
ICU	Intensive Care Unit
IOL	Intraocular Lens
IPC	Infection Prevention and Control
IPHS	Indian Public Health Standards
ITE	Information Technology Equipment
IV	Intra-Venous
LAMA	Leave Against Medical Advice
LaQshya	Labour Room Quality Improvement Initiative
LED	Light-Emitting Diode
M&F	Male & Female
MLC	Medico Legal Case
MS	Medical Superintendent
Nd-YAG	Neodymium-Doped Yttrium Aluminium Garnet
NHM	National Health Mission
NHSRC	National Health Systems Resource Center
N₂O	Nitrous Oxide or Dinitrogen Oxide
NQAS	National Quality Assurance Standards
NS/DNS	Nurse Superintendent/Deputy Nurse Superintendent
O₂	Oxygen
OBG	Obstetrics and Gynaecology
OT	Operation Theatre
PAC	Pre Anesthesia-Check-up
PIP	Programme Implementation Plan
PAO	Poly Alpha Olefin
RH	Relative Humidity
SNCU	Sick New-Born Care Unit
SOP	Standard Operating Procedures
SS	Stainless Steel
SSI	Surgical Site Infection
TSSU	Theatre Sterile Supply Unit
UPS	Uninterruptible Power Supply/Source
UTI	Urinary Tract Infection
UV	Ultraviolet
VFD	Variable Frequency Devices
WHO	World Health Organization

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CHAPTER 1

BACKGROUND

*D*istrict Hospital (DH) is the backbone for delivering comprehensive secondary care services. Under the National Health Mission there is a special focus on strengthening district hospitals for providing assured quality care which is affordable and accessible to all. It should be a hub for good quality clinical and curative services and should simultaneously be able to provide and guide preventive and promotive health care to all the beneficiaries.

Every district hospital must be sufficiently equipped to provide quality critical care services to the people. Assured services during emergency and trauma, various types of surgeries like Ortho, Eye, Obstetrics & Gynecology, ENT etc., maternal and child health care including delivery and management of complications through high dependency or intensive care units are some of critical parameters for assessing comprehensiveness of secondary care services.

Among the various specialty services which are designated to be provided under Indian Public Health Standards (IPHS), surgical services are the most vital, as they are the major contributors to high out of pocket expenditure.

The estimated total need of the region for surgical cases per 1,00,000 population per year in South Asia is 4520[1]. In India, for a district with an average population of 20,00,000, this amounts to 248 cases per day (approximately). If we assume 50% load come to public health facilities, this roughly amounts to 124 cases per day. Each of these cases will involve contact by a medical device or surgical instrument with a patient's sterile tissue or mucous membranes. Despite all measures and advancements in technology, in the developing world, the health care associated infection rate is 25% or more. Delivery of surgical services are hampered due to Hospital Acquired Infections. Even if OTs are available, ensuring basic quality in surgical services and adherence to the technical protocols remains one of the major challenges of the healthcare system.

The present OT complexes in many hospitals do not practice adequate zoning, sterilizing/aseptic protocols, unidirectional movement, linkages with CSSD and laundry, and segregated disposal of waste, resulting in compromised infection prevention protocols and practices.



To ensure quality surgical services standards at hospitals, Ministry of Health and Family Welfare, Government of India formed an expert group to develop guidelines on Operation theatre complex. After several rounds of deliberation, the guidelines have been developed to give a wider perspective for planning and designing the OTs at secondary care facilities. The guidelines also provide a comprehensive and holistic overview of OT design which complement the technical protocols.

Although OT complexes are available at both secondary and tertiary care hospitals, the current document details out the requirements for only secondary care facilities. However, the principles, design, infection prevention and control protocols, technical flow of services etc. can also be used as reference for tertiary care facilities. While renovating/modifying existing OTs, these principles may be applied for ensuring optimum service outcomes.



CHAPTER 2

INTRODUCTION

*A*n OT Complex is a significant part of any secondary or tertiary care hospital. An operating theatre, operating room, surgery suite or a surgery center is a room within a hospital where surgical and other operations are carried out in a sterile environment. The establishment and working of OT needs specialized planning and execution and is not to be viewed as the work of civil engineers alone. A “civil-mechanical-electrical-electronic-biomedical” 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.

In an OT complex, three major components are essential i.e. well planned OT infrastructure that facilitates zoning, adequate number of skilled HR and adherence to technical protocols. Thus, the layout of the complex should be such that it facilitates controlling infection, minimizes the risk of infection transmission and gives an enabling environment for providing quality surgical services.

The guideline also covers needs, preferences and safety of the medical/surgical environment for operationalizing an operation theatre.

2.1. SCOPE OF GUIDELINE

IPHS defines number of OTs required for different hierarchy of hospitals with different bed strengths in a district. For instance an OT complex with 200 beds should have four regular and one Emergency OTs with ancillary areas including post anaesthesia recovery, reception, sterile store and staff change facility.

The guideline is a ready reckoner which provides a comprehensive and holistic view in planning and designing of OT complex. Every effort has been taken to incorporate the existing best practices, emerging trends/concepts such as healing architecture focusing on ductless air handling unit with varying air pressure in different zones, work enhancing design, and humanizing environment. Effective utilization of human resource with their capacity building requirements have also been



covered in the chapters. Such OT complex once established will aim to minimize the incidence of infection and to improve the post-surgery outcomes at their health facilities. Enabling adherence to BMW practices by provision of technically correct autoclaving and storing area/linkages with CSSD/Mechanized laundry through dumbwaiters, pass box supported with UV radiation are some of the new trends which are part of this guideline.

End-users of this document will be hospital architect, planner, administrators, health surgeons and medical/nursing officers in charge of the OT. It is expected that this booklet will be a useful guide and quick reference source for planning, designing construction, administration and maintenance of OT complex in new as well as in existing health facilities. This will also help state and district programme officers in planning and improving OT services and reflect its requirement either in state health budget or in NHM PIPs.

2.2. OBJECTIVES OF THE GUIDELINE:

1. To describe the basic principles and functions of an Operation Theatre Complex for conducting safe and quality surgeries.
2. To function as a tool for district and state teams for establishing/renovating infrastructure of OT complex.
3. Defining the SOPs and job responsibilities, training requirements of the HR working in OT.
4. To describe infection prevention and control practices like cleaning protocols, sterilization procedures etc.
5. To recommend list of equipment necessary for operationalization of OT complex in a district hospital.

General Principles

For efficient functioning of an Operation Theatre, following principles should be considered from planning level:

- ✿ Every OT needs to be run with a zero tolerance for non-adherence of technical and infection prevention protocols, so maintaining discipline in OT is of prime importance.
- ✿ Design and layout plan of an OT complex should be such that the complex is divided into four zones i.e. Protective, Clean, Sterile and Disposal zones, based on varying degrees of cleanliness/asepsis, and is maintained by a differential decreasing positive pressure ventilation gradient from the inner zone to the outer zone.
- ✿ Entry of patients and staff should be restricted and only those who are on duty or called for by the OT staff are allowed to enter the complex. Entry and exits should always be through the defined routes only.
- ✿ Any OT staff once entered in the complex should leave it only after off duty except those who are required to accompany the patients for provision of medical care and services. However, any OT staff if re-entering the OT complex will have to follow the protocols of the OT including change of shoes, dress, etc.
- ✿ Every staff in OT has to follow the defined infection prevention protocols since keeping the operating room and its adjoining corridor sterile is one of the most important interventions to prevent infections in OT.



- ✿ Cleaning protocols of various zones is very critical, in which the pathogen count progressively diminishes from the outer to the inner zones (operating area). The protocol of cleaning various zones shall be such that in every changing zones/passage the quality of cleaning of the higher zone shall be applicable
- ✿ Supply and logistics for OT should be replenished only during off hours preferably when surgeries are not in progress. Only such important equipment and logistic should be allowed when OT is functional which are urgently required during surgical procedures and not available in the OT store. In no circumstance, patients/attendants should be asked to bring consumables, drugs etc. for any surgical procedure.
- ✿ Temperature, humidity, number of air exchange per hour, maintaining positive pressure ventilation, dedicated Air Handling Units for each operating room, decontamination and sterilization of equipment and linen, regular and timely disposal of Biomedical waste, adherence to cleaning protocols etc. are the key activities which need to be monitored daily.
- ✿ Before undertaking any surgery, the surgical and anaesthesia trolley should be ready and WHO surgical checklist should be adhered to.
- ✿ Quality assurance for the entire complex must be as per the process defined in GoI guidelines. All SOPs for clinical protocols and pre-post surgical documentation are other important parameters that must be adhered to for ensuring quality.
- ✿ While constructing a new OT, the above parameters and other design consideration given in the guideline needs to be incorporated in the layout plan itself. However, if the OT is already existing, some of its structure/area can be renovated for the flow of services based on the core principles indicated above.

Process and Flow of Services in the OT complex

OT complex is a critical care area, very sensitive and prone to acquire infections which can sometimes prove to be detrimental to patients. So, the design of the OT should be such that entry for either logistic replacement, staff or patient movement is restricted. Therefore, layout plan or design consideration is the first important step for establishing an OT complex.

In this guideline, all the important parameters for establishing and operationalizing OT complex has been given in a way that both technical and non-technical team members of health in the state and district can easily understand.

While explaining it the technical considerations have been prioritized. To begin with zoning, its classification and importance have been explained first followed by other design considerations, cleaning protocols, etc.

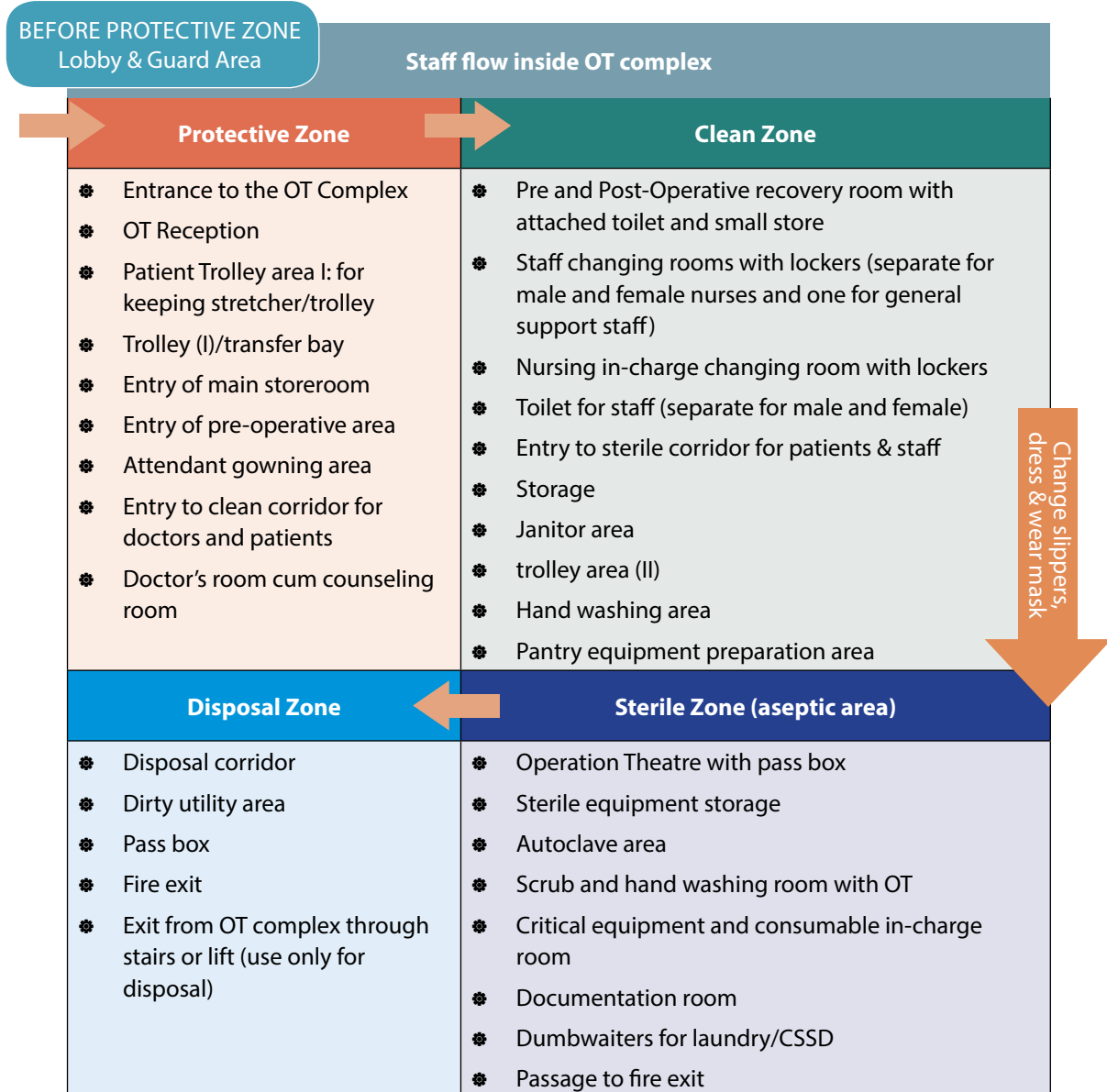
Zoning

It is a process of virtual or artificial division, of a place/area in which certain uses are permitted/prohibited. The concept of having zoning system in OT complex is to achieve a high degree of asepsis, thereby eliminating chances of nosocomial infections in post-surgery cases.

The OT complex is divided into four zones i.e. Protective, Clean, Sterile and Disposal, based on varying degrees of cleanliness/asepsis, and is maintained by a differential decreasing positive pressure ventilation gradient from the inner zone to the outer zone.



Fig:1 Flow of movement inside OT complex



The functionalities of each area are placed below:

Before Protective Zone

Buffer/Lobby: Outermost area of the OT is lobby/buffer area at main entrance where a dedicated space is given to OT guard for restricting access to protective zone round the clock.

OT guard area: This is a designated place for security staff/guards to restrict unnecessary entry into OT complex. Only OT staff and patient is to be allowed inside OT complex. No attendant except those who have been permitted by surgeon for attending pre/post-operative patients should be allowed entry in the OT complex. The duty guard should be oriented for the designated job and preferably shall not be put on rotation duty. They will ensure adherence to pre-requisites for entering into protective area (shoe change/shoe cap, mask, cap and hand hygiene). They will also ensure the first trolley change & will also maintain an entry and exit register for OT complex.



Shoe changing area: A small space for shoe change/shoe cap before entering into the protective zone both for the patients/attendants and staff. Doctors and staff may use shoe caps for coming till cleaning zone. There after they will wear slippers and dresses from OT. Guard will ensure shoe change before entering the complex.

Protective Zone

It is the outermost area within the OT Complex after the buffer/lobby area. Sub areas like OT reception, trolley store area (I), trolley bay, patient transfer area, counselling room, are located in this zone. This zone is maintained at an air- pressure slightly positive to general hospital corridors' air circulation.

Entry to protective zone: Patients, attendants and staff can enter into this zone through main entrance where normal hospital standards of cleanliness apply. However, everyone in this zone will adhere to basic infection prevention protocols like wearing of mask, cap, shoe change/shoe cap and hand hygiene. Receptionist will ensure that all patients' attendants or day care patients change their dress before entering the OT complex.

Patient entry: Trolley/wheelchair coming to OT will not be allowed to go inside the protective zone without a trolley change. The OT nurse from pre/post-operative room will ensure patient gets shifted to another trolley designated for use in the protective zone (**first trolley change**). Patient's case sheet is handed over to the nurse on duty or OT receptionist.

OT reception area: Receptionist will be in-charge of protective zone. Ensuring the shifting of patient from ward trolley to OT trolley at entrance; taking the case-sheet and facilitating shifting to the pre-operative area are certain key functions to be performed in this area. Patient details need to be verified and a computerized record for the same needs to be maintained. They would also function as a communicator between the patient's attendant and OT in-charge and will keep informing the progress/status of the patient to the attendants.

- OT reception will also provide gowns to the patient's attendants and ensure that whom so ever is going to pre-operative area should wear the gowns, cap and mask, since pre-operative preparation room is part of clean zone.
- The list of such patients who have been admitted for day care surgeries also to be maintained.
- OT administration will put in place a comprehensive system of communication such as Telephones, intercom and code warning signals. Every OT reception will have such system along with two way communication from patient's waiting area.

Trolley area I: Two time trolley change is recommended while moving patients from ward to Operation Table. First change will take place at entrance to protective zone where patient will be shifted to pre-operative area's trolley (trolley kept in trolley area I). After each use the trolleys need to be brought back into respective trolley areas after cleaning as per cleaning protocols.

Patient attendants changing room: This area will be used for patients' attendants and relatives who have been permitted to access the Pre and Post-operative area. This will be located close to the reception area. Provision for shoe cover/sandal change may be ensured. This room can also be utilized as changing room for Day Care Patients.

Movement from Protective to Clean Zone: When OT is ready for surgery then patient is to be shifted from pre-op area to OT i.e. from clean to sterile zone. Shifting of patient shall involve **Second trolley change** from trolley (II) area of clean zone.



- There is a trolley II area in clean zone for keeping a separate second OT trolley which is allowed inside the sterile zone or inside OT. (Trolley should have stand for IV fluid)
- After each use the trolleys need to be brought back to respective trolley bay after cleaning as per protocols.
- Entry for Staff and patient must be separate for moving from protective to clean & then to sterile zone.

When hospital staff (Doctor, Nurse, ward boy) move to the clean zone either directly from main entrance or from protective zone they first remove their foot-wear (or at-least wear shoe cover) and go bare foot till he/she enter their respective changing rooms in clean zone. In the respective changing room staff should wear OT slippers (**first slipper change**), change clothes and wear OT dress, mask and cap.

Note: Slippers kept in this zone should be of different design from that kept for entry to OT to prevent interchange.

Clean Zone

The clean zone isolates the sterile zone from protective zone and allows staff to move into sterile zone post change of attire. It includes Doctor's changing room, Nurse's (OT In-charge) changing Room, Staff Nurse changing room (separate for male and female), Pantry, staff toilets (M & F), Pre-post-operative recovery room, store room, trolley II area, Janitor room and passage to sterile zone with hand wash and slipper change facility. Staff can use pantry and washroom facilities available in this zone. The clean zone is maintained at positive pressure slightly at a level higher than the protective zone.

Pre and Post OT recovery room: For a 200 bedded DH, an eight bedded room (4 beds for pre-operative patients and 4 beds for post-recovery patients) is required. The Pre and Post-operative area must be separated by a curtain. The beds in this room should preferably be trolley beds and all trolley beds should have a designated area with wall mounted monitors and provision of electrical points in sufficient number. Each bed should have oxygen, suction and air outlets connected with manifold facility. Facility for round the clock monitoring vitals of the patients should be available here. Room should have attached toilets. Storing facility for medicines, consumable and linens should not be for more than 7 days. The room will have dedicated nursing station for constant monitoring and ensuring medications as per doctor's direction. At least 2 nurses will be required here to effectively monitor the pre and post-operative patients.

Store room: This is the main storage area for whole OT complex. This will act as a transit area from hospital's general store, CSSD and mechanized laundry. Staff and supplies coming from outside the OT complex will enter adhering to universal precautions and will not be allowed to go beyond the store room. A prior intimation is mandatory so that OT in-charge nurse can receive the sterilized and autoclaved equipment and linens whereas the storekeeper/OT technician will receive other inventories. The supply in the store shall be restricted to 7 days and weekly replenishment should be done for general supplies and daily for sterilized equipment and linens.

- Ideally the sterilized equipment should be brought to the OT through covered trolley or through dumbwaiters.
- Cleaning protocols of this store will be as per the clean zone (norms in annexure).



Trolley II area: This is the space marked for keeping second trolley for movement from pre-operative area to OT. After each use the trolleys need to be brought back in respective trolley areas after cleaning by damp mop with disinfectant/chemical/soap water (details are in annexure).

Pantry inside Clean zone: This is the area where packed food items and electric kettle etc. can be kept for light snacks and tea for the staff.

Movement from Clean Zone to sterile zone:

Supporting staff spend their time in clean zone for pre-operative preparations for planned surgeries. Doctors spend their time in clean zone till OT and patients get ready for the surgery/procedure.

Whenever doctors and nurses enter sterile zone from clean zone they first wear masks properly and wash their hands (follow 6 steps of hand washing). After entering to the sterile zone staff do not touch anything with washed hands and directly move towards the scrub area in sterile zone.

Sterile Zone

The inner most area in the complex where conditions are as sterile as possible. **All staff who might handle instruments for surgery, in this zone must scrub and wear gowns.** The sterile zone includes the operating room, scrub room, entry of theatre supply room for sterilized instruments, auto-clave room, sterilized equipment store room, equipment preparation room and documentation/record room. This zone is maintained at high air pressure just below what is at the operation theatre room so as to exclude entry of air from the other zones. This is also a “zero tolerance” zone for any violation of technical protocols and processes. The Nurse in-charge or OT in-charge has the responsibility to ensure this. The sterile zone is connected to dirty corridor or disposal area through an inter-lock hatch system at the fire exit.

Movement from sterile Zone to OT: Surgeon and assisting Nurses will enter sterile zone from a clean passage after washing hands and change to their respective OT slippers (**second slipper change**), move into the scrub area and wear respective sterile gown, cap and do surgical scrub for hands then wear surgical sterile gloves and enter into the OT. Now doctors and nurses are ready to touch the patient inside the OT for the procedure.

1. **Operation Theatre:** There are 4 Operation theatres present in the layout (annexure-1). These rooms are maintained at highest air pressure as to exclude entry of air from the sterile corridor. Each OT has pass boxes which will open into the disposal corridor.
2. **Pass Box:** Static pass box has been given in each OT for temporary storage of BMW, used equipment and used linens in respective zipper bags and taken out from its opening to the disposal corridor*. Fire safety needs to be ensured by allowing opening from both the ends in case of fire/smoke. *Position of Pass Box should be at a height of about 2.5 to 4 feet from the floor. In case UV radiation is used in the pass box appropriate steps may be taken to prevent damage to eyes of staff working in OT.*
3. **Dumbwaiter:** A dumbwaiter is a small freight elevator or lift intended to carry objects rather than people. One dumbwaiter is recommended in sterile corridor for carrying sterile articles

*The pass box has two openings, one on the OT side and other on the disposal corridor side. The valve system prevents simultaneous opening of the doors thereby preventing air from disposal corridor to come in contact with the air in OT.



from CSSD and mechanized laundry to OT complex. This works best when OT on another floor is directly connected to CSSD/mechanized laundry.

4. **Scrub area:** Situated in the sterile corridor. One Scrub area is common for 2 Operating rooms within the sterile area with Elbow operated or infrared sensor operated taps. It is essential to have non slippery flooring in this area. Scrub washbasin should have adequate depth and width allowing free hand and elbow movement at the same time preventing it coming in to contact while scrubbing. Design should also prevent/minimize water spilling outside scrub basin. Elbow taps have to be placed 10 cm above the wash basins.
5. **Theatre Sterile Supply Unit (TSSU):** In addition to the central supply of sterile instruments and linen, provision for TSSU is given taking into consideration the requirement for sterilizing certain category of equipment where there is a low turn-around time than usual is expected. The various subareas are explained below:
 - a. **Equipment preparation/decontamination area:** In this area, used equipment which are not planned/recommended to be sent to CSSD will be decontaminated and prepared for autoclave/sterilization.
 - b. **Auto-clave room:** All the decontaminated equipment will be autoclaved here as per the standard norms defined for type of the autoclave equipment used. In the Autoclaved area there should be provision for chemical sterilization/Plasma sterilization for equipment's like Laparoscope and various tubings etc.
 - c. **Sterilized equipment storage room:** Where sterile equipment and linen is stored before sending it on a surgical trolley into the Operating room.
6. **Critical equipment and consumable in-charge room:** This room is for stand-by equipment which will be required for OT during surgery. The cleaning protocols of this area should be same as that of sterile zone. It will also be used by the OT technician/bio-medical engineer for repairing/testing the OT equipment. It will remain open (without door) and should have provision for multiple electrical points for need based repairing/testing of equipment.
7. **Report writing/documentation room:** This area is placed in sterile zone where doctors and nurses will document/report the procedures for records. No paper should be allowed inside the Operation Theatre except monitoring chart. Progressively, OT records should be captured through digital or e-health records instead of paper based records. Electronic records will also help in analysing various protocols and outcomes on functionality outcome.

Movement of used equipment and linen from OT to CSSD/TSSU: Keep the used equipment in tray, cover it with lid after use, wrap it with cloth in which the set was brought and then double pack in a clean cloth before taking it to CSSD.

After each surgery all the soiled clothes/linen and any anatomical waste would be packed into bag which should be sealed either with zipper or any other means and send to the disposal zone via pass box.

Disposal Zone

It has an air pressure less than the sterile zone, includes dirty corridor and utility room where used instruments, suction bottles, waste material, used/contaminated equipment and soiled linen are temporarily stored before being collected for disposal or for cleaning and sterilization. It will have an exit which could also be used as fire exit in the time of need.



Functionalities of subareas in Disposal zone

1. **Dirty Utility Room:** BMW, used equipment and linens which are used during surgery and packed in the designated bags/buckets are kept in dirty utility room until they are sent to mechanized laundry and CSSD. BMW will be disposed as per BMW guidelines and rules.
2. **Disposal Corridor:** This corridor will run behind the OT rooms and will have common entry and exit gate near to dirty utility area. All the pass boxes (Hatch box) attached with all 4 OTs will open in this corridor. Ward boy/disposable collector can directly come into this corridor from the exit near to dirty utility area and collect the used/contaminated equipment, linens and (anatomical waste) disposal from here and take it to the CSSD/Laundry and dispose the waste as per the latest rules. There should be no mixing/movement of staff from this zone to rest of the areas of OT and vice-versa.



CHAPTER 3

INFRASTRUCTURE

The following sections contain information regarding location and design considerations that may be kept in mind while planning for an operation theatre complex:

Location

The location of OT should be in a quiet environment and in the innermost zone, away from patient/attendant's access area. It should be free from noise, contamination, possible cross-infection and any other disturbances. The design should allow enough natural light. It should also be ensured that the OT complex is not located adjacent to sewerage, garbage dump, urinal, toilets, boundary wall of other buildings. Norms for set-back area, fire hazard prevention and other disaster management guidelines should be adhered to. It should be well connected to the CSSD, Mechanized Laundry, Labor room, Emergency, Blood bank/storage, HDU/ICU and surgical wards etc.

In multi-story buildings, OT complex should not be located on top floor, and should have access through dedicated lift. Toilets and washrooms should not be directly above the OT to avoid seepage.

Planning the Layout

One of the most important considerations while preparing the layout design is to indicate a flow which in synchronization with the master plan of the hospital and enforces adherence to defined protocols in various zones. It is suggested while going through the guidelines, the layout annexed may be referred to for better understanding and planning.

Areas indicated in the layout are for a 4-theatre, OT complex and include all critical components. The number of OTs will be as per IPHS. However, most of the existing district hospitals may not have enough areas/space as indicated in the layout plan. In such scenarios, care must be taken to ensure



that the flow of services remain the same and core areas like operating rooms, sterile and clean areas are adequately spaced.

Other important Considerations:

The innermost area of an OT complex is where Operation Theatre rooms would be located. Given below are the norms for engineering design for constructing the OT room. It is important to consider these norms in order to ensure maintenance of sterile environment and minimize hospital acquired infections by regulating air pressure, humidity and temperature.

- a. **Size of rooms:** The number & size can be as per the requirement, but recommended size is 6.5 m x 6.5m x 3.5 m. Glass windows can be planned on one side only, however, such windows should be kept closed.
- b. **Operation table:** Only one operation table per OT is recommended. The operation table should be placed away from the entrance.
- c. **Doors:** Main door to the OT complex has to be of adequate width (1.2 to 1.5 m). Sliding doors are preferred as no air currents are generated. All fittings in OT should be flush type and made of steel. Hermetic sealing of the doors is recommended. Since people are the main source of airborne contamination, the number of persons in the OT should be kept to a minimum. Opening and closing of doors should be minimized as this interferes with the direction of airflow.
- d. **Ceiling:** should be made of cleanable, non-particulate shedding material. Lighting in the ceiling should be flush mounted and serviceable. **False ceiling not recommended**, if existing it should be hermetically sealed
- e. **Floor:** The surfaces of floors and walls of the OT should be as hard, non-porous and smooth as possible. Ceramic tiles are not ideal because the grouting between the tiles can harbour microorganisms. There should be no cracks and crevices since they can harbour microorganisms and cannot be cleaned properly.
- f. **Walls:** The wall should not have any crevices or joints. Tiles are not recommended due to the same reason. Walls should be impervious to moisture and be washable. Laminated polyester or smooth paint provides seamless wall; tiles can break, and epoxy paint can chip out. The joint between the walls and floor (Collusion corners) should be curved and to be covered with steel or aluminum plates for easy cleaning. Colour of paint should allow reflection of light yet soothing to eyes. Light colour (cream/off-white or green) washable paint will be ideal. A semi-matt wall surface reflects less light than a highly gloss finish and is less tiring to the eyes of OT team.
 - i. **Paint-** antimicrobial, anti-fungal and anti-dust
 - ii. **X-Ray illuminators:** There should be X-ray film illuminators preferably recessed into the wall.
- g. **Heat Ventilation and Air conditioning (HVAC):** HVAC system is recommended in OT due to the following reasons;
 - a. To reduce the bacterial load generated during the operating procedures in the theatre by appropriate air volume changes.
 - b. To prevent cross contamination from adjacent rooms.
 - c. To create air flow pattern that carries contaminated air away from the operating table.
 - d. To provide a comfortable environment for the operating team and patients with controlled temperature, humidity and ventilation



Heat

- ✿ Temperature between 21 C +/- 3 C. Temperature should not be adjusted for the comfort of OT personnel but for the requirement of patient, especially in pediatric, geriatric, burns, neonatal cases etc.
- ✿ Ideal RH is considered to be 55%.

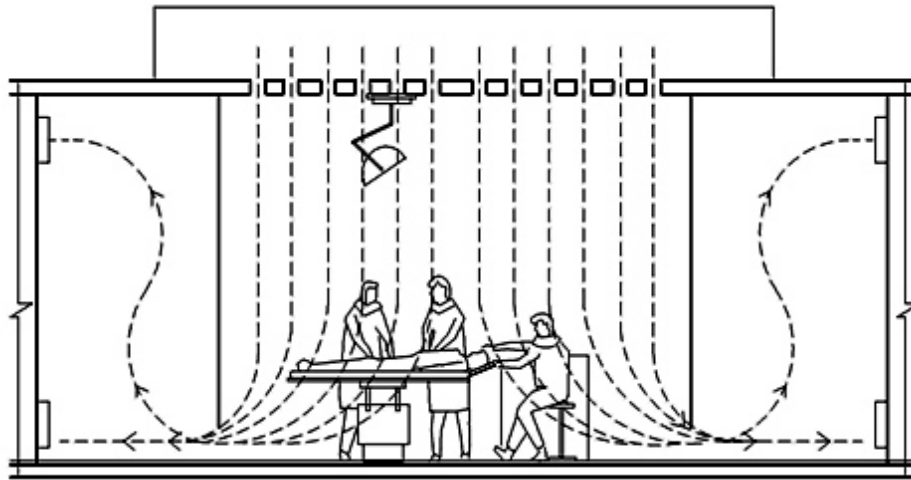
Ventilation & Air Conditioning:

Should be on the principle that the direction of air flow is from the operation theatre towards the main entrance. There should be no interchange of air between OTs. Efficient ventilation will control temperature and humidity in OT, reduce the contamination by micro-organisms and anaesthetic agents.

- ✿ Air changes are largely for the control of airborne organisms by dilution. Non re-circulating air systems heat/cool the air as desired and convey it into the operating room with ideally 20 air exchange and out of these, four should be fresh air exchanges per hour. The circulating system takes some or all of the air, adjusts the temperature and circulates it back to the room.
- ✿ Up to 80% re-circulation of air is sufficient to prevent buildup of anaesthetic and other gases like Desflurane, isoflurane and sevoflurane combined with nitrous oxide.
- ✿ Window & split A/c should not be used in any type of OT because they are pure re-circulating units with 2 to 5 air changes per hour and have convenient pockets for microbial growth which cannot be ward off.
- ✿ Every OT table should be supported with Ultraclean laminar air flow. The filtered air delivery must be 90% efficient in removing particles more than 0.5m.
- ✿ Air velocity: the vertical down flow of air coming out of the diffusion should be able to carry bacteria carrying particle load away from OT table. The airflow needs to be unidirectional and downwards on the OT table. The air face velocity of 25-35 FPM (feet per minute) is recommended.
- ✿ Air suction inside the OT should be 12 inch above the floor and through at least four suction vents in each OT.
- ✿ **Air curtains:** air curtains or air showers should be there at all entry points which are present between the zones.
- ✿ There should be provision of displaying all the critical parameters inside the OT through a composite monitoring tool (electronic device) for checking the critical markers i.e. **Air pressure** (barometer), **HEPA working status**, **Air cycle per hour**, **Temperature** (thermometer) **and Humidity**. Device should be placed on the door of OT or outside the Operation theatre room. It should produce loud alert sounds whenever OT requirements are not fulfilled.
- ✿ **Positive Pressure:** There is a requirement to maintain positive pressure differential between OT and adjoining areas **to prevent outside air entry into OT**. Positive pressure will be maintained in OT at all times (operational & non-operational hours). The minimum positive pressure recommended is 2.5 Pascal (0.01 inches of water).
- ✿ There should be separate AHU for each OT. There should be a separate unit for the sterilized area and one each for clean and protective area.



Fig: 2 Ideal air flow movement inside Operation theatre



Air Handling Unit

Airborne bacteria originate primarily from the skin of persons in the operation theatre (OT). The bacteria carried on the skin reaches the air through skin scales, which are constantly being shed by the persons in the room. After remaining suspended in the air, the skin scales carrying the bacteria settle on various surfaces, equipment and on the floor of the OT. Appropriately circulated clean filtered air removes such airborne organisms.

Air should be circulated by positive pressure through high efficiency particulate air (HEPA) filters. These are special filters, which can remove particles greater than 0.3 micron at an efficacy level of 99.7%. Bacteria of size 0.5–1 micron get removed by use of such HEPA filters.

HEPA filters should be monitored for efficiency on a regular basis and changed when required.

The ventilation rate is expressed as the number of air changes per hour. For an OT, the recommended ventilation rate is 20 air changes per hour.

To prevent contamination of the clean zones, an appropriate pressure gradient is to be maintained between zones.

Highest positive pressure is maintained in the ultra-clean areas. The higher pressure allows air to flow to less clean areas around the doors and openings and prevents the entry of air from the less clean area.

Within the rooms air inlets should be at high level and outlets at low level so that the clean air moves downwards through the room and towards the contaminated floor where it is exhausted through the outlet.

Ducts in AHU are very common sites for microbes to grow and then they become the cause of post-operative infection. Cleaning of these ducts are quite a difficult job. Different models of AHU with duct and without ducts are available in the market. If possible and available ductless AHU is preferred in the operation room.

Maintenance: Even during the non-functional hours, AHU blower should be operational round the clock (may be without temperature control). Variable frequency devices (VFD) may be used to conserve energy. Air changes can be reduced to 25% during non-operating hours through VFD, provided positive pressure relationship is not disturbed during such period.



Regular maintenance of AHUs should include validation of following points:

- ✿ Temperature and Humidity check
- ✿ Air particulate count
- ✿ Air Change Rate
- ✿ Air velocity at outlet of terminal filtration unit/filters
- ✿ Pressure Differential levels of the OT with respect to ambient/adjoining areas
- ✿ Validation of HEPA Filters by appropriate tests like **DOP** (Dispersed Oil Particulate)/**POA** (Poly Alpha Olefin) etc.; repeat after **6 month** in case HEPA found healthy.

Medical gas facility

Every OT should have oxygen, nitrous oxide, four bar pressure medical compressed air, medical vacuum, scavenging terminal outlets and at least four electric sockets. Pipeline supply system should be able to cut off from mainline if the problem occurs anywhere along the delivery hosing/tubing. Ensure supply of Gas & suction (control, supply & emergency stock) for all OTs & post OT recovery areas where patients are retained. Oxygen, gas and suction pipe to be connected with central facility and standby local facility should also be available.

The gas pipeline should be connected to a definite area “manifold room” to be designated in the vicinity of District Hospital as per gas cylinder rule 1981, Medical gas pipeline system and Indian explosive act 1884. Manifold room should be in a cool, clean room that is constructed of fire resistant materials. It should be located in separate area on the ground floor away from main building. It should not be situated in basement area. Conductive flooring must be present but is not required if non-inflammable gases are stored. Adequate ventilation to allow leaking gases to escape, safety labels and separate places for empty and full cylinders to be allocated.

Maintenance of Operation Theatres

Electrical Power Supply:

Power system design is of major importance in the construction of any facility that will house sensitive electronic/information technology equipment (ITE). As far as possible, all the major equipment and its electrical load should be considered while planning the electrical load for each of the OTs and other supportive areas of OT complex.

Following criteria are ideal with respect to electricity in OT complex:

- ✿ Electrical load calculation should be based on equipment likely to be used. This should be supplemented with appropriate current carrying capacity cords.
- ✿ Use of circuit breakers/interrupters is desirable if there is an overload or ground fault.
- ✿ Power line should be of 220 Volts
- ✿ Suspended ceiling outlets should have locking plugs to avoid accidental disconnection.
- ✿ Insulation around ceiling electrical power sources should withstand frequent bending and flexing. They should not develop cracks and should not damage wires. Wires inside rigid or retractable ceiling service column can help to some extent
- ✿ Multiple outlets should be available.



- ✿ Emergency power: OT electrical networks need to be connected to the emergency generators with automatic two-way changeover facility.
- ✿ It should be ensured that the earthing of all the equipment including operating table, cautery is working/functional.

Clean electric power supply:

Distribution of electric load along with load balancing to various equipment and installations in a facility is very important since overloading at any point can result in mis-happening like electric fire hazard or damage the equipment. Similarly, fluctuation in voltage also adversely effects the equipment and hence automatic voltage regulators which regulate fluctuating input power voltage and maintain constant output voltage should be provided. So, putting electrical installation is a specialized job and must be given due importance to ensure proper care with reduced risks to the patient.

Adequate no. of electric points of 5 Amp and 15 Amp, on the various walls (at < 1.5 m height from the floor) needs to be ensured for easy connection. Use of explosion proof plugs, plug connector and socket is essential to ensure safety against explosion. Earthing of the electric point should be checked daily.

New electrical appliances should have a minimum 3-star rating from Bureau of Energy Efficiency or equivalent recognized regulatory authority to minimize the energy input.

Monitoring: Constant digital display for neutral and earthing should be there. (The voltage between neutral and earthing should not be more than 5 volt otherwise it can harm the semiconductor devices. Hence digital display should be installed to monitor the voltage between neutral and earthing).

General lighting: Natural daylight is preferred where ever possible, high level windows which give a visual appreciation of the 'outside world' can be considered in the OT. Colour corrected fluorescent lamps (recessed or surface ceiling mounted) to produce even illumination of at-least 500 Lux at working height, with minimal glare are preferred.

- ✿ About 2000 Lux light is needed to correctly assess the patients color.
- ✿ **Operating area:** Overhead light should be shadow-less and give 25000-125000 Lux of light (50000 to 100000 Lux at the center and at-least 15000 Lux at the periphery).
- ✿ About 10-12 inch of focus of light gives adequate illumination both at depth as well as surface of body.
- ✿ Lights should be freely movable both in horizontal and vertical ranges. Pendant systems are preferred.
- ✿ Halogen lights produce less heat and hence preferred (non-heat generating lights should be used, non-dust settling lights)
- ✿ An auxiliary light for a second surgical site is often beneficial
- ✿ Inverter of adequate capacity to be installed after considering OT light, anaesthesia machine, monitors, cautery etc. until the backup generator takes over
- ✿ Clock: It is essential for orientation to time and timing certain procedures e.g. tying tourniquet in arterial surgery. This should also be recessed and wired electrically.



Fire exit/entry:

Provision for emergency exit is to be provided on either end of the sterile corridor. It should be ensured that the emergency exit is not blocked by keeping operation theatre machines or trolleys. One should be able to open all the doors quickly in an emergency situation. The fire extinguishers have to be placed as per the fire safety norms. Before operationalization of the OT complex, DH should take license from the fire safety department and install all instruments as per the fire safety rules. They should be tested periodically along with fire drills for the staff.

- ✿ **Lift :** Dedicated lift at the exit point of disposal zone which will be exclusively utilized for carrying used equipment, linens and BMWs to the respective areas i.e. Mechanized laundry/ CSSD/BMW storage area.

Plumbing and water supply:

- ✿ Provision for adequate & continuous soft water supply: Besides normal supply of water, a separate reserve emergency overhead tank of soft water should be provided for operation theatre. These tanks need to be cleaned and tested every three months.
- ✿ Proper drainage system as per BMW rules.
- ✿ Water supply points should be available in the following subareas:
 - a. Trolley area I
 - b. Scrub areas & wash basins
 - c. Pantry
 - d. Autoclave rooms
 - e. Dirty Utility
 - f. All toilets



CHAPTER 4

HUMAN RESOURCE & TRAINING

OT requires dedicated and experienced staff for all shifts. The requirement of staff has been calculated based on number of functional OT shifts. So, deployment of HR should be based on same. However, all HR indicated below are part of District Hospital and no standalone appointment specific to OT is to be made. Hiring of any additional HR beyond IPHS should have justification based on performance and caseload.

Doctors:

Specialists posted in the District Hospital are responsible for providing the services as per service basket mentioned in IPHS. The work of specialists is to be organized in such a way that demands of specialist OPD and the required OT functions are met.

Nurses:

Two nurses will be needed to cover every OT shift. OTs that will be functional round the clock on a 24/7 basis (e.g. Emergency OT and OBG OT) will need six nurses to provide 24-hour cover. On the other hand, other OTs that may run for one shift only (e.g. Eye OT, Ortho OT and General OT) will need two nurses to cover each of these shifts. There should also be a nurse in-charge of the OT complex and two nurses for the common pre-op and post-op areas. For different levels of district hospitals, different number of nurses will be required, as mentioned in the table below.

Associate Health Professional:

One OT technician and a TSSU assistant will be required for every shift in all OT complexes. They are responsible for ensuring functionality of all equipment used in OT and TSSU respectively. For different levels of district hospitals, number of associate health professionals required will be as per the table given below.

Support Staff:

Housekeeping services are essential in providing a safe, clean, aesthetic and hygienic environment for not only the patients, but also for the health care providers. Number of staff required in protective, clean, sterile and dirty zones, for both cleaning and housekeeping services is given in the table below.

Security Guards:

- Entrance to the OT complex should be only one. In case, there are any other entrances, that needs to be closed. However, separate entry/exit for dirty zone is recommended. So, in every OT complex, at least two guards will be required, one at main entry of the complex and other on the rear side at entry/exit of dirty utility. This will help complete restriction of any unwanted persons in the OT complex.
- Security guards should be made available round the clock for restricted access to areas ensuring safety of staff, property and essential commodities.
- All security guards positioned at the fire exit doors should be trained in fire safety.

S. No.	Designation	50 bedded	100 bedded	200 bedded	300 bedded	400 bedded	500 bedded	SDH-100 bedded
	Number of OT	2	3	4	5	5	5	3
	Nurses	11	13	22	24	24	24	13
1.	O.T. technician	4	5	8	9	9	9	5
2.	TSSU Assistant	3	3	3	4	4	4	3
	Cleaning staff							
	OT – protective + clean – 1 Dirty – 1 Sterile – 1 + 1 for each increase in OT	7	7	8	9	9	9	6
	Housekeeping							
	OT – protective + clean – 1 Sterile – 1 + 1 for each increase in OT	4	4	6	6	8	8	4
	Security Guards	3	3	3	6	6	6	3

Training: The staff posted in the OT complex is either clinical or non-clinical. All the clinical staff are normally trained for clinical work during their pre-service teaching and training and hence may only need CME. however, all the staff will need trainings and orientation on infection prevention and biomedical waste management, sterilization, autoclaving, team building, leadership, behavioral management, work place management, equipment maintenance etc. This needs to be reflected in



the PIP. Maintenance & running an OT complex is a specialized and skillful job. The staff working in the OT is exposed to long stressful environment for saving lives. So, it is of utmost importance that staff working in OT is trained & motivated for leading healthy behavior and able to reduce their mental stress. They also need to be trained & oriented for various technical processes, which are essential to practice high quality services in OT. A few short duration trainings have been advised below, which the staff can further extend and add.

Name of Training and duration	Component of training	Target Participants	Trainers	Quality check of training
Organizational behavior and management of OT Duration: 3 hours	Teamwork, stress management, room wise protocol	All staff working in OT complex	NHSRC, Medical colleges, Paramedical institutes and Supporting institutes	Pre and Post test
How to maintain sterilization of OT - monitoring & quality check Duration: 3 hours	Hand hygiene, AHU maintenance, cleaning protocol, BMW practices, microbiological sampling, knowledge about cleaning and maintenance of HEPA filters and HVAC	OT in-charge, nurses, OT assistant, guard and cleaning staff	NHSRC, Medical colleges, Paramedical institutes and Supporting institutes	Pre and Post test
Equipment maintenance & Record keeping Duration: 3 hours	Indenting, AMC, CMC and cleaning, handing and taking over of critical equipment, record maintenance and reporting	Senior anesthetist, OT technician and OT in-charge and OT nurses	NHSRC, Medical colleges, Paramedical institutes and Supporting institutes	Pre and Post test
Other Areas Duration: 1 day	Surgical safety measures,, schedules for the OT, maintaining records & report (including MLC) and crisis management (fire safety & disaster management)	Doctors and staff nurses	NHSRC, Medical Colleges, Paramedical institutes and Supporting institutes	Pre and Post test



CHAPTER 5

QUALITY POLICY

To support the clinical care and wellness of patient by providing safe, hygienic and safe environment to reduce the risk of post-operative infection.

Statutory requirements

The design and planning of an OT complex will need compliance with mandatory regulations Municipal Corporation, Pollution Control Board, Fire Safety Department, Water supply and Drainage department etc.

OPERATIONAL MANAGEMENT OF OPERATION THEATRE COMPLEX

Policies and Procedures:

OT Administration:

- Management of OT is team-work. Clinicians, Nurses and Allied Health Professionals all work together for a long duration in a closed & stressful environment.
- A high level of motivation is needed for maintaining high output, high degree of asepsis and quality assurance. Normally a senior Anesthetist is designated as Officer In-Charge of OT for day to day administration, coordination and regular maintenance of OT.
- For day to day running of OT, the OT in-charge will be responsible, however, the overall functioning and maintaining its operational status will be the responsibility of Medical Superintendent and their team i.e. hospital manager, matrons etc.
- There should be a laid down Standard Operating Procedure (SOP) on functioning of OT, roles and responsibilities of staff members, infection control measures, cleaning and sterilization of OT.



OT Scheduling:

- ✿ It is a very important aspect of OT management. Daily sequence of operations in consultation with surgeons & accordingly scheduling various OTs in the complex is the responsibility of OT in-charge.
- ✿ There is a need for planning of OT schedules, timely preparation of operation list to avoid delay in starting operations, its completion, post-operative care and shifting to ward. Punctuality needs to be adhered to for ensuring it.

Operation List:

- ✿ List should be made well in advance and circulated to all concerned, one day prior and before lunch time. Copies of OT list should be sent to all the concerned persons. There should not be any cancellation of operations due to any management problems.
- ✿ Cancellation should be a rare event. Cancelled list of operations should be reviewed periodically to check for any unnecessary cancellations.

Infection Control Measures in OT

- ✿ A detailed cleaning protocol which includes frequency, cleaning agent and processes for various zones of the OT complex is placed at Annexure 7.
- ✿ Detailed process for sampling and Fumigation is also placed at Annexure 3.

Quality Indicators

- ✿ Practice of WHO safe surgery checklist in the OT
- ✿ Report on any Anaesthesia/surgery complications
- ✿ Number of adverse events per thousand surgeries
- ✿ Surgical site infection Rate (as a % of major surgeries)
- ✿ Incidence of re-exploration surgeries
- ✿ Percentage (%) of culture test reported positive (air sampling, settle plate1)
- ✿ Number of autoclave cycles failed in Bowie dick test out of total autoclave cycle
- ✿ CSSD/TSSU productivity index
- ✿ Downtime of critical equipment used in OT should be a maximum of 5%. There should always be backup available to ensure 100% functionality of OT. Every OT should measure downtime for Anaesthesia equipment, Defibrillator, Autoclave, functionality of pendants, C-arm, cryosurgery units and slit lamp. (Any other critical equipment can be added)
- ✿ Apart from above mentioned critical equipment, downtime of remaining critical equipment should not be more than 5% in a year or should not be more than 1.5 days in 1 continuous stretch

Performance indicators of OT

- ✿ C-section Rate
- ✿ Proportion of C-section done at night
- ✿ Number of major surgeries done per month



- Number of major surgeries per surgeon
- Operation cancellation rates

Records and Registers

Every OT needs to be managed systematically and professionally for which maintaining proper records is one of the vital activities. This helps in analyzing and reviewing the performance, cleanliness, adherence to clinical and technical protocols, functionality of equipment, availability of equipment/drugs etc. and also help in finding the gaps for corrective actions.

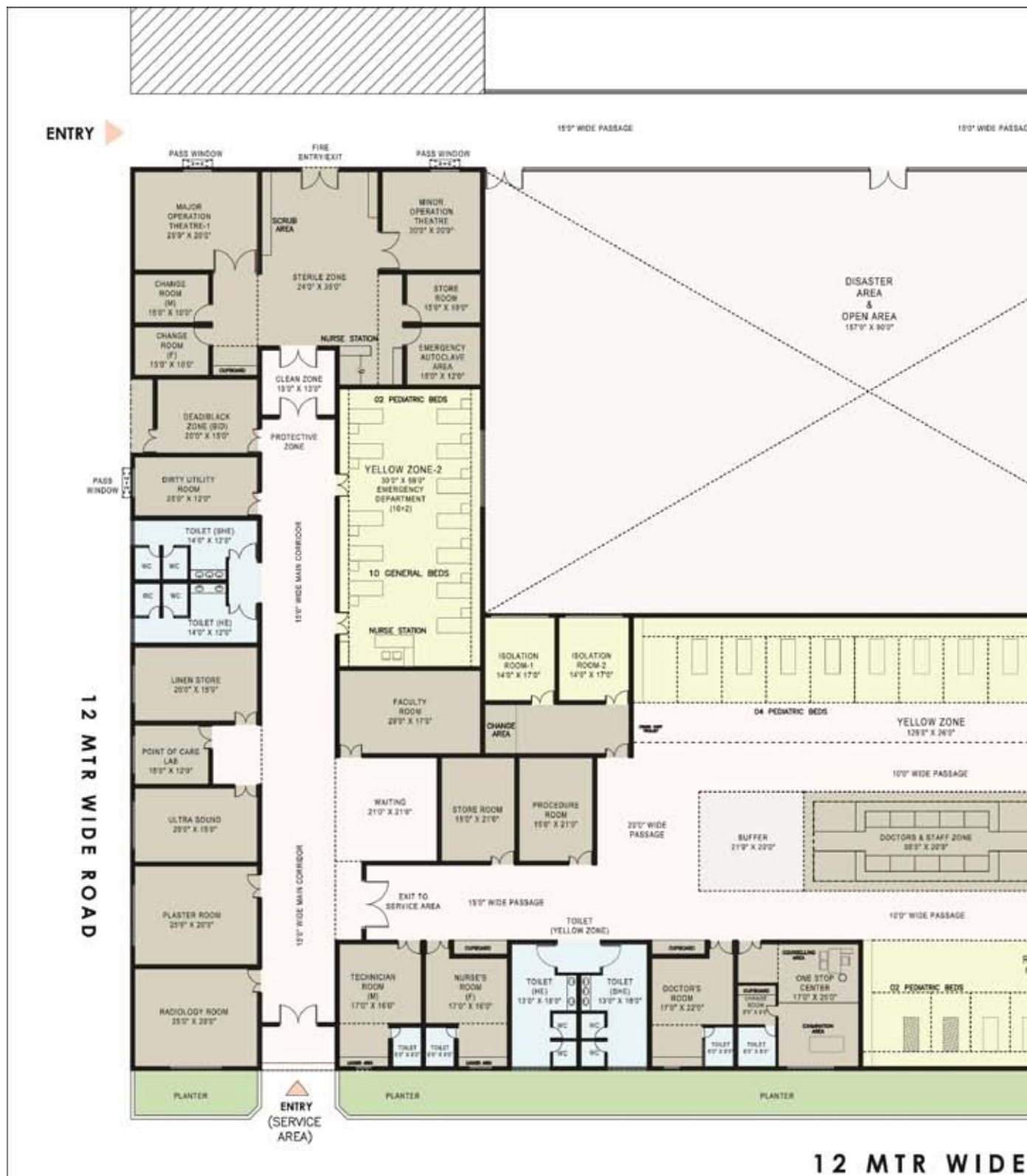
Every OT must maintain the critical records and registers as indicated in Annexure-5.

Monitoring and supervision

- Various functions and infrastructure suggested in the guideline needs to be sustained for ensuring quality in service delivery, This can only be ensured through regular rounds of monitoring and surveillance.
- Daily round of OT complex needs to be taken by Matron, Hospital manager, OT in-charges (doctors and nurses) for ensuring adherence to various protocols.
- Civil and electrical engineers should also monitor the OT every three months for ensuring adherence to infrastructural norms.
- Staff taking rounds need to change the dress before entering the OT.
- The exclusive responsibility of ensuring this lies with OT in-charge.
- Checklists for LaQshya and NQAS can be utilized for supervision and certification of OTs.

A photograph of an operating room, heavily filtered with an orange-red color. The room features a large surgical table in the center, two large overhead surgical lights, and various medical equipment and monitors in the background.

ANNEXURES



EMERGENCY AREA LAYOUT PLAN
PROPOSED COVERED AREA - 47100 SQFT





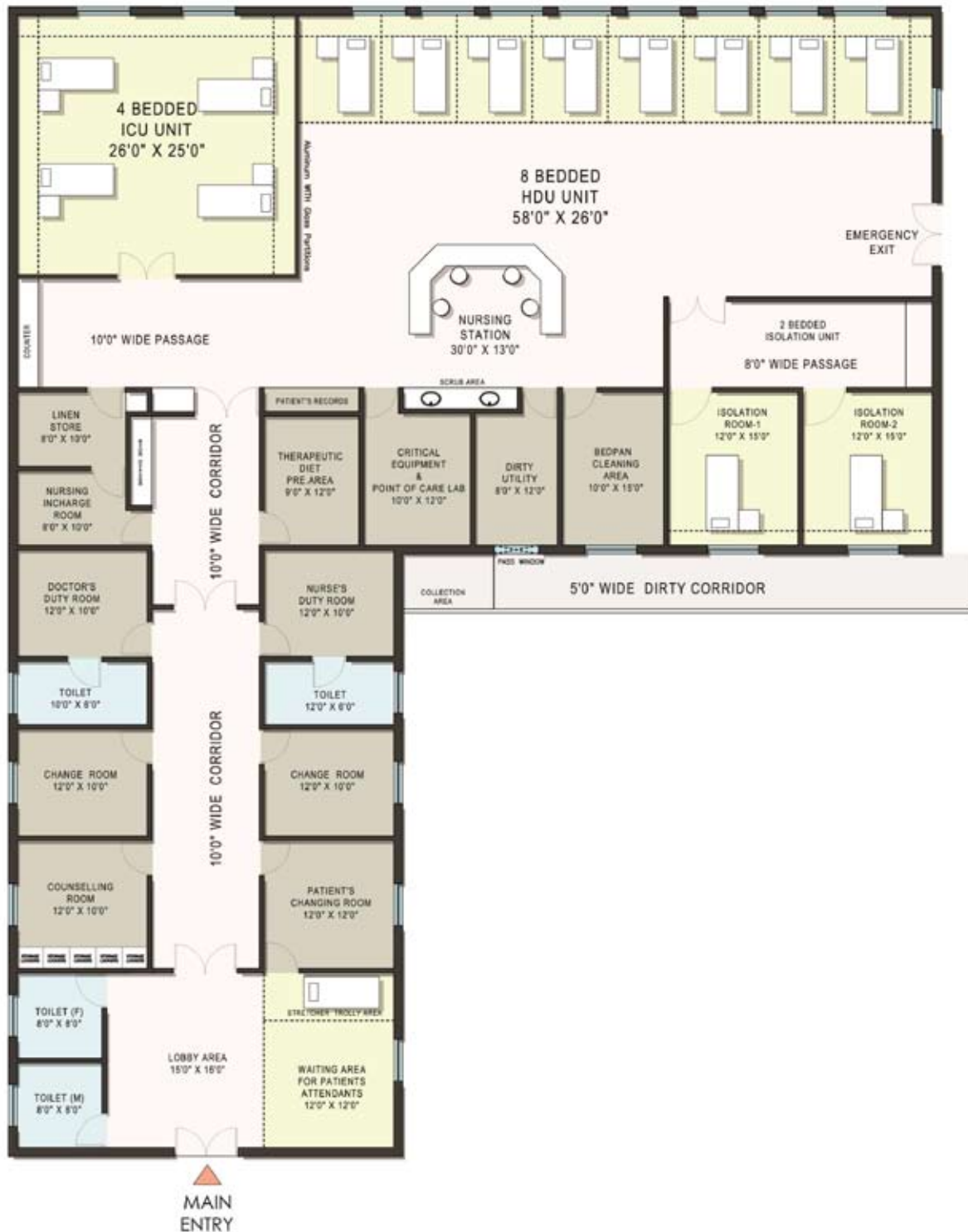
2 NOS OT COMPLEX LAYOUT PLAN



**2 NOS OT COMPLEX
PROPOSED COVERED AREA - 10500 SQFT**



DIETARY COMPLEX
PROPOSED COVERED AREA - 8500SQFT



**GENERAL HIGH DEPENDENCY UNIT [HDU FOR 8 BEDDED & 4 BEDDED ICU & 2 BEDDED ISOLATION AREA]
PROPOSED COVERED AREA - 6400SQFT**



CENTRAL STERILE SERVICES DEPARTMENT [CSSD]
PROPOSED COVERED AREA - 10500 SQFT



4 NOS OT COMPLEX LAYOUT PLAN



**4 NOS OT COMPLEX
PROPOSED COVERED AREA - 16500 SQFT**



Annexure – 7

CLEANING PROTOCOL FOR OT COMPLEX

OT is a high risk and critical care area: There must be a system of regular rounds comprising of MS or Designated officer (Infection control officer/Microbiologist etc.), Matron/Nursing Officer and Health Manager to the OT complex to ensure adherence to the cleaning protocol.

Activities	Frequency	Agent Used
Cleaning should start from innermost zone to outermost zone.		
Sterile Zone		
Operation Theatre floor	Morning, evening, after every surgery and as and when required	Damp Mop with detergent and water followed by disinfection with 0.5% chlorine
Mopping. (Care to be taken in case of special epoxy flooring)	Morning, evening, after every surgery and as and when required	Damp mop with detergent and water followed by disinfection with 0.5% chlorine
OT table and OT stretcher	Morning, evening, after every surgery and as and when required	Clean with swab dipped in soap water. Let it dry and then disinfect with 0.5% chlorine/70% Isopropyl Alcohol Disinfect the swab separately in chlorine solution.
Instruments	After every surgery	De-contaminate the instruments before cleaning with detergent. Alternatively, use zipper bags (re-usable and autoclavable) for keeping the instruments before sending to CSSD for decontamination and sterilization. Use a leak proof and puncture covered container for transport to CSSD.
Sterile corridor	Morning, evening and every two hours	Damp Mop with detergent and water followed by disinfection with 0.5% chlorine
Equipment like Anaesthesia machines, monitors, ventilators, infant warmers/baby cribs etc. or other equipment/furniture.	After each procedure/ as & when required, whether used or not in last 24 hours	Damp Mopping, dry followed by disinfection with 70% isopropyl alcohol. Monitor screen should not be mopped with any solvent. Cleaning of these screens should be done as per recommendations.
Clean Zone		
Doctor's/nurses/ technician room	Morning, evening, and as and when required	Detergent & water
Washroom & wash basins	Morning, evening, every 2 hours and as and when required	Wash with detergent & water, then dry, disinfect with 0.5% chlorine
Store rooms	Morning, evening, and as and when required	Detergent & water

Activities	Frequency	Agent Used
Clean corridor	As per sterile zone cleaning frequency i.e. Morning, evening and every two hours	Damp Mop with detergent and water followed by disinfection with 0.5% chlorine
Pre and Post-operative recovery room	4 Times a day including morning and evening	Damp Mop with detergent and water followed by disinfection with 0.5% chlorine
Pantry	4 Times a day including morning and evening	Detergent & water
Slippers	Once a day and as and when required	Detergent & water
Shoe change area	Once a day	Detergent and water
Protective Zone		
Protective corridor	Morning, evening, and once in two hours	Damp Mop with detergent and water followed by disinfection with 0.5% chlorine
Trolley wash	Clean after each use if not in use, once a day	Damp mop with detergent/alcohol and water
Mops	After every use	Soak in chlorine solution (0.5%) for 30 minutes. Wash again with detergent and water to remove the bleach
Disposal Zone		
Disposal corridor	Morning, Evening and as and when required.	Damp Mop with detergent and water followed by disinfection with 0.5% chlorine
Dirty Utility room	Morning, Evening and as and when required.	Damp Mop with detergent and water followed by disinfection with 0.5% chlorine
Bio Medical Waste Management	Thrice a day and when bags are 3/4th full present in Dirty Utility area	As per BMW rules, 2018
Fumigation	Routine fumigation is not recommended but may be done under special circumstances such as after construction/ renovation and/ or major civil and maintenance work, while commissioning new OT or reporting of any infection in the OT.	– Agent recommended: Hydrogen peroxide or combinations of silver nitrates (depending on the availability in the market). – *use of aldehyde containing compounds e.g. Formaldehyde is contraindicated in hospitals.

I. FUMIGATION/FOGGING:

- ❁ Fogging is no more recommended as a routine procedure in International Infection Control Guidelines including those by CDC as the developed countries have all modern critical parameters required for OT with a well-equipped Heat Ventilation Air Conditioning (HVAC) system. However, it can be done in special circumstances as mentioned above.



- ✿ The method of fogging is recommended mainly to ensure uniform application of the disinfectant to all surfaces in the room. At the same time, the age old tradition of formalin fumigation is not recommended as it is difficult to perform, dangerous to use (especially the liquor ammonia), unreliable (as conditions required for bactericidal activity are difficult to maintain) and formalin itself is carcinogenic.
 - ✿ ***This guideline recommends the use of hydrogen peroxide for fogging, but at least one of the following conditions have to be met for fogging to be done otherwise routine fogging is not recommended.***
 1. Fogging is not required for an OT with a HEPA filtered positive pressure air supply system.
 2. OT which do not have a HVAC/HEPA filter system.
 3. Commissioning a new OT/renovation or other civil works/outbreak of disease.
 4. In case validation of HVAC/HEPA has not taken place, as per Validation criteria led down in the guideline.
1. Fogging should be done if any of the following points are considered to be unsatisfactory:
 - I. the ventilation system design is appropriate and system performance is validated during installation at least twice a year and availability of its records.
 - II. all parameters in every validation testing should be within permissible limits.
 - III. Validation system should be done every 6 months for various standards which includes checking of:
 - i. temperature and humidity
 - ii. air particulate count
 - iii. air change rate circulation
 - iv. air velocity at outlet of terminal filtration unit/filters
 - v. pressure differential levels of the OT with respect to ambient/adjoining areas.
 - vi. Validation of HEPA filters by appropriate tests
 - IV. maintenance of the ventilation system is done periodically in terms of cleaning of pre filters, micro vee filters at an interval of 30 days.
 - V. preventive maintenance of all parts of AHU as per manufacturer's recommendations.
 - VI. HEPA filters are changed at the time intervals recommended by the manufacturer or based on results of the validation tests.
 - VII. records of maintenance filter replacement are available
 - VIII. Weekly air count monitoring using settle plates/air sampler is done
 - IX. results are within acceptable limits and test reports are available
 - X. Surface cleaning protocols are implemented correctly with OT cleaning staff knowing clearly how they are supposed to perform the cleaning.
 - XI. Adequate time is given for OT cleaning.

Once the decision is taken to conduct fogging, following steps need to be undertaken:

1. Wear a gown, cap, mask and utility gloves
2. Clean blood spills, remove waste, clean and disinfect items used in surgery

3. Inspect all surfaces in the OT in detail for visible soiling/dust. Clean any soiling with a disinfectant.
4. Wipe and clean all equipment completely i.e. wipe the entire OT table, OT lights, trolleys, anaesthesia machine.
5. Lastly, clean and mop the floor twice (scrub by hand or a floor scrubber machine if possible) with 0.5% chlorine solution beginning at the end farthest from the door and moving towards it.
6. Cover all electronic equipment with plastic covers. the fogging liquid should not enter them.
7. Turn off the ventilation system
8. Place the fogger in one corner of the OT (preferably near a door so it can be taken out easily) on a trolley. place a double folded towel under the machine (to prevent it from slipping off as it vibrates when running).
9. Direct the nozzle to the opposite corner of the room elevated at 45 degrees
10. Start the fogger and close the OT
11. Allow the fogger to run until a fog can be seen in the OT atmosphere. Check though the door window.
12. Once a suspended fog is seen, wear a cap and mask, open the OT door, turn off the fogger and remove it to the outside.
13. Keep the OT closed for at least one hour. it may be used any time after this.
14. Note: - inspect the floor for wet patches after opening the OT. all surfaces should be dry. if water deposits are present keep the OT closed to allow them to dry naturally (turn AC on if available). Do not wipe the water with sterile mop.
15. Check floor and working surfaces for excess stickiness (the foot slips or there are white streaks of deposit). This can be removed using detergent and water. If excessive stickiness or deposits are observed, check the dilution of the cleaning and fogging solution and correct it if excess chemical was added during preparation. If the problem still persists, reduce the fogging time by 1-2 minutes and monitor.
16. *Similar procedure to be followed in case of fogging OT after renovation/any civil work/in case of any outbreak where OT was closed for a long time.*

II. SURVEILLANCE AND MONITORING:

ROBUST SURVEILLANCE SYSTEM IS THE BEST AND IDEAL WAY FOR MONITORING INFECTIONS IN THE OT

- ✿ Standard precautions, transmission based precautions and routine systematic cleaning are the most crucial steps in maintaining the asepsis in critical areas including OT for preventing any HAIs and must be backed by routine surveillance and monitoring as discussed in this section.
- ✿ Any critical area including OT needs to be continuously and routinely monitored for its infection prevention control protocol adherence through supervisory rounds by NS/DNS, Hospital Manager and OT in-charge.
- ✿ Microbiologist or Infection Control Nurse should also take a separate round for checking the adherence to protocols and SOPs for infection control and cleaning protocols and report about



the compliance to the Medical Superintendent for corrective actions if any. This should also include regular orientation and training of the hospital staff.

- ✿ Apart from the activities mentioned above routine surveillance mechanism should be in place in OT and other critical areas which will help in early identification of warning signals for pseudo-outbreaks/HAls.

Type of Surveillance

- ✿ **Active surveillance** by systematic collection of data by a designated trained hospital infection control professional/nurse needs to be done.
 - ✿ **Passive surveillance** is to be done by reporting of any occurrence of suspected HAI by clinicians or ward staff nurses.
 - ✿ Following surveillance activities need to be carried out-
 1. Clinical or patient based surveillance by their outcome as a part of Clinical governance.
 2. Laboratory/Investigation data related
 3. Process based surveillance like, catheter insertion, surgical sites, handling of sharp wastes, infection control practices.
 4. Environmental surveillance and monitoring
- I. **Clinical/patient-based surveillance:** This involves counting of HAls, assessing risk factors, and monitoring patient care procedures and practices for adherence to the principles of IPC.
- II. **Laboratory-based surveillance:** This surveillance is based solely on the findings of laboratory studies of clinical specimens. The laboratory should watch for clusters of pathogens that may indicate an outbreak, emergence of multidrug-resistant organisms, and the isolation of highly infectious, unusual or virulent pathogens. These unusual events or trends must be reported early to the HICC. The microbiology laboratory should also carry out studies on patterns of AMR for common isolates and new or emerging pathogens and patterns of resistance. This information is reported to the HICC and various clinical units of the health care facility.
- III. **Process and outcome surveillance:**
- ✿ This is an audit of a practice or process of IPC such as hand hygiene or care bundles. Outcome surveillance aims to detect an HAI event such as SSI, UTI, etc.
- IV. **Environmental Surveillance:**
- ✿ This requires a targeted microbiological sampling which connotes to a monitoring process that includes
 - Written, defined, multidisciplinary protocol for sample collection and culturing
 - The traditional use of settle plates (i.e., the sedimentation or depositional method) for routine microbial culture is not recommended. This is because fungal spores remain suspended in air and it does not quantify the volume of air being sampled.
 - Analysis and interpretation of results using scientifically determined or anticipatory baseline values for comparison; and
 - Expected actions based on the results obtained.
 - ✿ **Routine environmental microbial culture is not recommended** (since 1970s) because the rates of HAI have not been associated with the level of general microbial contamination of air or environment.

- ✿ With infection prevention and control (IPC) guidelines in place, inanimate environment does not significantly contribute to HAI. It is expensive and time-consuming practice for which no meaningful standards exist³.
- ✿ The **indications** for carrying out environmental sampling are:
 - To support an investigation of an outbreak of disease or infections when environmental reservoirs or fomites are implicated epidemiologically in disease.
 - To monitor a potentially hazardous environmental condition, confirm the presence of a hazardous chemical or biological agent, and validate the successful abatement of the hazard.
 - Quality assurance: To evaluate the effects of a change in infection-control practice or to ensure that equipment or systems perform according to specifications and expected outcomes.
 - Research: Well-designed and controlled experimental methods and approaches can provide new information about the spread of health-care associated diseases

A. Air culture:

Routine air culture is not recommended because it represents indoor air quality at a singular point of time which can be affected by various factors like indoor traffic or temperature/humidity/time of the day.

Indication

Air sampling in Operating theatres should be done in these circumstances:

1. **Empty OT:** The OT should be left unoccupied for 15 min before performing the test. This should be performed
 - At the time of commissioning of the OT
 - As a part of investigation of theatre acquired infection with a possible airborne element of transmission; or
 - After any changes that may affect airflow supply rates or distribution pattern like changes in the fabric of the theatre or changes to the distribution ductwork

Prerequisites for air sampling at the time of OT commissioning:

- ✿ Clean and dust free and door should be closed
- ✿ AHU should be operating continuously at normal flow rate for at least 24 hrs prior to test
- ✿ All people should be out of both the operating rooms and any area that feeds air into the operating room (such as the preparation room)
- ✿ Sufficient time must be allowed for the ventilation to dilute and disperse the contamination generated during the setting-up of the sampler
- ✿ Theatre must be empty for 15 min before sampling
- ✿ Clothes worn by the person sampling makes no difference
- ✿ When commissioning an ultraclean theatre by microbiological sampling, samples must be taken



- ✦ one at each corner of the unidirectional airflow zone perimeter,
 - ✦ halfway along each side of the perimeter,
 - ✦ one at each corner of the inner zone,
 - ✦ one in the center.
2. **Working theatre:** Air should be sampled close to the wound site during operations, that is within 300 mm of the wound

Procedure: Air sampling should be done using slit sampler

- ✦ The sampler should be clean before use. It should also be run briefly in the theatre before the agar is loaded to blow any contamination out of the sampler. At least two samples per theatre should be collected as this lessens the possibility of technical errors.
- ✦ Nutrient agar to be used. Plates should be poured such that the surface is flat (no lumps, no slope).
- ✦ Air volume to be sampled: greater than 0.25 m³ is recommended; around 1 m³ is optimal.
- ✦ Plates to be incubated for two days at 37°C.

Frequency of Sampling: The frequency of sampling should be decided by each institution based on the means available, however at least once a month is recommended.

B. Environmental surveillance of Air Handling Unit

1. The humidifier and cooling coil in air handling units should be disinfected at least on a six-monthly basis.
2. If any suspicion arises as to the possible contamination of the system, swab tests should be performed from all drain trays and cooler battery/cooling coil tubes and fins.
3. It is inappropriate to carry out such microbiological investigations on cooling coils as they do not contribute significantly to the microbial quality of air delivered by the system. Similarly, investigations on humidifiers is also inappropriate since they generate humidity via steam, in which case they pose a negligible risk.
4. If there is a build-up of biofilm on a cooling coil, cleaning with a steam cleaner or any effective method of physical removal of biofilm is acceptable. The use of five parts per million chlorine for disinfection is unlikely to make any contribution to its removal.
5. **Engineering controls:** Maintaining adequate ventilation minimizes airborne microorganisms in three ways:
 - a. By filtration of supplied air;
 - b. By dilution of contaminated air in the theatre; and
 - c. By preventing entry of contaminated air from areas outside the theatre.

Budget:

The budgetary requirement of an OT should be part of the overall health facility plan. Equipment, consumables, cleaning material, and other day to day maintenance of OT should also be reflected under the budget head of the health facility. For assessing one time or recurring needs of the OT, the

following heads need to be considered, comprehensively analyzed and then budget estimates can be prepared.

1. Infrastructure:

Ideally, Stand-alone plan for one or two OTs should not be done. Any addition of OT should be part of overall infrastructural strengthening of critical care areas in the existing District Hospital. Need based renovation can be undertaken to meet the flow and plan indicated in the present guideline.

While reflecting budgetary demand for OT, justification should be clearly reflected on the lines suggested above. The total square meters/feet which is to be constructed and renovated also needs to be clearly mentioned along with accessories and fittings. The infrastructural cost will vary for renovation and new construction. As such, it is not being estimated here.

2. Human Resource:

For smooth running of OT complex of a district hospital, adequate number of various surgical specialists and anaesthetists along with other support staff including cleaning and security staff are crucial. So, as per the norms indicated in IPHS, budgetary requirements for hiring of additional staff needs to be reflected here as per the state's norm.

3. Equipment

A suggestive list of equipment for running core surgical specialties have been indicated here in the guideline. However, the equipment reflected is to ensure some essential surgeries which every OT must perform. So, while reflecting demand for equipment, it is essential to indicate upfront the commitment for improving either range, type or number of surgeries envisaged. The gap analysis in terms of what is available, and what is required needs to be undertaken along with quantity and estimated price.

It is difficult to give indicative budget for renovation/strengthening of presently functional OTs or a new construction since it will depend upon its size, type and extent of renovation/construction and prospective plan for improving the range of surgeries, availability of equipment etc. So, here in this guideline only processes for assessing the need and reflecting the budgetary requirement has been explained.

Annexure – 8

ROLE AND RESPONSIBILITIES

Placed below are some important responsibilities, however, MS & OT incharge can give additional responsibilities.

Important checklist	Person Responsible
✿ Restrict the unnecessary entry into OT complex ✿ Ensure shoe change/shoe cap, Cap, mask hand hygiene of all staff and attendants before entry in to OT complex. ✿ Ensure first trolley change at the entry gate of OT complex. ✿ Maintain an entry and exit register	OT Guard
For patients: ✿ Shifting of patients from ward trolley to OT trolley ✿ Verification of identity (name, address, age etc.) and Surgeon order for conducting surgeries/procedure and it should be computerized in prescribed form ✿ Ensure dress change of patients before entering OT complex ✿ Ensure filling of Consent form (It should be clearly mentioned on the consent form that the jewelry and other valuables of the patients have been returned to the patient attendants. The list of valuables should be clearly mentioned. Signature for receiving by the attendants must be taken.) For OT complex ✿ OT receptionist will be official communicator between OT in-charge and attendant; she/he will keep informing the progress/status of the patient. ✿ She/he will ensure security restriction and unauthorized entry in clean area of OT complex. ✿ She/he will ensure to wear the gowns, cap and mask to all staff and who so ever are going to pre-operative area. ✿ She/he will also be an in-charge for up keeping of counselling room.	OT Receptionist
Pre and Post-Operative area ✿ Ensure PAC (Pre Anesthesia Check-up) of all patients undergoing surgery and the documents should be uploaded and stored in computer. ✿ Ensure Surgical safety checklist, pre-post-operative checklist and verification of operating part of all patients ✿ All the events during the surgery should be properly documented for Medico Legal Purposes. ✿ Ensure functionality of oxygen, suction, air outlets and monitors. ✿ Ensure all drugs as per emergency drug list for seven days and cleanliness of pre and post-surgical room, store and toilet.	Anesthetist and Pre-op OT nurse

Important checklist	Person Responsible
Ensure functionality of all equipment of OT complex as per the following indicators: ✱ Temperature and humidity check ✱ Air particulate count	OT Technician
✱ Air change rate calculation ✱ Air velocity at outer of terminal filtration unit/filter ✱ Pressure differential level of the OT with respect to ambient/adjoining areas ✱ Validation of HEPA filter by DOP (Dispersed oil particulate)/POV (Poly Alfa olefin), every six month. ✱ Ensure Pendant service in OT room ✱ Ensure lux light of every room of OT complex as per protocol. ✱ Maintain list of equipment with specification, manufacture detail and AMC/CMC information. ✱ Responsible for functionality of equipment of OT complex, if any equipment is not working then she/he will inform respective officials and ensure functioning of OT with the support from back-up equipment. ✱ Ensure cleanliness of all equipment as per the protocol and maintain daily documentation of equipment autoclaving and sterilization through CSSD and TSSU.	
For OT ✱ Ensure preparing of surgical & anesthetic trolleys. ✱ Periodic cleaning, BMW practices, microbiological sampling. (Swab culture or air sampling/settle plate method and sensitivity test of OT (OT Table/Shadow-less lamp/floor/OT trolley/Shelf or platform over which sterilized drums are kept) has to be done. Register of the same as well as documents, in case of any positive growth of organism is found, should be maintained) ✱ If microbiological lab is not available in the hospital, then send the sample to the microbiology department of the nearest medical college. ✱ Keeping records of microbiological sample taken and reports received. OT store ✱ Keeping 7 days store of Consumables and other supplies like gloves, catheters, Ryle's tubes, infant feeding tubes, suction cannula, mucus extractors etc. in buffer as per the load. OT store register should be maintained properly. ✱ Ensure up-keeping of furniture of OT complex. Management of OT ✱ Cleaning of floors and other area should be done as specified in the housekeeping SOP. Frequent rotation of cleaning agent should be adhered to, to avoid microbial resistance. ✱ Ensure functionality of Pass box, Dumbwaiter, electrical connections, plumbing & water supply and pantry appliances in prescribed check-list, daily and as per the need. ✱ Ensure workforce management and attendance of Para medical staff working in OT complex. ✱ Ensure record keeping of OT complex area such as Pre-post area, store, reception room, changing rooms, counseling room, Operation Theater, autoclave room BMW process and cleaning records in room wise record keeping format attached with guideline. ✱ In consultation with nurse in-charge will prepare the duty roster.	OT In-charge Nurse



Important checklist	Person Responsible
Consent form ✱ Consent form for the surgery should be obtained from the relatives of the patient. ✱ Ensure that the jewelry and other valuables of the patient have been returned to the patient's attendant and signature for receiving by the patient's attendant must be taken.	
✱ Supporting surgeon ✱ Supporting nurse in-charge and technicians ✱ Counting and cleaning of equipment ✱ Keeping the trolleys ready for surgery ✱ Maintaining sterilization ✱ Adhering source segregation of linens	Nurse
✱ Ward Boy and Girl will ensure overall cleaning of OT complex as per prescribed protocol in the guideline. ✱ She/he will ensure cleaning as per their time schedule that is maintained by nurse in charge. ✱ Compromised cleaning should not be acceptable in OT complex and it should be continuously monitored by the nurse in charge and anesthetist.	Ward Boy/Girl
✱ Planning and mapping of district hospital for identification of site for OT services. ✱ Hiring architect for establishing OT services at district hospital as per the norms. ✱ Estimation of budget and reflecting the requirement in state or NHM PIP. ✱ Releasing the budget on time to districts. ✱ Issue of guidelines including translation of guidelines/manuals into local language. ✱ Linking OT strengthening with functionality of specialized services and planning for short & long term hiring up of specialists and paramedics OR paramedical staff. ✱ Utilizing resources of NHM flexibly for strengthening of OT services such as equipment, infrastructure developments, HR hiring & training, drugs and consumables as per DH guidelines. ✱ Ensuring all the equipment are covered under equipment maintenance guideline. ✱ Analysis and review of performance and patient feedback for assessment of comprehensive utilization of OT services.	State program officer

Note- Job responsibilities given above are indicative. Hospital in-charges can allocate the responsibilities based upon their faculty strength, staff situation and local conditions. However, it is mandatory that clear responsibilities are assigned for accountability and ensuring OT protocols. There should not be any verbal direction and always written communication should be given to ensure functionality.

Annexure – 9

REGISTERS/RECORDS

S.No	Name Of The Register	Key Information Recorded In The Register	Frequency Of Updating	Person Responsible	Supervisor
1	Major and minor surgeries register				
2	Operation list				
3	Handing over/taking over of critical instruments				
4	Equipment inventory including functionality & AMC status				
5	Cleaning checklist				
6	Microbiological sampling record				
7	Inventory for drug, equipment and consumables/articles				
8	Duty Roster				
9	HVAC/HEPA maintenance				
10	Entry/Exit Register for OT				

Annexure – 10

EQUIPMENT

The list of the equipment shown here are for planning purposes only. Any procurement of equipment should be based on its gap analysis, availability of HR, generic specification, outcome expected and quality parameters envisaged along with clauses for service warranty and maintenance. High end and costly equipment need to be avoided since this also requires very sophisticated handling and maintenance which most of the times is not adhered to or supervised by the senior staff. So, if such equipment is purchased, for the purpose of maintaining hygiene, efficiency and quality, in that case, SOPs for handling and maintenance of such equipment should be clearly defined. OT in charge, technicians and nurses must ensure its adherence.

Common equipment list for one OT:

S.no	General
1	OT Table
2	OT light - Ceiling Double Dome
3	Mayo Stand
4	Surgical Trolley
5	Equipment Trolley
6	Emergency & Drugs Trolley
7	Anaesthesia Trolley (Complete with Ambu bags and other items)
8	Difficult Airway Trolley- Bronchoscope, LMAs and intubating bougie
9	Anaesthesia work station
10	Electrical Suction
11	Laryngoscope with 5 Blades (LED)
12	Defibrillator (AED plus Manual with ECG)
13	Flash Autoclave - (Chamber capacity of app. 20 liters/cycle.
14	Surgical Diathermy - Bipolar
15	ECG Machine - 6 Channel
16	Crash Cart
17	Bowl Sterilizers - Different Sizes
18	Oxygen Cylinder D type
19	Washer Disinfector - 30- 45 Ltrs
20	Patient Trolley
21	Blood Warmer
22	IV Stand
23	Glucometer

Anaesthesia Equipment list for OT

S.no	Anesthesia Equipment
1	Anaesthesia Machine
2	Anaesthetic - laryngoscope Magill's with four blades
3	Endotracheal tubes: different sizes
4	Magill's forceps (two sizes- Adult & Paediatrics)
5	Connector set of six for E.T.T.
6	Catheter mount for connecting ETT
7	Airway female* (to be provided as per need)
8	Airway male* (to be provided as per need) – Both Guedel Oral Airway and Nasopharyngeal Airway
9	Mouth prop*(to be provided as per need)
10	Tongue depressors* (to be provided as per need)
11	O2 cylinder for Boyles- D type
12	N2O Cylinder for Boyles-D type
13	CO2 cylinder for laparoscope* (to be provided as per need)
14	Spirometer
15	Exchange Transfusion Sets* (to be provided as per need)
16	Adult Resuscitation Kit (to be provided as per need)
17	Neonate Resuscitation Kit (to be provided as per need)
18	Emergency First Aid Kit (to be provided as per need)
19	Multi Para Monitor - Desirable if Anaesthesia work station available in OT
20	Defibrillator (AED plus Manual with ECG)
21	Infusion Pump
22	Pressure bags for pushing blood during massive transfusion
23	Patient Trolley
24	Oxygen concentrator
25	Electric suction apparatus

Specific equipment list for Ortho OT:

S.no	Ortho Instruments
1	Tourniquet - (Different Sizes: 3",4",6" – 1 each)
2	Circle age wire 1.2mm
3	Template for contouring plates small and large DCP/LCDCP
4	2 Rods each of 400mm
5	Reamers for square nails
6	Measuring gauze for K Nails
7	Guide wire for K.Nails
8	Wrench for D.H.S screw



S.no	Ortho Instruments
9	Impactor
10	K Nail Extractor with two hooks
11	Standard set of screws for open fixation
12	Malleolar and cancellous screws
13	D.C.P (Narrow and broad)
14	Jess Allen key
15	Inner screw final Tighter(Pair)
16	Rod bender, Holder and Holdere heavy duty
17	Punch Forceps(small and large)
18	Open and round spanner
19	Scale
20	Trocar tip passing pin
21	Flower tip reamer
22	Instruments for Square Nails and Rush Nail: Impactor for Square Nails
23	Spare Hooks for extractor
24	Centering Sleeve for Tap
25	Jess: Spanner 10mm
26	Compression Device
27	T-Handle (Wrench)
28	T-Handle (Wrench)
29	MacDowell's Dissector
30	Durer Elevator
31	Self-Retaining Retractor Medium
32	K. Wires Sets (Different Sizes: 1.0mm, 1.5mm, 1.8mm, 2.5mm) -1 each
33	Plaster Cutting Instruments set: Lorenz plaster Shears
34	Rasp for Bipolar Prosthesis
35	DCP Load & Neutral Drill Guide (3.2mm) for 4.5mm Screws
36	Template for contouring plates Large DCP/LCDCP- (Different Sizes: (7H* 120mm),(9H* 155mm),(12H * 210mm))
37	Schantz Screws (Different Sizes:2.0mm, 2.5mm, 3.0mm, 3.5mm, 6.5mm)
38	Extractor with Two Hooks
39	Rush Nails :(Different Sizes:(2mm,2.5mm,3mm,3.5mm,4mm,5mm,6 mm) * 18 to 30cm (1 each) with 2cm variation
40	Diamond Pointed Awl
41	K. Nail Setting Device
42	D.H.S. Triple Reamer
43	D.C.S. Triple Reamer
44	Screw Set (Small Fragment): Cortex Screw(3.5mm)
45	Screws each of 64 & 68mm

S.no	Ortho Instruments
46	Reconstruction Plate (3.5mm)
47	Container with S.S. Trays
48	Extractor Rod
49	Round Hammer
50	Spanner Ordinary
51	Guide Wire (1.8mm*30' Long)
52	S.S. Box with screw Tray For Nail & Instrument
53	Drill Bits Sets (2.7mm, 3.2mm Extra Long 8') - 1 each
54	Skin Grafting handle-(Small, Large) - each
55	Spanner Ordinary
56	Guide Wire (2mm*16" Long)
57	Guide Wire Threaded (2mm*16" Long)
58	C.C. Drill Bit Long with Q.C. For (6.4mm, 8mm Screw) - each
59	Guide Wire (3mm*40" Long)
60	Drill Bits 4mm Extra Long 10" Long
61	Introducer (Hammer Unit)
62	Extractor Rod
63	Round hammer
64	Spanner Ordinary
65	Drill Bits (3.2 mm Extra Long 8')
66	Vise Grip
67	Distractor (6mm)
68	Compressor (6mm)
69	Pin Cutter (18mm)
70	Rod Cutter
71	Trocar
72	Pulse lavage system
73	Herbert Screw Set : Herbert screw zig
74	OT Table Electro Hydraulic - Ortho
75	OT light-Ceiling Double Dome
76	Mayo stand
77	Equipment Trolley
78	Emergency & Drugs Trolley
79	Electrical Suction
80	Surgical Diathermy- Bipolar
81	ECG Machine-6 Machine
82	IV Stand
83	Glucometer



S.no	Ortho Instruments
85	Basic Arthroscopy
86	Autoclaveable Electric Drill and saw
87	Bone cutting, drilling and reaming system
88	C-arm
89	Plaster Cutting saw (Manual)
90	Manual hand drill

General equipment list for Eye OT:

S.no	Eye Equipment(OT and Wards)
1	Cryosurgery Unit
2	Ophthalmoscope - Direct
3	Slit Lamp
4	Retinoscope
5	Nd-YAG laser
6	Perimeter
7	Binomags
8	Color vision chart
9	Snellen Chart
10	Distant Vision Charts
11	Near Vision Charts
12	Foreign Body Spud and Needle
13	Lacrimal Cannula and Probes
14	Lid Retractors (Desmarres)
15	Punctum Dilator
16	Rotating Visual Acuity drum
17	Torch
18	Trial Lens Set with Trial Frame Adult/Children
19	Operating Instruments set
20	IOL operational set
21	Operating Microscope
22	A -scan
23	Bio meter
24	Keratometer
25	Auto Refractometer
26	Flash Autoclave - (Chamber capacity of app. 20 liters/cycle.
27	Applanation Tonometer - Desirable
28	Phacomachine - Desirable

General equipment list for Obstetric OT:

S.no	Operation Theatre - Gynae
1	OT Table
2	OT light - Ceiling Double Dome
3	Mayo Stand
4	Surgical Trolley
5	Equipment Trolley
6	Emergency & Drugs Trolley
7	Anaesthesia Trolley (Complete with Ambu bags and other items)
8	Difficult Airway Trolley- Bronchoscope and intubating
9	Anaesthesia work station
10	Electrical Suction
11	Laryngoscope with 5 Blades (LED)
12	Defibrillator (AED plus Manual with ECG)
13	Flash Autoclave - (Chamber capacity of app. 20 liters/cycle.
14	Surgical Diathermy - Bipolar
15	ECG Machine - 6 Channel
16	Crash Cart
17	Bowl Sterilizers - Different Sizes
18	Oxygen Cylinder D type
19	Washer Disinfector - 30- 45 Ltr
20	Patient Trolley
21	Blood Warmer
22	IV Stand
23	Glucometer
24	Open care Radiant warmer
25	Hysteroscopy
26	Fetal Doppler
27	CTG Monitor
28	Delivery Kit
29	Episiotomy kit
30	Forceps Delivery Kit
31	Craniotomy
32	Vacuum extractor
33	Pulse Oximeter baby & adult
34	Electric Suction apparatus
35.	Pressure Bags for pushing blood during massive transfusion

Annexure – 11

SURGICAL SAFETY CHECKLIST

Surgical safety check list in the operation theatre		
Sign in (Period before induction of anesthesia)	Time Out (Period after induction & before surgical incision)	Sign Out (Period from wound closure till transfer of patient from OT room)
☐ Patient has confirmed ✿ Identity ✿ Site ✿ Procedure ✿ Consent ☐ Site marked/Not Applicable ☐ Anesthesia Safety Check Completed ✿ Anesthesia Equipment ✿ ABCDE ☐ Pulse Oxymeter on Patient and functioning DOES PATIENT HAVE A: Know Allergy ☐ No ☐ Yes Difficult Airway/Aspiration Risk? ☐ No ☐ Yes, and assistance available Risk of >500 ml Blood loss (7ml/kg in children) ☐ No ☐ Yes and adequate I.V. access & Blood/Fluids Planned. Signature of Nurse	☐ Confirm all team members have introduced themselves by name & role ☐ Surgeon, Anesthetist & Nurse verbally Confirm ✿ Patient ✿ Site ✿ Procedure ANTICIPATED CRITICAL EVENTS ☐ Surgeons reviews: What are the critical or unexpected steps, operative duration & anticipated blood loss ☐ Anesthetist reviews: Are there any patient specific concerns ☐ Nursing Team reviews: Has sterility been confirmed? Is there equipment issue or any concern? Has Antibiotic prophylaxis been given with in the last 60 minutes? ☐ Yes ☐ Not Applicable Is Essential Imaging Displayed? ☐ Yes ☐ Not Applicable Signature of Surgeon	Nurse verbally confirm with the team: ☐ The name of the procedure recorded ☐ That instrument, sponge, needle counts are correct (or not applicable) ☐ How the specimen is labeled (including Patient name) ☐ Whether there are any equipment problems to be addressed? ☐ Surgeon, Anesthetist & Nurse review the key concerns for recovery and management of patient & post- op orders to be given accordingly ☐ Information to patients attendant about procedure performed, condition of the patient & specimen to be shown ☐ Histopathology form to be filled properly & return all the records & investigation to attendant/patient Signature of Anaesthetist

Annexure – 12

SAMPLE FORMAT FOR MONITORING & SUPERVISION AT OT COMPLEX (TO BE DISPLAYED OUTSIDE OT)

Room No:

Timings:

Employees (On duty) in the OT complex

Designation (as applicable)	Name
Surgeon	
Anaesthetist	
OT technician	
OT nurse in-charge	
OT nurse	
Ward boy	
Cleaning staff	
OT receptionist	
Guard	

Cleaning Protocol: Cleaning starts two hours before 1st surgery and after every surgery & at the end of all the surgeries.

Sr.No	Name	Frequency of Cleaning	Material Used to Clean	Person Responsible
1	Protective zone corridor			
2	Clean zone corridor			
3	Pantry			
4	Toilets			
5	Sterile zone corridor			
6	OT table			
7	TSSU			
8	Trolleys			
9	Disposal zone corridor			
10	Dirty Utility room			
11	Store room			
12	Critical equipment area			

**Performance Chart**

S.no	Indicators (only major surgeries)	Previous month	Current month
	Number of general surgeries		
	Number of Ortho surgeries		
	Number of eye surgeries		
	Number of ENT surgeries		
	Number of C-section		
	Number of microbiological sample collection		
	Number indicating infection		
	Number of paediatric surgeries		
	Any other surgeries		

All the above sections should be put at an appropriate place for transparency.

Doctors on duty, OT list of patients and surgeries in progress need to be displayed either electronically or on a board.

Name of patient – type of surgery – Date of Surgery

Annexure – 13

CHECKLIST FOR OPERATION THEATRE (OT)

SECTION A: STRUCTURE

CHECKPOINTS	YES	NO	COMMENTS (Mention which is not present in the facility)
1. Availability of departmental signage - Numbering main department and internal sectional signage (including restricted area signage, zones of OT)			
2. Warning light is provided outside OT and it is used when OT is functional			
3. The facility displays 3.1. Updated duty roster 3.2. OT schedule 3.3. Protocols 3.4. Work Instructions			
4. Availability of wheelchair or stretcher for easy access to the OT			
5. The facility has a layout and demarcated areas as per functions 5.1. Zones of OT (Protective, Clean, Sterile & Disposal) and ensures unidirectional flow of materials 5.2. Changing rooms 5.3. Scrub area (deep sink with elbow tap) 5.4. Pre-operative 5.5. Post-operative room 5.6. Sterile Supply Unit/TSSU, 5.7. Dirty utility area 5.8. Store			
6. The facility ensures safe, comfortable environment and essential infrastructural components 6.1. The Non-structural components in the facility are properly secured (cupboard, cabinets and hanging objects). 6.2. Floor and walls of the facility are covered with vitrified tiles with seamless joints and easy to clean 6.3. The facility has 24*7 supply of water and electricity (with 2 tier back up with UPS) 6.4. Positive pressure, Humidity (50-60%) and temperature (20-25°C) is regularly maintained with Air Handling Unit and is recorded			



CHECKPOINTS	YES	NO	COMMENTS (Mention which is not present in the facility)
6.5. Lighting adequate for all work areas in the facility (general area: 300-500 lux and illumination at OT table 100000 lux)			
6.6. Corridors are wide enough and there is unidirectional flow of goods & services			
6.7. Piped medical gases: (oxygen, nitrous oxide, Medical compressed air & vacuum)			
6.8. OT has sufficient installed fire extinguisher (ABC type) and has separate fire exit escape route planned.			
6.9. Availability of color coded bins at point of waste generation			
7. Security arrangement at OT (Security personnel, CCTV etc.)			
8. Complaint box is available			

SECTION B: PROCESS

CHECKPOINTS	YES	NO	PARTIAL COMPLIANCE (Mention which is not present in the facility)	Comments
1. OT service is available 24*7				
2. Scheduling of patients is done				
3. There is a defined procedure before entering the main OT area				
3.1. Changing of external foot wear				
3.2. Changing of clothes				
3.3. Washing hands				
3.4. Wearing personal protective equipments (mask, apron/drape, gloves, head cap etc.)				
4. There is a procedure to take informed consent				
4.1. General consent				
4.2. High risk consent				
4.3. Anaesthesia consent				
5. Patient attendant is informed about the clinical condition and treatment provided				
6. Privacy and confidentiality is provided to all patients				
6.1. Patients are properly draped/covered before and after procedure				
6.2. Availability of screens between two OT table				
6.3. Patient records are kept at secure place				
6.4. No unnecessary displaying of patient details				

CHECKPOINTS	YES	NO	PARTIAL COMPLIANCE (Mention which is not present in the facility)	Comments
7. Behaviour of the staff is empathetic and courteous				
8. There is a procedure to monitor Pre-operative assessment (Physical examination, results of lab investigation, diagnosis and proposed surgery)				
9. There is a process for ensuring the identification before any clinical procedure 9.1. Patient ID band 9.2. Verbal communication				
10. Treatment plan, first orders are written on BHT				
11. Anaesthesia note is recorded and any adverse event is also recorded and reported.				
12. Ensuring availability of functional and sterilized instruments as per the case				
13. There is a process for identifying and cautious administration of high alert drugs as per need and is documented.				
14. Every medical procedure and advice is accompanied with proper date, time and signature in a comprehensible writing. (operative notes)				
15. There is procedure for recording details of the surgeries/event (white board inside OT : birth/death details, count practice of instrument and items, timings etc.				
16. Post-operative procedure is followed 16.1. Monitoring records before discharging 16.2. Post-operative notes and orders				
17. There is an established criteria for shifting patients 17.1. To SNCU 17.2. ICU 17.3. Higher centres 17.4. Ward				
18. Segregation of different category of waste as per guidelines				
19. There is a procedure for disinfection 19.1. General items and equipment 19.2. Sharp items 19.3. Disposal items				



CHECKPOINTS	YES	NO	PARTIAL COMPLIANCE (Mention which is not present in the facility)	Comments
20. There is an established procedure for documentation and reporting of various activities on daily basis of the following: 20.1. Each and every procedure as per SOP 20.2. Each cycle should be done 20.3. Maintenance and breakdown of equipment. 20.4. Stock maintenance for the consumables 20.5. Periodic cleaning of the equipment like Washing machine, drums, shelves etc. 20.6. Default sterilization/sterilization defects 20.7. Spill management 20.8. Fumigation 20.9. Periodic calibration and breakdown of instruments				
21. There is a designated departmental nodal person for daily rounds and internal audits.				

SECTION C: OUTCOME

CHECKPOINTS	COMMENTS
Proportion of emergency services performed in the night	
Unscheduled/emergency surgery rate	
Number of surgeries per surgeon	
Number of adverse events per thousand patients	
Pre-operative death rate	
Proportion of general anaesthesia to spinal anaesthesia	
Number of major surgeries performed	
Operation cancellation rates	
Number of swab culture reported positive	
Downtime critical instruments	
LAMA rate	



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