Control System of Sterilization Zone (CSSZ)

A project submitted in practical fulfilment of the requirements for the Degree of B.Ss (Honor) in Biomedical Engineering

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الآية

قال تعالى:

(وَعَلَّمَ آَدَمَ الْأَسْمَاءَ كُلَّهَا ثُمَّ عَرَضَهُمْ عَلَى الْمَلَائِكَةِ فَقَالَ آَمَنَّا بِإِلَهِكَ الَّذِي خَلَقَنَا وَمَا قَبْلُنَا الْأَفْوَانَ))

ثمَّ قَالُوا لَنَا إِلَّا مَا عَلَّمَنَا وَلَا نُسِبِّحَنَّ إِلَّا مَا سِبِّحَنَاٰةٰ (31)

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صدق الله العظيم

البقرة (31 ، 32)
Dedication

We dedicate this project to our great families and friends who exerted valuable efforts to enrich our spirits and reinforce our wills and energies and constantly work to support us, in particular I extend my gratefulness and thankfulness to my father El sayed Mohammed Khair who did not preserve any effort to ensure my success in all that I have done, he was a great source of motivation and courage for me.

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To all those we forgot to mention

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Abbreviations

ASHRAE  American Society of Heating, Refrigerating and Air-Conditioning Engineers.

CCU  Coronary Care Unit.

CSSD  Central Sterilization Supply Department.

HEPA  High Efficiency Particular Air.

HVAC  Heating, Ventilation and Air Conditioning.

ICU  Intensive Care Unit.

OPD  Outpatient Department.

OR  Operation Room.

OSHA  Occupational Safety and Health Administration.

OT  Operation theatre.

SARS  Severe Acute Respiratory Syndrome.

TSSU  Theatre Sterile Supply Unit.

UCVS  Ultra Clean Ventilation System.

VNT  Ventilation.
Abstract

The purpose of our project is to study overall design and planning of Sterilization zone and Operation Theater and design a control system for the region.

As the role of Biomedical Engineer discipline has evolved not only internationally but also locally in Sudan, biomedical Engineering has gained momentum as a main resort in healthcare planning.

This project provides solution for healthcare providers guide them in proper design and construct a sterilization and operation theater in accordance to international standards, also discusses the healthcare facility design in general and the surgical complex design in particular and an analyses of the complex processes, problems, and services was done.

The study was conducted by comparing Ten healthcare facilities from different sectors (private, public and army) with the international standards provide by international organizations and institutions, obtain the evaluation for the founded results.
المستخلص

الغرض الأساسي من هذا المشروع هو دراسة التصميم والتخطيط فيما يتعلق بالمنطقة المعقمة ومجمع العمليات وأنظمة التحكم في النظام بأكمله.

مع تطور الدور الذي يقوم به المهندس الطبي الحيوي ليس فقط على المستوى الدولي بل حتى داخل السودان اكتسبت الهندسة الطبية الحيوية حجماً إضافياً باعتبارها مرتكزاً أساسياً عند التخطيط المنشآت الصحية.

يوفر هذا المشروع الحلول للذين يقومون بتوفير العناية الصحية ويقدم المعرفة المتصلة بالتصميم السليم والإنشاء الخاص بمجمع التعقيم والعمليات وذلك وفقاً للمعايير الدولية، كما أنه يتناول تصميم ما يتعلق بالعناية الصحية بشكل عام وتصميم مجمع الجراحة بشكل خاص وتحليل العمليات المعقدة والمشاكل المتوقعة والخدمات التي يتم تقديمها.

تم إجراء الدراسة عبر إجراء مقارنة عشرين منشأة صحية من مختلف القطاعات (خاص، عام وعسكري) بالمعايير الدولية التي تلتزم بها المنظمات الدولية والمؤسسات الطبية الكبرى، ثم تم تقييم النتائج التي تم التوصل إليها.
Chapter One

Introduction

1.1 General Overview:

Through the study of engineering it has often been stated the engineering profession has multiple functions, from design, service, instruction, education, development, planning and so on.

No one can deny the role engineers have in developing every aspect of human life and healthcare is no exception to this simple truth.

Throughout our study we have noticed that Biomedical Engineers in real life play vital role in healthcare planning, all of which was not reflected clearly in senior year projects and have been left to large degree to Architect thesis. Although Architectural projects in healthcare planning provide comprehensive overview over many aspects of planning and design yet there is a missing touch that couldn’t be found outside the Biomedical Engineering boundary due to the functional knowledge about both instruments and process.

As the health care facilities development in Sudan is fast catching up during the last years there have been stupendous growth in this area but must needs to be done in area of infrastructure, human resource development, protocol, guidelines formation and research which are relevant to the country circumstances and to meet the international standard recommended by national societies.
This project is intended to provide the reader with an overview on design, the elements that designer of healthcare facility should pay attention to in one of the most fast growing healthcare facilities which are surgical complexes, all of which combines with a simple design and guidelines on instruments specifications, location and interior design. Also the research will be finalized with comparison between our concept of design and ten real life cases study.

1.2 Problem Statement:

Operation Theatre (OT) design is complex and should be include both clinically oriented and design team members, each team member will bring specialized skills and knowledge to focus on the project at hand, which may be a remodeling, an expansion, or completely new OT.

It is likely that the biomedical engineer would have been involved in healthcare and OT projects.

Unfortunately, in third world countries most healthcare providers have little experience designing and constructing the OT, which may lead to shifts from the international recommendations and standards decided by international organizations.

Optimal OT design can help to reduce medical errors, control and reduce infections and can play a role in reducing costs.

This study focuses in the effectiveness of a biomedical engineering consulting in the design of an ideal OT according to standards and circumstances which plays a significant role in the complex design.
1.3 Objectives:

The general objective of this project is to develop and upgrade sterilization system in Sudan's hospitals.

Specific objectives are to:

- Control the redline zone.
- Access to design ensures the lowest rate of pollution or kill it altogether.
- Drafting a proposal that analyzes the current specifications in order to improve them.

and controls be placed on a standard specification free of bacteria and viruses ensures the safety of the patient and medical staff and the surrounding community.

1.4 Methodology:

To answer the research questions, we have used classical research methods such as reference and standard book combined with the practical study of available projects designs and their instruments specifications efforts.

Through the utilizing of biomedical engineering book of knowledge and in cooperation with a team composed of architect experience, building services designers, interior design professionals and service providers concept this project intend to have a look on the main functions of surgical complex, try to advice the best solution that could be implemented in our facility, logistics, material flow, staff movement and patient care process.
All this associated with our justification for shape, space and location. A simple design that reflect all of the mentioned above is made as a result of comparing Ten different local complexes randomly chosen, five complexes in public hospitals, three complexes in Army hospitals and two in private hospitals.

Finally, the common mistakes made in our local are identified in order to provide practical solutions on how to avoid them.

1.5 Thesis layout:

This thesis contents of seven chapters, chapter one includes a brief introduction and general overview of sterilization area and operation theater. Chapter tow includes a theoretical fundamental when chapter three includes the background studies, chapter four includes the study cases analysis, chapter five contents of the result design, chapter six includes the discussion and chapter seven includes the conclusion and recommendation.
Chapter Two

Theoretical Fundamentals

The operations department is one of the most important sections in the hospital and that because it relates to human life.

It is important to keep it in a high degree of organization and determine the movement inside it to maintain a system of sterilizing, and therefore special space must be allocated to it in order to achieve the closed system, good governance and care and lack of pollution.

2.1 Hospital Design:

A decision on hospital buildings must be based on multiple factors besides cost, like fire protection, strength of construction material, hygiene, building health, environmental protection, sound isolation, energy saving, durability and utilization rate, among others. Even after initial completion of the hospital building, systematic data collection and feedback for addition, modification and upgrading of the infrastructure must be ongoing [1].

Built-in flexibility in design is becoming more crucial, mainly because technology is quickly obsolete and patient population is constantly changing. For example, single rooms may be more useful to have as they can be converted to isolation rooms more readily during an outbreak. Healthcare buildings are a complex environment with a need for specialized areas like high wear and tear areas, circulation areas, wards, specialized theatres and
hazardous material chain of disposition. Choice of material and finish is also important and needs to be mainstreamed into the planning stages [2].

This chapter is an overview on the general design parameter of complex, considering both facilities and the human factor required to reach the maximum efficiency of the facility, as so this chapter discuss the operation theater design parameter. Sterilization process, the process of patient, staff and material movement is also demonstrated as well as the categories of staff required.

2.2 Hospital design for better infection control:

The physical design and infrastructure of a hospital is an essential component of its infection control measures to minimize the risk of transmission of any infectious disease. Thus is must being a prerequisite to take these into consideration from the initial conception and planning stages of the building. The balance between designing a hospital to be an open, accessible and public place and the control to reduce the spread of infectious diseases is a necessity.

When historical and traditional hospitals were built, there were minimal concerns of new emerging infectious diseases. Today, with a more progressive outlook, it is the fundamental requirement to adopt a holistic view of the design and management of hospitals. Designing hospitals to be open, public spaces can make it difficult to control the spread of infectious diseases [2].

The ease of travel and transportation today helps people cross borders easily. They can harbor, carry or catch infectious agents readily. During the
Severe Acute Respiratory Syndrome (SARS) outbreak it became clear that the multiple public entrances in hospitals make it difficult, and often costly, to control entry and thus infiltration of infectious diseases [3].

2.3 Hospital design and Hand Hygiene:

Hand washing has been recommended as the single most important practice to control hospital acquired infection.

Improving general infection control measures and procedures as well as preparedness has the potential to enhance routine healthcare on a daily basis as well as increase our chance of a successful handling of the next pandemic.

One key component of limiting the spread of healthcare related infectious diseases is adequate infection control practice. A cornerstone of this is ensuring good hand hygiene. In isolation rooms, observation and general wards, there are personalized hand washing facilities within each room to reduce cross-contamination. These isolation rooms help to prevent direct and even indirect contact transmission and droplet transmission. Access to examination gloves, alcohol-based hand-rub and trash containers or receptacle is also important. Many have the perception that unavailability or inadequate hand washing facilities and sinks contribute towards poor compliance. Few studies have prospectively evaluated the association between hand hygiene compliance and building plan and design [4]. They concluded that peer and team behavior have greater impact on good habits rather than just building design and ergonomics.
2.4 Operation Theater (OT):

The OT is a facility within a hospital where surgical operations are carried out in a sterile environment.

2.4.1 Function of operation room:

The main function of the OT is to provide special environment where life saves or life improving procedures are carried out on the human body by invasive method under strict aseptic conditions in controlled environment by special trained personnel to promote healing and cure with maximum safety comfort and economy.

2.4.2 Types of operation room:

Types of operation theater differ according to its function:

- General surgery OR
- Orthopedic OR
- Delivery OR
- Organ transplant OR
- Neuro surgery OR
- Pediatric OR

2.4.3 Operation room flexibility:

The older concept was using different OT for different procedure. The newer direction is groping and flexibility by means of using the same theater for more than one type of operation. All major OR should be nearly identical as possible to facilitate scheduling of various surgical procedure. Grouping helps to reduce the cost and the space.
2.4.4 key planning and design parameter:

Operation theater should be planed so as to ensure:

- Its critical important for hospital planner to assess surgery needs before design- of new construction renovation- begins [5].
- The size of the complex depends on the number of beds in the hospital; which depends on the population of the city, and the type of hospital (general or has specific specialty), the type of the complex itself and the level of technology available in it.
- Avoidance of unrelated hospital traffic flow in the area.
- Convenient function relationship and communication with the surgical ward, intensive care unit (ICU), central sterilization supply department (CSSD), blood bank, medical imaging and laboratory serves.
- Avoidance of any outdoor source of noise.
- Provision for reasonable future expansion/alteration. Anticipate ways and means to permit growth in an orderly fashion without upsetting the basic relationship of internal organization or without extending line of travel to unacceptable or uneconomical length.
- In OR, anesthetic room, recovery room preoperative area, the color of walls and ceiling should be such that they don’t alter the observers of sky color. This will facilitate patient monitoring and management.
- Doors should be of the sliding type with minimum 1.2m width in areas where patient movement is anticipated like the OT, preoperative and recovery room. the sliding door are preferred to the double action left type since they are more user-friendly, save space and prevent air turbulences. Ideally, the door should be electrical operated, it also should
be sealed to ensure sterilization correct air pressure, and they facilitate quicker, safer disaffection, keep contamination risks under control, and facilitate acoustic and noise control. But they are relatively expensive and inconvenient for use in Sudan [6].

- Corridor should not to be less than 2.85m in width to facilitate the movement of trolley and stretchers.
- Walls and ceiling should be aesthetically pleasing, non-porous, and fire resistant, water and stain prove, non-reflective and easy to clean. They should not cause a buildup of statistic electrical charge.
- The ceilings should be painted with washable paint and corners of the room should be rounded off (coved) to prevent any collection of dirt and dust.
- Floors should be smooth, non-slip and made of impervious material that is conductive enough to dissipate static electricity but not conductive enough to endanger personnel from shock (epoxy).
- Taps in the scrub room should be knee/elbow operated preferably electronically controlled, active by infrared sensor.
- Essential pharmaceutical storage including refrigeration facilities should be available.
- An OR should have facility for high speed autoclave sterilizer to meet the immediate/emergency requirement of sterilizing equipment. This autoclave should be placed at the set-up to provide quick handling.
- There should be power backup with provision for standby.
- There should be awaiting room with toilet facilities for the patient’s attendants.
• Pass-through cabinets allow the transfer of supplies from outside the OT. They help to ensure the rotation of supplies from storage can be used only for passing supplies as needed.
• X-ray film illuminators should preferably be recessed into the wall as shown in appendix.
• Sound level in OT should be limited to 25-35 db. The reverberation time in OT should be to bellow one second.
• The surgical suite location must mesh with the total circulation pattern so the patients can be moved to and from surgery with a minimum of travel through other hospital departments.

2.4.5 Service areas of the operation room:

a. Preoperative areas: this should facilitate the movement of both stretchers as well as ambulatory patients not requiring stretchers.

b. Anesthetic room: this should provide for anesthetic trolleys and equipment and should have direct access to the circulation corridors and ready access to OR. It should be designed to facility cleaning. It should also have sufficient power outlets and medical gas panels.

c. Recovery unit: these should content a medication station, hand washing and nurse station.

d. Staff amenities: separated areas/rooms should be provided for male and female staff containing lockers, shower and toilet. These areas should be designed to allow one-way traffic i.e. personal entering from outside the surgical suite to changing and move inside. Duty rooms should be provided for nurse and doctor.
e. **Set-up areas:** this is clean workroom where clean/sterile material are arranged prior to their use in the OR. Its function includes holding of sterile supplies and packs, preparation for dressings and instruments trolley. If theater sterile supply unit (TSSU) is not available, flash sterilization of unsterile specialized instrument is also carried out here. It should be located so that it has direct access to the OR and center supply/theater sterile supply unit.

f. **Storage areas:** the design should allow ease of access to the storage areas for the delivery of consumables. Controlled access from an external corridor is recommended. Store room are best designed in an elongated rectangular shape to allow easy access to all items. Storage areas include the following:

- Sterile storage for pharmaceuticals, sterile materials and equipment should be located near the OR assembly area.
- There should be provisional for adequate refrigerated for blood storage.
- Storage bays that are preferably recessed in to the corridor walls should be provide for equipment such as stretcher, wheelchairs and portable X-ray machines for quick use.
- Storage for damaged equipment should be near the bio-medical engineering room.
- Storage for housekeeping equipment and cleaning tools should be included. It should contain genitor locker(s) and sink(S), and its recommended to be next to the toilets.
2.4.6 Operation theatre zoning:

Operation complex should be designing with the aim of minimizing the risk of surgical suite infection generated by the staff and equipment movement. The complex is divided into four zones according to the required level of sterile.

**Red zone:** or the sterile area, it is the innermost zone of the suite with the highest level of cleanliness and asepsis this zone includes: operating suite, scrub room, anesthesia induction room, set-up room and sterile storage.

**Orange zone:** the clean zone is around the sterile zone and has air pressor positive in comparison to productive zone. This zone includes: Pre-operative check in area (reception) and recovery room duty room store.

**Yellow zone:** it’s productive zone outside the clean zone acts as a barrier between the clean zone and the rest of hospital access to this area is entirely separate as people enter and leave in their street clothes. This zone includes: reception waiting area, trolley bay and hanging room.

**Green zone:** or the disable area. It includes: dirty utility and disposal corridor.

2.5 Sterilization:

The aim of sterilization is to treat medical supplies in such a way that they can be used safely without unnecessarily endangering the patient or the user. To ensure that equipment and materials are safely sterilized, it is essential for the person using them to be well trained and for the autoclave to
be in perfect condition. Is the process of destroying all forms of microbial life on inanimate surfaces, including bacterial spores.

### 2.5.1 Central Sterilization Supply Department (CSSD):

A centralized department for disinfection and sterilization, also called the Central Sterile Processing, generally used in modern hospitals.

Is a service catering to the needs of a hospital or a group of hospitals for the supply of sterilized articles to all the departments including the wards, outpatient department OPDs, other special units and the operation theatre in case there is no Theatre Sterile Supply Unit.

#### 2.5.1.1 Objectives of the central sterilization supply department:

Here are some of the central sterilization supply department objectives:

- Provide sterilized material from a central department where sterilizing process is carried out under properly controlled conditions
- Provide an efficient, economic, continuous supply of sterile material to all areas of the hospital and reduce the hospital infection rate.
- Alleviate the burden of work of the nursing personnel, by enabling them to devote more of their time to patient care
- Provide facilities for in-service teaching and training of nursing and ancillary personnel in the sterilization practices.
- Undertake operation research techniques for improving sterilization practices and to participate in research pertaining to supply of equipment.
- Prolonged life by proper care of equipment.
2.5.1.2 Advantages of the central sterilization supply department:

The most important advantage of the (CSSD) is cleaning, disinfection, inspection, packing, sterilization, storing and distribution are carried out by specialized, experienced personnel. This ensures better control and more reliable results, also reduces risk of hospital-acquired infections, pooled resources require less personnel and equipment, freeing the hospital staff to concentrate on the patients' well-being and more economical.

2.5.2 Organizing the sterilization department:

Before an instrument can be used, a whole range of measures must be taken to prevent it from being a danger to the patient. Sterilization is only one link in the chain of activities required to make an instrument sterile at the moment of use. Each link involves specific methods and techniques that prevent contamination of instruments, materials and living tissue. This is called the aseptic technique and is designed to prevent contamination of instruments, materials and living tissue. It includes, for example, covering the patient during the operation with sterile drapes, cleaning the operating table, and cleaning and decontaminating the patient’s skin with iodine before starting the operation.

The aseptic technique must also be followed in the sterilization department. Hospitals in the developed world employ various methods of organizing the entire instrument sterilization process (collection, pre-disinfection, cleaning, disinfection, packaging, sterilizing, distributing and storage). In the field, this task may not exist or may be carried out by a
specialized department that may not even be in the same premises as the health facility.

2.5.3 The Flow of Instruments through the Central Sterile Supplies Department:

Ideal CSSD consists of four zones, instruments should go respectively through those zones as shown in figure (2.1).

![Flow of Instruments through Central Sterile Supplies Department](image)

Figure (2.1): the flow of instruments through the (CSSD)

2.5.3.1 The cleaning zone:

Also called the dirty zone, it is the area in which reusable instruments are collected, registered, cleaned and dried. These activities can all be carried out in the same room, provided that all steps are carried out in one direction only and that nothing ever moves back towards the dirty zone – dirty and clean items must never cross, as shown in figure (2.2).

The cleaning zone should be laid out in a way that facilitates this flow. In some settings, a wall will separate the dirty zone from the clean zone, although the two have to be connected via a doorway (or a wicket) to facilitate the transfer of instruments.

All items must be checked to ensure they have been properly cleaned before they leave the dirty zone, and before being dried and packaged. Any
items that are not properly clean must be re cleaned before they can leave the dirty zone. Finally, the dirty zone should be easily accessible from the operating, obstetric and surgical emergency departments to facilitate the reception of reusable instruments. It must also be located next to the clean zone.

Figure (2.2): the flow of instruments through the (CSSD) step No. 1

2.5.3.2 The packaging zone:

Also called the clean zone. this is the area for checking/inspecting instruments, reassembling instrument sets, high-level disinfection, packaging and storage of packages ready to be sterilized, as shown in figure (2.3), damaged instruments should be set aside for the attention of the senior nurse.

The clean zone should be separated from the dirty zone by a wall, with a door (or a wicket) connecting them to facilitate the transfer of material and it should be located between the dirty zone and the sterile zone.
2.5.3.3 The autoclaving zone:

Also called sterile zone, this is the area in which the instruments ready to be sterilized by steam sterilization in an autoclave are registered. Shown in figure (2.4). The appropriate heating source for the autoclave is defined with the technical resource person (trained hospital technician). The choice between electricity/gas/kerosene will depend on the type of autoclave, the level of the health facility and the availability of electricity/fuel; this should be discussed with the biomedical engineer.
2.5.3.4 The storage and distribution zone:

This is the area in which sterile packages are stored until distributed. It is important to have a storage place in which instruments and sterile items are protected from the risk of recontamination, i.e. dust, insects, damage to packages, humidity, light, and in which their sterile status is maintained until they are used. It should be located next to the autoclaving zone, in a separate room. All zones are shown as the ultimate layout of the sterilization room in figure (2.5).

2.5.4 Quality assurance:

To ensure that instruments and supplies are sterile when used, monitoring of the sterilization process is essential. Here are some of the quality assurance tests:

Table (2.1): quality assurance tests in the (CSSD)

<table>
<thead>
<tr>
<th>Test</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning monitoring testing</td>
<td>For washer disinfectors.</td>
</tr>
<tr>
<td>Ultrasonic testing</td>
<td>For ultrasonic energy in ultrasonic baths.</td>
</tr>
<tr>
<td>Protein testing</td>
<td>For protein residue.</td>
</tr>
<tr>
<td>pH testing</td>
<td>For detergent residue.</td>
</tr>
<tr>
<td>Blood testing</td>
<td>For blood residue.</td>
</tr>
<tr>
<td>Mechanical indicator</td>
<td>Can identify process errors in packaging or loading.</td>
</tr>
<tr>
<td>Chemical indicator</td>
<td>Detect sterilizer malfunction or human error in packaging or loading the sterilizer.</td>
</tr>
<tr>
<td>Biological indicator</td>
<td>Detects no sterilizing conditions in the sterilizer.</td>
</tr>
</tbody>
</table>
2.6 Disinfection:

The process of destroying all pathogenic microorganisms, but not bacterial spores

- **High-level**: Includes powerful sporicidal chemicals (glutaraldehyde, parasitic acid and hydrogen peroxide).
- **Intermediate-level**: Includes Chlorine-containing compounds, alcohols (small surfaces), some phenolic, and some iodophors.

- **Low-level**: Includes quaternary ammonium compounds, some phenolic, and some iodophors.

### 2.7 Air filtration:

The hospital presents a complex set of environments, each with its own unique air filtration needs. Air must be filtered to provide air that’s safer and healthier for both patients and hospital employees, and free from dusts, bacteria, viruses and other air contaminants.

Choosing the right filtration system is of critical importance. Flanders Precisionaire The world leader in the air filtration industry has over 50 years’ experience dealing with critical air filtration requirements.

Air Filtration Requirements for Sensitive areas such as Operating rooms, nurseries, isolation rooms, delivery rooms, intensive care rooms, recovery rooms, is an Equipment with a minimum of 2 filter banks. Bank No 1 shall be located upstream of the conditioning equipment and shall have an average efficiency of at least 25 percent. Bank No 2 shall be located downstream of the supply fan and all cooling and humidification equipment shall have an average efficiency of at least 90 percent.

The operating theatre ceiling is the most important part of a hospital ventilation system. Also called Ultra Clean Ventilation System (UCVS), these sophisticated systems are actually a combination of a variety of elements, including gas tight welded pressure chambers, air filter housings or filter grids, High Efficiency Particulate Air (HEPA) filters, priming illumination and air diffusers.
2.8 Proper Air Quality:

Proper air conditioning is helpful in the prevention and treatment of diseases.

Factors that determine the need for air conditioning in hospital facilities are the need to restrict air movement within and between various departments, the specific requirements for ventilation and filtration to dilute and remove contaminants in the form of airborne microorganisms, viruses, hazardous chemicals and radioactive substances, also different types of temperature and humidity requirements for various areas, permit accurate control of environmental conditions and control of air quality and air movement.

2.8.1 Filtration:

Proper air filtration for the surgical suite ultimately requires at least a 90 percent final filter in accordance with the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard. Many surgical suites incorporate the use of high-efficiency particulate filters HEPA. But this may be overkill. Most airborne microorganisms are in the 0.5m to 5.0m diameter range.

2.8.2 Humidity:

Operating room humidity is the most important comfort factor recognized by surgeons. A relative humidity of 50 percent helps to dissipate electrostatic charges, which can be hazardous in an oxygen-rich environment. This humidity level also controls airborne bacteria. Humidity lower than 35 percent may cause drying of mucous membranes and hypothermia of patients during lengthy procedures. Floating particulate increases in conditions of low relative humidity, and the fact that the
incidence of wound infections may be minimized following procedures performed in those operating rooms in which the relative humidity is maintained at the level of 50 to 55 percent are advantages.

Humidity much above 55 percent causes undue sweating by surgeons and operating personnel. Unfortunately, when surgeons become uncomfortable, operating room personnel have been known to open windows or leave doors open. This, obviously, places the patient at a higher risk of infection.

2.8.3 Temperature:

Along with humidity, temperature plays an important role in comfort, but has not been indicated to be a direct factor in infection control. Rather, a comfortable environment in the operating room can reduce hazards created by misusing or abusing the operating room environment.

It is recommended the surgical suite temperature be maintained in a range of 68 degrees F to 75 degrees F, with controls for selecting any desired temperature within this range. In practice, for small rooms filled with personnel and heat emitting equipment, achieving the low end of this range can be difficult and may require dedicated chiller units.

2.8.4 Summary of air quality:

The more hospital engineers and surgeons understand the safety issues involving surgical Heating, HVAC, the better they can focus their efforts to reduce infection rates of surgery patients and also to lessen the financial burden of business interruption.

It should no longer be an issue for hospital engineers to simply keep the surgeon from complaining that it is too hot in surgery. There are very specific reasons for maintaining proper air flow, direction, humidity and
temperature in surgery. These factors not only benefit the patient, but reduce the risk of litigation brought against the hospital by patients who develop infections.

Surgery is a vital service provided to the community and important to a hospital’s financial well-being. Without a well maintained surgical air handler and surgical HVAC system, the entire surgical suite can be shut down, effectively closing down other hospital departments as well.

2.9 Triangle of health services:

Any health establishment consists of three main divisions which together express the efficiency of that establishment and any defect in these divisions lead to the disturbance in the health service providing. These three divisions are Healthcare facilities, medical equipment’s and tools, and medical staff as shown in figure (2.6).

Figure (2.6): Triangle of Health Services.
Chapter Three

Background Studies

Bill Drake (2006), The general Ventilation and Air Conditioning (HVAC) design requirements include a mix of design principles and a number of specific requirements. These requirements relate only to issues relevant to infection control, as the guidelines are not intended to be a design manual for health facilities beyond those aspects considered issues for infection control [9].

The establishment and working of the operation OT needs specialized planning and execution and is not a simple civil engineering work. A "civil-mechanical-electrical-electronic-bio medical" combo effort driven and coordinated by the needs, preferences and safety of the medical/surgical team forms the basis for starting and maintaining an operation theatre. Anesthesiologists, by virtue of their knowledge of the intricacies of physiology, physics and biomedical aspects of medicine and constant proximity to the operation theatre should preferably be involved from the early stages of planning of operating theatres [10].

Medical science and related health facility planning is an emerging sector of health infrastructure development. Medical technology, health transition, patients’ expectations, epidemiological and demographic changes all impact provision of healthcare. The advancement in scientific and technological research has taken the healthcare skills and facilities to state-of-the-art level. The improvement in the qualitative aspects of healthcare,
the exponential escalation in the case of construction of hospitals and resource constraints offer new challenges in effective utilization and conservation of resources. It is thus, imperative that planning and designing of hospitals is done holistically and scientifically.

Anjali Josepha and Mahbub Rashidb (2007), Hospital design may help improve patient safety directly by reducing nosocomial infections, patient falls, medication errors and, sometimes, even by reducing patient morbidity and mortality.

Hospital design may also help improve patient safety indirectly by reducing staff stress, staff walking and patient transfer, and by improving handwashing compliance. Although research on the links between hospital design and safety has increased over the past few years, there is still a need for more focused studies. Some reported contradictions on these links also need to be resolved. Meanwhile, the growing body of evidence in the field may already have an impact on how hospitals should be designed in the coming years.

A report by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) cited the physical environment as a root cause in 50% of patient falls [11], but studies have shown contradictory evidence on the topic. A recent review and meta-analysis of randomized controlled trials did not find any evidence for the independent effectiveness of environmental modification programs on patient falls [12]. Some studies, however, have shown that most patient falls occurred in the patient room and that bedrails were the only design element linked strongly with falls. Other studies have
shown that comprehensive multi-intervention strategies that include environmental modifications could be effective in reducing falls [13].

Analysis Study for the Operating Theatre and Sterilization Department in Hospital this project shows that from the studying to some operating theatre problems in design and other concepts in local area, ideal specifications and consideration in operating theatre and sterilization department should be in place in order to achieve the maximum efficiency. These standards include:

1. The surgical suite must be relatively isolated within the hospital in order to exclude unauthorized person.
2. The surgical suite and in particular the operating theatres themselves must be bacteriological isolated from rest of the hospital.
3. The surgical suite must provide instant access to all of the equipment, supplies and instruments required for the procedures without the necessity of leaving the protected area.
4. The suite serves to centralize requisite staff, a condition that has become more vital than ever as the surgical staff has involved into a coordinated team of highly trained specialists.
5. Data management and control program of the operating theatre and sterilization department should be in place.
Chapter Four

Study Cases Analysis

4.1 The Design Team:

OT design should be approached by a multidisciplinary team consisting of, but no limited to, the OT medical director, the OT nurse manager, the chief architect, hospital administration, and the operating engineering staff. The chief architect must be experienced in hospital space programming and hospital functional planning; the engineers should be experienced in the design mechanical and electrical systems for hospital, especially OR. The design team should be expanded as appropriate by adding members of other hospital departments working with and/or in the OT, to assure that the design meets its intended function. In addition, environmental engineers, interior designers, staff nurses, physicians, patients and families may be asked for comments on how to provide a functional and user-friendly environment. The developmental team should assess the expected demands on the proposed OT based on an evaluation of its sources of patients, admission and discharge criteria, expected rate of occupancy, and services provided by other area hospitals. The ability to provide specific zoning must be determined by analyzing physician resources, staff resources, and the availability of support services (medical equipment).
4.2 Layout and Design:

Theatre managers, infection control team, surgeons and anesthetists should be involved in the planning of the theatre design/layout. Ideally, the operating theatre suite should be a purposely built independent complex located away from the main flow of traffic but in an area easily accessible to the critical care, surgical and maternity wards and the supporting service departments.

4.3 Ventilation (VNT) Humidity and Temperature:

Ventilation should be on the principle that the direction of air flow is from the operation theatre towards the main entrance [7]. There should be no interchange air movement between one OT and another. Efficient ventilation will control temperature and humidity in OT, dilute the contamination by micro-organisms and anesthetic agents. Ventilation system is shown in figure (4.1).

There are two types of air conditioning systems: re-circulating and non re-circulating. Non re-circulating systems heat / cool the air as desired and convey it into the operating room with ideally 20 air exchange per hour. Air is then exhausted to outside. Anesthetic agents in the OT air are also automatically removed. These are thus ideal but are expensive.

The circulating system takes some or all of the air, adjusts the temperature and circulates air back to the room [8].

The broad recommendations include:

a. 20-30 air exchanges / hour for re-circulated air.

b. Only up to 80 percent recirculation of air to prevent buildup of anesthetic and other gases
c. Ultraclean laminar air flow - the filtered air delivery must be 90% efficient in removing particles more than 0.5 mm.

d. Positive air pressure system in OT: It should ensure a positive pressure of 5 cm H$_2$O from ceiling of OT downwards and outwards, to push out air from OT.

e. Relative humidity of 40-60 percent to be maintained [7].

f. Temperature between 20$^\circ$-24$^\circ$ 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.

g. The control of microbial contaminants in the operating rooms are usually do through high efficiency air filters.

h. Humidity must be less than 68 percent.

i. Temperatures should be maintained between (20$^\circ$ to 23$^\circ$ C), to reduce bacterial growth and suppress static electricity.
4.4 Analysis:

Compared to standard specifications the ten cases we studied during the project here is the analysis:

4.4.1 Ventilation:

Comparing the ventilation system in the Ten complexes in study with the ideal system of ventilation, temperature, humidity, ventilation and pressure analysis result is shown in figure (4.2)
4.4.2 Floor:

Floors should be smooth, without cracks and breaks, made of materials that will reduce static and should not endanger the safety of personnel. The surface of the floor shall provide a path of moderate electrical conductivity between all persons and equipment making contact with the floor to prevent the accumulation of dangerous electrostatic charges. The floor covering should be specified, such as continuous thick and tough vinyl, and the manufacturer’s guidelines for cleaning and maintaining the floor must be available in the cleaning policy. The floor covering should be curved up the wall to 2.5 cm, thus ensuring that edges are coved and easier to clean than right angled floors.

The floor surface must be suitably hard, nonporous and appropriate for frequent cleaning and there should be no cracks. The floors should have a nonslip surface, to prevent staff from slipping and injuring themselves.
When floors are being cleaned, a warning sign “wet floor” should be put up to warn the personnel, comparing the result of the cases in study with the standard specifications, the analysis result is shown in figure (4.3).

![Bar chart](image)

Figure (4.3): comparison between standard floor and floors in the study cases complexes

### 4.4.3 Wall, Corner and Roof:

It is recommended that all surface materials should be hard, nonporous, fire resistant, waterproof, stain proof, seamless and easy to clean. In addition, the corners of the walls and the floor should be coved (round) and smooth for easy cleaning. Comparison between standard corners and corners in study cases is shown in figure (4.5). Washable Stainless steel board for the walls is ideal, because it lasts a long time and can withstand a daily washing program. Cheaper paint has a tendency to break off and may fall in an open surgical wound. Tiles are generally not recommended as these are difficult to clean and collect dust easily. The walls and ceiling
often are used to mount essential devices and equipment to reduce crowding of the floor area therefore the walls must be solid and robust enough to carry the weight of equipment. The ceiling may be used for mounting an operating microscope, or an electrosurgical unit in addition to the operating light and boom.

Surface materials also include roofs, comparison between standard roofs and roofs in study cases is shown in figure (5.6).

The walls must be fitted with outlets for oxygen, other medical gases and vacuum, and where possible, an anesthetic gas scavenging system should be fitted at floor level. There is also a need to fit multiple electric outlets on the walls. In the cases of study, walls evaluation is shown in figure (4.4).

Figure (4.4): comparison between standard wall and walls in the study cases complexes
Figure (4.5): comparison between standard corners and corners in the study cases complexes

Figure (4.6): comparison between standard roof and roofs in the study cases complexes
4.4.4 Sensor washer:

The recommendation of materiel madid it is Stainless steel. It should be Highest quality and focus on details with a Touch less sensors (open in pot your hand automatically and self-closing in few second). 1-3 person work stations and Custom size. As shown in figure (4.7), comparison between standard washer and washers in the study cases complexes is shown in figure (4.8).

Figure (4.7): sensor washer
Figure (4.8): comparison between standard washer and washers in the study cases complexes

4.4.5 Doors:

Ideally, sliding or swing doors (self-closing) with sensor should be used in the OT. Sliding doors, as shown in figure (4.9) are recommended which must remain closed at all times, particularly during an operation because the microbial count in the air rises every time doors swing open from either direction. There must be a clear glass viewing window in the door to prevent frequent opening and closing of the door. The doors of the OT will require baffle plates to balance the airflows.

Comparing the standard door with doors in the complexes in study is shown in figure (4.10).
Figure (4.9): sliding door

Figure (4.10): comparison between standard door and doors in the study cases complexes
4.4.6 Communication:

Telephones, intercom and code warning signals are desirable inside the OT. [8] One phone per OT and one exclusively for use of anesthesia personnel is desirable. Intercom to connect to control desk, pathology and other OTs as well as use of paging receivers (bleeps) is also ideal. A code signal, when activated, signals an emergency state such as cardiac arrest or need for immediate assistance.

Figure (4.11): comparison between standard communication system and communication systems in the study cases complexes
4.4.7 Central Sterilization Supply Department:

As a result of comparing the standard CSSD with the CSSDs in study, figure (4.12), this project proved that only few of the complexes in study apply rules and standard specification.

Figure (4.12): comparison between standard (CSSD) and (CSSD) in the study cases complexes

4.5 Safety Procedures:

According to the Occupational Safety and Health Administration (OSHA), most injuries sustained by hospital employees occur in operating rooms. Because of sharp objects such as needles and scalpels, as well as other potentially dangerous medical devices.

These procedures not only improve safety for employees, but promote a clean workplace, which in turn facilitates a better, safer experience for patients.
Chapter Five

Operation Theatre and Sterilization Zone Design

This chapter will provide the overview of process present in three main aspects patient, staff and materials. Also will discuss step by step the way care is delivered to patient. Staff activities and take place to deliver care, also materials will be classified according to type and their flow to points of use will be recognized.

This chapter contains the design that proposed after comparing Ten operation complexes with the ideal layout and international specifications.

5.1 Staff required to manage the facility:

Choosing the staff is a very delicate issue in planning and design any healthcare facility since they are the dynamo that running any facility. Furthermore, the surgical complex is the most sensitive part of the hospital since its concerning very complicated equipments, highly sterile areas, and patient in critical status. This includes

- **Administrators**: reception, statistics, accountants, social workers, etc.

- **Doctors**: including surgeons, house officer, etc.

- **Nurses**: including preparation, surgical nurses, technical nurses, etc.

- **Anesthesiologist**.
- **Technicians**: including medical gas technician, lab technicians, sterilization technicians, etc.

- **Housekeepers**.

- **Biomedical Engineers**.

- **Security**.

Each one of these should have specific qualifications.

### 5.2 Process Analysis:

One of the most essential elements in design is the functional analysis of process present in healthcare facility. The process model includes analysis of both human and material flow present in service production.
Figure (5.1): flow diagram of human and materials in the operation complex

Key:
5.2.1 patient Process:

Patient represent the reason behind the establishment of any healthcare facility. The correct analysis of care activities applied on them is key factor in the correct design of the facility and estimation of requirements. As the project aim is to provide guide for surgical complex facility; a main process will be analyzed

Patient gets registered at the complex reception from the ER, ICU, wards, or converted from another hospital. Patient process in the OT starts by admitting him to the preoperative room

Preoperative room → anesthesia room → operating room → recovery room

After the operation, the patient state is evaluated by the doctor in the recovery area do decide whether he could be released or should be admitted to the ICU or words for further observation.

The movement and flow of patient through corridors shown in Figure (5.2).
5.2.2 Staff Process procedure:

Operating theater staff includes the entire human factor involved in the healthcare delivery process within the facility. The staff includes

- **Doctors** represent surgeons, registrars, and house officers. Medicine students are not counted here since they will be able to observe the surgery from the teaching room.

 starts at the reception → changing room → scrub- up → operating room.

As shown in figure (5.1).

After the procedure they take another way out.
• **Nurses** this includes preparation nurses, recovery nurses and surgery assistants.

  Starts at the reception → changing room → to the area at which they serve. As shown in figure (5.1).

**5.2.3 Material Flow:**

Throughout the process of delivering care to patients, materials are used, some materials are reused in order for care staff to provide patient related services. Material transport logistic is one of the key factors in establishing a functional successful healthcare facility and surgical complexes are no exception. The flow of material inside the operation complex is shown in figure (5.3). Movement directions of staff – patients and materials are shown in figure (5.6).

There are three main types of materials used in provision of care, which are

**5.2.3.1 Reusable Items:**

Several items are used over and over again such as surgical sets, linens, plastic bowels, metal syringes … etc.

Storage → set-up room → operating room → dirty utility → CSSD → back to storage.

Storage → anesthesia room, preoperative room, recovery room, or scrub-up room → dirty utility → CSSD → back to storage.
5.2.3.2 Disposable Items:

Items used for only one time such as syringes, blood bags, plastic forks, some patient sheets, catheters … etc.

Storage → consumer (OR, anesthesia room, recovery room, scrub-up room, preoperative room) → dirty utility → soil area at CSSD → to the medical waste to be treated.

5.2.3.3 Consumable:

Items that consumed by patient such as food, drugs, IV fluids, blood … etc.

(Food) from kitchen → cold store → distribution.

(Drugs) from drug store → distribution and consumption.
Figure (5.3): flow of material inside the operation complex
5.3 The Design:

The complex was designed according to function and sterilization level. sketched design is shown in figure (5.4), then with architect assistance the final design was reached, as shown in figure (5.5).

5.3.1 The Reception:

Has an ID system for staff to prevent unauthorized entrance, and a security station in case of any problem. Also has a glass made door to alert the security man at the entrance in case an ambulance or emergency case arrived.

It is the main entrance for the operations complex where all of the actions, such as to receive patients or the needs of some devices and equipment, as long as they will pass through the filter before arriving in the operating room.

It also is the place where the replacement of wheelchairs and stretchers carrying the patient to preparation room because the latter is in a higher level of sterilization

5.3.2 The Filter:

Is a limited area between two gates where occurring the sterilization of equipment and tools passing to the OT from any other department in the hospital, also when taking anything from the complex to any of the other hospital departments. it is very effective in reducing infection.
5.3.3 The Corridors:

Where people movement is possible.

5.3.3.1 The Main Corridor:

Is the patient corridor, about 3m in width to allow stretcher movement.

5.3.3.2 The Staff corridor:

A special corridor for medical staff, allows them to transport from the entrance to the complexes parts, and it’s a one-way direction, about 1.5m in width.

5.3.3.3 The Dirty Corridor:

Has two major functions:

– Transport dirty tools, materials, dirty clothes, and scrap (wastes) after the operation to its specialized place until cleaning, sterile or disposal them.

– Transport the staff towards the changing rooms after finishing surgery.

5.3.4 Changing Rooms:

Clean section: exist from changing room to staff corridor and exists the whole staff are cleaning.
dirty section: the turning way to changing room by side of dirty corridor and deposing dirty clothes and shoes in specific place inside this part and return into changing room to wear normal clothes.

5.3.5 The Preparation Room:

Designed to act as part of the patient travel track.

5.3.6 The Recovery Room:

Located near the OR to provide quick transport of the patient considering his sensitive condition after operation.

5.3.7 ICU and CCU:

Are chosen since they are the most needed. Their location is away from the reception and the co-patient area as shown in figure (5.5). Each are unit has storage area for equipment's for quick emergency use. Each unit must also have a nurse station in the center of the room to enable monitoring of the entire unit.

5.3.8 The operation room (OR):

Is located so that it guarantees the minimum travel for the patient, far from the traffic flow, and to facilitate the circulation of sterile and dirty materials as shown in the design fig (5.5).

Also includes compact window open on dirty corridor to transport the instruments and tools to central sterile supply department.

5.3.9 Biomedical Engineering Section:

is available to provide quick interference from engineers in case of any equipment or system failure.
5.3.10 Central Sterilization System Department:

Is divided into three zones as shown in the figure (5.5).

Movement directions of staff – patients and materials are shown in figure (5.6).

5.4 Advantage of this design:

Flexible - accomplishable to change of areas inside, whole complex depending on number of requiring rooms from 3 to 6 rooms, during construction regarding to the type of hospital.

Takes in consideration all deferent zoning. And Compares between different models.

Also pays attention for all feature structure and interest of little details, adds a modern feature the filter area for filtering any equipment before entering the OT or going out.

The design helps in reduce the spread or accumulation of bacteria and contamination or infection diseases.
Figure (5.4) sketched design of the operation complex
Figure (5.5) layout of the operation complex
Figure (5.6) movement directions of staff - patients and material
Chapter Six

Discussion

As the main objective of this project is to develop and upgrade sterilization system in Sudan's hospitals, control the redline zone and access to design ensures the lowest rate of pollution or kill it altogether, drafting a proposal that analyzes the current specifications in order to improve them. And ensures the safety of the patient and medical staff and the surrounding community.

The reference standard for a good ventilation system, humidity and temperature rates inside the sterilized area are selected to have 20-30 air exchange per hour, relative Humidity of 40-60 percent to be maintained. Temperature should be adjusting between (20°- 23° C) to reduce bacterial growth.

Hospitals are founded to be in the standard level of ventilation system represent 40% of Ten study cases compared with the standard.

As shown in figure (4.3) the comparison between standard floor and floors in study cases, 80% of hospitals in study were founded within the standards.

40% of the complexes in study were founded within the standards walls specifications, only 30% were founded within the standard corners recommendations. But, 80% were within the standard of roof finishing.

About 50% were founded within the standard as they use sensor washer.
Only 20% of complexes in targeted hospitals within the standards door requirements and 80% out of standards.

Most of the visited sites were founded not fulfilling the needs of communication system only 40% were founded within the standards as they have one phone per OT.

About 80% of the visited sites met the standards in the Central Sterilization Supply Department recommended specifications.

This project took in considerations habits and environmental factors to rise up with a practical design that is easy to apply, using classical research methods and standard book combined with the practical study of available projects designs and their instruments specifications efforts, and with help of biomedical engineers, architects, doctors and administrators.

In this design the area or size calculations have not been discussed and that because the area of any health facility depends on many factors, including the location of the facility, type and purpose. One of pros of this design is that can be applied in the case of a small facility contains up to three ORs, or large one that may contain up to six ORs depending on type of the facility.

The design proposed according to function and sterilization level in the facility, with hope that the design is to be taken reliable and apply for better healthcare facilities design and functions.
Chapter Seven

Conclusion and Recommendations

7.1 Conclusion:

Ten local study cases has been discussed, then general standards of designing hospitals, operating theatres and sterilization departments were overviewed. As a result, an operation theatre complex and sterilization department has been scientifically designed. The designed OT complex tried to solve some of Ten local complexes problems. It provides a more sterilized and clean area, with organized traffic flow of patient, staff and material, and better services.

7.2 Recommendations:

Finally, this work recommended that:

- The international design standards combined with the environmental and local tradition must be considered when designing a healthcare facility.
- Design process should be established by a team comprising of hospital engineer, architect, hospital administrator, financial expert, and health statistician.
- Hospital should have a periodic program to check and measure the environment issue such as humidity, temperature, air flow and infection rate in the OT and Sterilization Department.
– Sterilization processes should be inspected daily due to the critical function they cover.
– The design, the implementation, and the management of the facility must be in a way to make it easier to do the right thing, and harder to do the wrong thing.
REFERENCES


