Study on Efficiency of CSSD Services

Internship Training
At
LLH Hospital, Abu Dhabi

By
Shiji Samuel

Under the guidance of
Dr. S.D. Gupta

Post Graduate Diploma in Hospital & Health Management
2012–14

Institute of Health Management Research
Jaipur
2014

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TO WHOMSOEVER MAY CONCERN

This is to certify that Ms. Shiji Samuel student of Post Graduate Diploma in Hospital and Health Management (PGDHM) from Institute of Health Management Research, Jaipur has undergone internship training at LLH Hospital Abu Dhabi from 10th March to 22 May.

The Candidate has successfully carried out the study designated to him during internship training and his approach to the study has been sincere, scientific and analytical.

The Internship is in fulfilment of the course requirements.

I wish him all success in all his future endeavours.

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Dr. S.D. Gupta
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The certificate is awarded to

Shiji Samuel

In recognition of having successfully completed her

Internship in the department of

Quality

and has successfully completed her Project on

Study on Efficiency of CSSD Services

10th March - 25th May 2014

LLH Hospital, Abu Dhabi

She comes across as a committed, sincere & diligent person who has a

strong drive & zeal for learning

We wish her all the best for future endeavours

Hodan Ibrahim Alsheikh.
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CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled study on efficiency of CSSD services and submitted by Shiji Samuel Enrollment No.1373 under the supervision of Dr.S.D. Gupta for award of Postgraduate Diploma in Hospital and Health Management of the Institute carried out during the period from 10 th March to 25th May 2014 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Signature

ABSTRACT

The purpose of this study is to identify customer satisfaction on CSSD services and operation, design the process map with main outputs of process and success indicators & measure efficiency of the entire process.

In the methodology, Research Hypothesis is formulated in this stage of study. Researcher uses Descriptive or Survey Research Design where researcher attempts to describe and explain conditions of the present by using many subjects and questionnaires to fully describe a phenomenon. Survey research design /survey methodology is one of the most popular for dissertation research. Detailed analysis of the questionnaire will be performed and project into various data representing tools. Also, external measurement after the customer feedback is performed in this phase fishbone analysis, FMEA, PDCA etc.

Through a deep analysis of the operation of CSSD during course of the research, as a researcher, nearly 60% of the customers receive instrument between 2- 4 hours shows CSSD department is working efficiently. But, few customers states it takes more than 6 hours which shows there is a scope of improvement. Nearly 79% of CSSD users are satisfied with the performance of CSSD.

ACKNOWLEDGEMENT

Firstly, I sincerely thank the Almighty God for his glorious blessing infinite mercy, abundant love and spiritual guidance all the way through my life. Then I extend my sincere thanks to my parents for their valuable encouragement.

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1.1 Introduction

Adequate disinfection of the environment and provision of properly sterilized materials for all diagnostic and treatment procedures is a necessity. Sterilization of instruments and consumables is more effective when carried out in a separate unit, the central sterile supply department (CSSD). The central sterile services department (CSSD), also called sterile processing department (SPD), is an integrated place in hospitals and other health care facilities that performs sterilization and other actions on medical devices, equipment and consumables; for subsequent use by health workers in the operating theatre of the hospital and also for other aseptic procedures, e.g. catheterization, wound stitching and bandaging in a medical, surgical, maternity or pediatric ward. The operations usually consist of cleaning of previously used devices, like stainless steel tools, with a sterilizing liquid. After drying the device on a stand (not by hand or cloth) it gets wrapped in a specialized paper bag, tape-sealed and then sterilized by gas or in a steam autoclave, according to the prescripts in place at the facility. CSSD faces many problems like crowded OR, missing instrument and trays, infection control issues lack of training, monitoring and reporting, and missing knowledge and error detection. All of these issues exacerbate the rising costs surgical procedures, increasing numbers of patients, and facilities designed for a different time and healthcare standard. The rallying cries to hospital leadership are just as common-more staff is need, longer mandatory training, better communication between departments, and integration between disparate systems. Unfortunately, none of these critical issues are a silver bullet to solve the problems and few of these initiatives are undertaken

1.2 Research objective

- To measure customer satisfaction on CSSD services and operation.
    a) CSSD staff feedback
    b) CSSD services end user feedback
- Design the process map with main outputs of process and success indicators.
- To examine and measure efficiency of the entire process.
- To give recommendation to LLH hospital management on the areas for process improvement.

1.3 Problem Identification

Today, CSSD is facing several challenges such as higher surgical volumes, overburdened process capacities, lack of viable sterile process outsourcing alternatives, expensive machineries, missing instrument and trays, infection control issues lack of training, monitoring and reporting, and missing knowledge and error detection etc. Administrators have learned that simply increasing spending on capital equipment, space, instrumentation and human resources has not assured the long-term solutions needed to effectively address these concerns. An in-depth study of these services will add to the means of controlling cost, providing quality in supplies and equipment, and promoting the most effective utilization of personnel, machine and materials.

1.4 Scope of the study

a) Expected outcome of Research

- To understand what customer expects and what is been delivered. Through this survey, researcher can identify the factors/problems affecting operation of CSSD
- To understand the flow diagram of the CSSD operation and determine non value added steps and eliminate them.
- Measure efficiency of sterilization from the data collected from the user. Also, determine steps to reduce defects and other contributing factors which affect process.
- Identify the gaps of process as per PDCA processing principle and take measures to reduce them.
- Make necessary comments to improve process.

b) Limitation

Efforts will be made to make the study as accurate as possible, 100% accuracy cannot be claimed because of the following reasons: -

- Scope of the study is limited to LLH Hospital, Abu Dhabi
- Sample selection is done selectively because each process is time consuming.
- The study demands data over longer period (i.e. More than 6 months) for effective analysis.
- Lack of literature availability about CSSD efficiency.

1.5 Review of Literature

The design and implementation of service delivery processes plays a key role in the overall competitiveness of modern organizations. For example, Roth and Jackson (1995) [(1)] provide clear evidence that process capability and execution are major drivers of performance due to their impact on customer satisfaction and service quality. Thus, any study of the efficiency of service organizations must focus on the role of process design and performance.

According to Dan Johnson (2011) [(4)] in his paper, CSSD faces several problems high surgery volumes, inadequate sterile processing capacity to meet current volume, inadequate instrument inventory, uncertified or undereducated staff, available outsourcing alternatives for sterile processing , transparent hospital infection rates. According to him, an optimized workflow relieves CSSD staff of non-productive repetitive tasks and helps cultivate an environment in which staff seeks to improve efficiency, strengthen customer relationships and reengineer processes to be more productive.

Chapter 2
Industry Analysis

2.1 Historical Background of the Industry

Ancient records show that antiseptics date far back into history; the ancient Chinese, Persians, and Egyptians had methods for water sanitation and antisepsis for wounds. The ancient Greeks and Romans used silver vessels to store fresh liquids and wine. Settlers in the Australian outback put silverware and Pioneers of the American West put silver and copper coins in drinking water to keep it fresh and prevent algae; settlers in the Australian outback put silverware in drinking water for the same purpose. Mercuric chloride was used to prevent sepsis in wounds by Arabian physicians in the Middle Ages. Hypochlorite and iodine were introduced as a treatment for open wounds in 1825 and 1839, respectively.

In 1861 Louis Pasteur [(6)] proved that microorganisms caused spoilage and could be transported via the air. He placed broth in flasks with long S-shaped necks, then boiled the broth and observed that no microorganisms grew in the flasks. These experiments were the basis for the development of aseptic techniques. Pasteur showed that heat could kill microorganisms; this process was later named pasteurization. Using the knowledge gained from Louis Pasteur, a scientist named Dr. Ignaz Semmelweis reduced the number of postpartum infections (puerperal sepsis) in the wards of Vienna's lying-in hospitals by urging doctors to wash their hands between patients.

By the mid-nineteenth century, post-operative sepsis infection accounted for the death of almost half the patients who underwent major surgery. Later in the 1860's, an English surgeon named Joseph Lister heard about Pasteur's work.[(6)] He began soaking his surgical dressings in carbolic acid (phenol) because he had heard the previous year that carbolic acid had been used to treat sewage in Carlise and the fields that had been treated were now free of parasite-causing disease. This led to a dramatic decrease in the number of post-operational infections. Before the discovery of antisepsis by Lister, about 80% of surgical patients contracted gangrene. In 1870, Lister's antiseptic methods were used by Germany during the Franco-Prussian war, where they saved the lives of many Prussian soldiers. Although Germany and several other countries

followed Lister's procedure of sterilization, England and America were still in opposition to his "germ theory." The turning point for Lister came on October 26, 1877, when he had the opportunity to perform a simple knee operation (wiring a fractured kneecap, which entailed deliberate conversion of a simple fracture into a compound fracture), which often resulted in generalized infection and death. News of this operation was widely publicized; its success forced people to accept that his methods greatly added to the safety of operative surgery. The culmination of his emphasis on the principle of preventative medicine was the opening of the Institute of Preventative Medicine in 1891. These are a few of the reasons why Joseph Lister is often referred to as the "father of antiseptic surgery."

Paul Ehrlich [(6)], a German scientist, later advanced the idea of using chemicals to kill microorganisms by testing many more compounds. He eventually found a chemical that was successful against syphilis. Another scientist that had a significant impact on the field of sterilization was Ernst von Bergmann. He is credited with introducing steam sterilization under pressure for treating instruments and all other medical equipment used for a surgical patient. A famous surgeon from John Hopkins, William Stewart Halsted, introduced sterile rubber gloves to the field of medicine when his fiancée's hands became irritated from constant washings and antiseptics.

2.2 Current status of CSSD industry

According to Alpen Capital, the GCC healthcare market is projected to grow at an annual rate of 11% to USD43.9 billion by 2015 from an estimated USD25.6 billion in 2010. Outpatient and inpatient markets are expected to account for 82% and 18%, respectively, of the overall market size. Saudi Arabia is projected to be the fastest growing market along with the UAE.

The demand for number of hospital beds is expected to be 93,992 in 2015, an addition of 8,669 beds from 2010, which is in line with the expected supply looking at the number of projects in the pipeline. The number of beds remains in line with the current GCC average and below the US and European averages. The gradual improvement of healthcare infrastructure and standards in the GCC along with increasing insurance penetration should see an increase in number of patients opting for treatments locally, thus seeing an increase in demand for hospital beds

The Association for the Advancement of Medical Instrumentation (AAMI) states that the CSSD should be designed to "allow adequate space for all functions and should promote efficiency by minimizing distances between related areas. It further suggests that "workflow patterns should also be designed so that items are moved progressively from being contaminated to being safe to handle." CSSD is a booming industry because of the technical expertise and technology used in this field. But, CSSD faces many problems like crowded OR, missing instrument and trays, infection control issues lack of training, monitoring and reporting, and missing knowledge and error detection. All of these issues exacerbate the rising costs surgical procedures, increasing numbers of patients, and facilities designed for a different time and healthcare standard. Hence, apart from technical knowledge, management skills should be developed among CSSD staff to meet day to day challenge.

2.3 Current and Future trends of Healthcare industry in UAE

The United Arab Emirates (U.A.E) remains one of the most peaceful and economically stable regions of the world. As one of the largest exporters of gas and oil, the economy of UAE has experienced more than 114 fold increase at a tremendous growth rate over the last 40 years. The healthcare sector is among the 14 major areas attracting large forms of investment, forming part of the UAE Investment Map. Rapid increase in the population and income of UAE as well as movement towards a sedentary lifestyle are some key drivers of healthcare in the region.

The government of UAE is highly committed to the healthcare sector and continuously strives to create a viable atmosphere for all stakeholders in the market including investors, professionals and individuals. The population of UAE in 2010 was 7,511,690 as GDP stood at 283 Billion United States Dollars. Total health expenditure amounted to 3.7% of the total GDP, a drop from 4.37% in 2009. Public health expenditure formed an average of 76% of total health expenditure for both 2009 and 2010. The government of UAE allocates about 8.77% of total expenditure to public health annually. UAE has above regional records in terms of healthcare facilities and resources in terms of physicians, nurses and mid-wives per 1000 population. Economically, Abu Dhabi holds close to 60% of total GDP of UAE as Dubai struggles to catch up at 30%; both Emirates are at par in terms of population. Dubai, on the other hand has proven to be more successful in generating revenue from the non-oil sector of the economy.

The UAE healthcare sector can primarily be divided into two regions; Abu Dhabi on one side and Dubai with the Northern Emirate s on the other. The UAE Healthcare Industry is made up of key autonomous players such as the Ministry of Health, Dubai Health Authority, Abu Dhabi Health Authority, among others. Data recorded from key regulatory bodies and other health establishments revealed a total of 86 hospitals, 2,665 clinics and health centers, 12,752 physicians, 2,916 dentists and 9,592 bed spaces; data pertaining to health indicators, 2010. These are further classified into government and private portions of health facilities and resources over the years 2007 to 2010.

The government of UAE has announced plans to turn the country into a major destination for medical tourism and therefore have formulated plans to implement this. Many multi-national companies and market leaders including Saudi German Group, Cleveland and DM Healthcare have also put in place strategies to expand within the UAE healthcare market. New players, including Landmark Group, are expected to diversify into the healthcare market in coming years. Indeed, the region still suffers from important gaps in all areas of healthcare, from human resources through to hospital equipment and facilities. However, with affluent patients across the world willing to travel to receive the best medical treatments, Abu Dhabi sees the potential of the global healthcare market and intends to compete successfully by creating world-class healthcare facilities in the Emirate. The growth of the medical sector depends on the investment in technology that Abu Dhabi is in the position to make thanks to its strong economic base. According to HAAD, Abu Dhabi population is expected to double by 2030, requiring up to 20 new medium-to-large hospitals and 23 clinics and therefore creating immense business opportunities for any healthcare manufacturer, dealer or distributor. Plus, the Emirate presents an important capacity gap in terms of hospital equipment such as critical care beds. Thus, the optimal occupancy of beds in intensive and critical care wards is 75%, the Abu Dhabi facilities reported nearly 100 % occupancy.

Recruitment companies should also benefit from the development of the healthcare market in the region as it is estimated that 3100 additional doctors 5800 nurses would be required in Abu Dhabi by 2030 to cater the needs of its growing population. According to a recent report from Reuters, the United Arab Emirates' pharmaceutical sector

experiences a year-on-year growth of 11.3%. By 2014, the total drug expenditure should reach AED 8.3 billion (US$ 2.2 billion), which amounts to a compound annual growth rate of 9.86%. The United Arab Emirates, with the second highest diabetes rate in the world and cardio-vascular diseases being one of the highest causes of death, cannot avoid an increase in drug usage. A study from the Dubai Chamber of Commerce highlights the fact that the local pharmaceutical sector is quite small and therefore relies mostly on imports – 64% from Europe – creating new business opportunities for any pharmaceutical company.

Chapter 3

Central Sterile Service Department

Adequate disinfection of the environment and provision of properly sterilized materials for all diagnostic and treatment procedures is a necessity. Sterilization of instruments and consumables is more effective when carried out in a separate unit, the central sterile supply department (CSSD). Today, CSSD is facing several challenges such as higher surgical volumes, overburdened process capacities, lack of viable sterile process outsourcing alternatives, expensive machineries, etc. Administrators have learned that simply increasing spending on capital equipment, space, instrumentation and human resources has not assured the long-term solutions needed to effectively address these concerns. An in-depth study of these services will add to the means of controlling cost, providing quality in supplies and equipment, and promoting the most effective utilization of personnel, machine and materials. CSSD Department in LLH hospital comprises of 4 employees (one CSSD technician and three CSSD nurses).They are working in two shifts – (7am to 3pm) & (3pm to 11pm).

3.1 Major Function and Scope of CSSD

- Decontamination of instruments for surgery, the delivery room, emergency department, nursing divisions, clinics, and/or offsite urgent care facilities, etc.
- Instrument set assembly and packaging.
- Sterilization services
- Patient equipment cleaning, distribution, and billing
- Case cart system for surgery and/or the delivery room
- Managing loaner instrumentation and implants
- OR scheduling and/or billing
- Staffing surgical core areas
- Acquisition of special order implants and supplies
- Monitoring operating budgets for other departments within the facility.

3.2 Basic CSSD Process Workflow

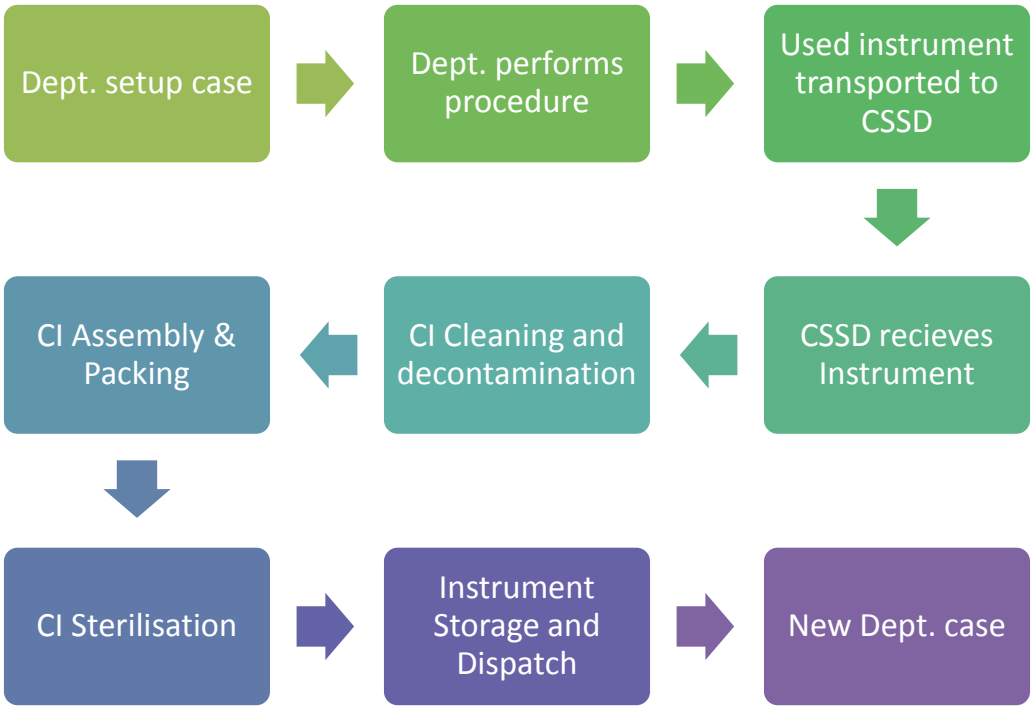


Fig 3. Basic CSSD process work flow

Legend Dept.: Clinical Department

CI: Contaminated Instruments

After the procedure, Operation theatre / other clinical departments send the contaminated instruments to the CSSD.CSSD receives the instruments and proceed to ***cleaning and decontamination area***, where reusable equipment, instruments, and supplies are cleaned and decontaminated by means of manual or mechanical cleaning processes and chemical disinfection. Clean items are received in the ***assembly and packaging area*** from the decontamination area and are then assembled and prepared for issue, storage, or packed / sealed for further processing (like ***sterilization***). After sterilization, items are transferred to the ***sterile storage area*** until it's time for them to be issued. Several major functions are carried out in the ***distribution area***: case cart preparation and delivery; exchange cart inventory, replenishment and delivery; telephone-order and requisition-order filling; and, sometimes, patient care equipment delivery.

3.3 Various Processes in CSSD Operation

3.3.1 Receiving Contaminated Instruments

After the procedure / treatment, used instruments will be transported to the CSSD for cleaning and reuse. Equipment should be covered and supplies should be moved in covered carts, closed totes or containers, or closed plastic bags. The CSSD maintains a log book for the process and both user as well as CSSD staff signs and check the instruments for any defects. Then, it will be preceded to Decontamination area for pre-cleaning.

Fig 4.CSSD Receiving area

3.3.2 Cleaning and Decontamination Process

Decontamination is the physical or chemical process that renders an inanimate object that may be contaminated with harmful microbial life safe for further handling. The objective of decontamination is to protect the preparation and package workers who come in contact with medical devices after the decontamination process from contracting diseases caused by microorganisms on those devices.

Steps in the Decontamination Process

1. **Attire** - Personnel working in the decontamination area should wear protective clothing, which includes a scrub uniform covered by a moisture-resistant barrier, shoe covers, rubber or plastic gloves, and a hair covering. During manual cleaning processes, when splashing can occur, safety goggles and a face mask should be worn.
2. **Sorting** - sorting begins at the point of use. Handling of contaminated items should be minimized unless the user of the device is already wearing full personal protective attire, such as following care in the operating room. In areas where workers are wearing no or minimal protective attire, sorting should consist only of removing disposable sharps and discarding other single-use items.
3. **Soaking** - This is necessary only if you have lumens or other complex designs instruments that are filled with debris or if the devices are very bloody and cannot be rinsed or wiped at the point of use.

Fig.5 Decontamination area

4. **Pre-cleaning**

During Pre-cleaning phase, the instruments are brushed to remove hard debris or stains. These instruments are then preceded to Washer for further cleaning.

5. **Cleaning**

Many types of cleaning equipment are available, the LLH uses following depending on its requirement:

a) Washer/decontaminator - the washer/decontaminator is used to clean heat-tolerant items. The cycle consists of several washes and rinses, followed by a steam sterilization cycle appropriate for the types of items contained in the load. Although subjected to a cycle designed to sterilize clean items, items processed in a washer/decontaminator should not be assumed to be sterile at the end of the process. The reason for this is that items enter the washer/decontaminator with an unknown, but probably very high, level of microbial contamination, which the sterilization cycle may not be able to completely destroy. LLH uses Bellimed WD 170 for this process.

Fig 6. Washer Disinfector

b) Ultrasonic Washer -The ultrasonic washer is used to remove fine soil from surgical instruments after manual cleaning and before sterilization. The equipment works by converting high-frequency sound waves into mechanical vibrations that free soil from the surface of instruments. The high-frequency energy causes microscopic bubbles to form on the surface of the instruments and as the bubbles implode, minute vacuum areas are created, drawing out the tiniest particles of debris from the crevices of the instruments. This process is called cavitation. LLH uses Sultan Prosonic 2000 for this process.

Fig 7. Ultrasonic Cleaner

3.3.3 Packing and Assembly

1) Inspection

After cleaning, all instruments should undergo inspection before being packaged for reuse or storage. Box locks, serrations, and crevices should be critically inspected for cleanliness. Instruments with cutting edges such as scissors, rongeurs, chisels, curettes, etc., should be checked for sharpness. There should be no dull spots, chips, or dents. Hinged instruments such as clamps and forceps should be checked for stiffness and alignment of jaws and teeth. Tips should be properly aligned, jaws should meet perfectly, and joints should move easily. Ratchets should close easily and hold firmly. Any instruments with pins or screws should be inspected to make sure they are intact. Plated instruments should be checked to make sure there are no chips, worn spots, or sharp edges. Worn spots can rust during autoclaving. Chipped plating can harbor soil and damage tissue and rubber gloves. If any problems are

noticed during the inspection process, these instruments should be either cleaned again, or sent for repair depending on the problem observed.

Fig 8. Instrument Assembly

2) Packing

After the instruments have been cleaned and inspected, they are typically assembled into sets or trays according to recipe cards that detail instructions for assembling each set or tray. Instruments and other items that are prepared for sterilization must be packaged so that their sterility can be maintained to the point of use. The materials and techniques used for packaging must allow the sterilant to contact the device during the sterilization process as well as to protect the device from contamination during storage and handling before it is used. The packaging material selected must also permit the device to be removed aseptically. LLH uses Envelope style of packing for Nonwoven packing. Blue coloured pouches are used for steam sterilization process and white coloured pouches are used for Plasma sterilization process.

Types of Packaging:

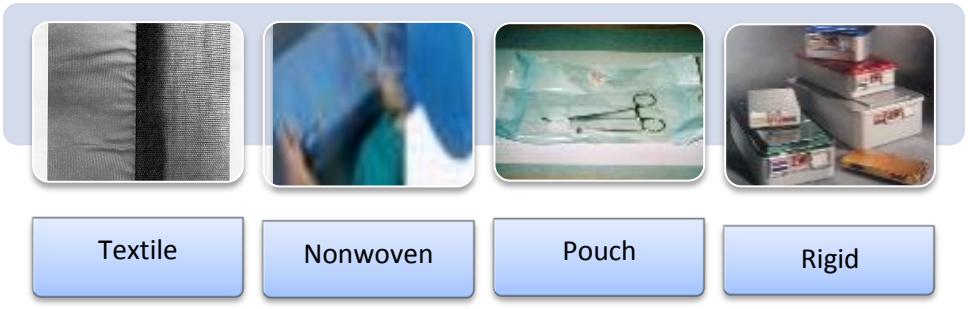


Fig 9.Types of packing

3) Sealing: Sealing is done only on pouches. During this process, sealer imprints expiry date and lot number on the pouches and makes instrument safe. LLH uses Belimed Sealer.

Fig 10. Sealing Machine

3.3.4 Sterilization Process

Bacterial spores are the most resistant of all living organisms because of their capacity to withstand external destructive agents. Although the physical or chemical process by which all pathogenic and nonpathogenic microorganisms, including spores, are destroyed is not absolute, supplies and equipment are considered sterile when necessary conditions have been met during a sterilization process.

Methods

Reliable sterilization depends on contact of the sterilizing agent with all surfaces of the item to be sterilized. Selection of the agent to achieve sterility depends primarily upon the nature of the item to be sterilized. Time required to kill spores in the equipment available for the process then becomes critical.

a) Steam Sterilization

Heat destroys microorganisms, but this process is hastened by the addition of moisture. Steam in itself is inadequate for sterilization. Pressure, greater than atmospheric, is necessary to increase the temperature of steam for thermal destruction of microbial life. Death by moist heat in the form of steam under pressure is caused by the denaturation and coagulation of protein or the

enzyme-protein system within the cells. These reactions are catalyzed by the presence of water. Steam is water vapor; it is saturated when it contains a maximum amount of water vapor.

Direct saturated steam contact is the basis of the steam process. Steam, for a specified time at required temperature, must penetrate every fiber and reach every surface of items to be sterilized. When steam enters the sterilizer chamber under pressure, it condenses upon contact with cold items. This condensation liberates heat, simultaneously heating and wetting all items in the load, thereby providing the two requisites: moisture and heat.
No living thing can survive direct exposure to saturated steam at 250 F (120 C) longer than 15 minutes. As temperature is increased, time may be decreased. A minimum temperature-time relationship must be maintained throughout all portions of load to accomplish effective sterilization. Exposure time depends upon size and contents of load, and temperature within the sterilizer. At the end of the cycle, re-evaporation of water condensate must effectively dry contents of the load to maintain sterility. LLH uses Belimed 6-6-6-VS 2 Steam Sterilizer. It is a two doored sterilizer which has standard programs for different type of instruments.

Fig 11. Sterilizer

Standard programs available in Belimed 6-6-6-VS 2

Program/Temperature	Application	Sterilization time (min)	Drying time (min)
FRVV-VMT/134°C	Solid materials to be sterilized: • Packaged instruments • Empty glass containers • Empty metal containers	3–5	20
FRVV-VMT/134°C	Materials to be sterilized from which air cannot be easily displaced • Textiles	3–5	6
FRVV-VMT/121°C	Porous materials to be sterilized • Rubber articles	20	6
FRVV-VMT/134°C	134°C special	30–60	6
Test programs and utilities			
VOVV-VMT/134°C	Heating program	3–5	3
Vacuum test		–	–
Bowie-Dick test		3.5	3

Fig 12. Programs in Belimed Sterilizer

b) Hydrogen Peroxide Plasma Sterilizer

Hydrogen peroxide is activated to create a reactive plasma or vapor. Plasma is a state of matter distinguishable from solid, liquid, or gas. It can be produced through the action of either a strong electric or magnetic field, somewhat like a neon light. The cloud of plasma created consists of ions, electrons, and neutral atomic particles that produce a visible glow. Free radicals of the hydrogen peroxide in the cloud interact with the cell membranes, enzymes, or nucleic acids to disrupt life functions of microorganisms. The plasma and vapor phases of hydrogen peroxide are highly sporicidal even at low concentrations and temperature. LLH uses HMTS – 80E Plasma Steriliser. It enables the operator to select the desired cycle via a colour touchscreen interface, which displays sterilization information and graphical representation of the cycle stages. At the end of the cycle, packs are ready for use or storage, with no aeration, cooling or drying required. The hydrogen peroxide agent is provided in a convenient 20- cycle bottle which is easily

installed at the side of the machine. The 20 cycle capacity means fewer changes and\ less work for the staff.

It performs validated sterilization of a wide range of instruments such as Surgical endoscopes, Electronic powered devices, Single lumened flexible endoscopes, including ureteroscopes, cystoscopes, bronchoscopes

Fig 13. Plasma Sterilizer

3.3.5 Shelving and Distribution

Sterilised instruments are transferred to the shelves and then distributed to the respective departments.

3.4 Quality Assurance

To ensure that instruments and supplies are sterile when used, monitoring of the sterilization process is essential. Various types of quality indicators are following

a) Mechanical Indicators

Sterilizers have gauges, thermometers, timers, recorders, and/or other devices that monitor their functions. Most sterilizers have automatic controls and locking devices. Some have alarm systems that are activated if the sterilizer fails to operate correctly. Records are maintained and review for each cycle. Test packs (Bowie-Dick test) are run at least daily to monitor functions of each sterilizer, as appropriate. These can identify process errors in packing or loading.

Fig.14 Bowie Dick test

b) Chemical Indicators

A chemical indicator on a package verifies exposure to a sterilization process. An indicator should be clearly visible on the outside of every on-site sterilized package. This helps differentiate sterilized from unsterilized items. More importantly, it helps monitor physical conditions within the sterilizer to alert personnel if the process has been inadequate. An indicator may be placed inside a package in a position most likely to be difficult for the sterilant to penetrate. A chemical indicator can detect sterilizer malfunction or human error in packaging or loading the sterilizer. If a chemical reaction on the indicator does not show expected results, the item should not be used. Several types of chemical indicators are available:

1. Tape, labels, and paper strips printed with an ink that changes color when exposed to one or more process parameters.
2. Glass tube with pellets that melts when a specific temperature is attained in sterilizer.
3. Integrating or wicking paper with an ink or chemical tablet at one end that melts and wicks along paper over time under desired process parameters. The color bar reaches the "accept" area if parameters are met.

Fig.15. Autoclave Tape

c) Biological Indicators

Positive assurance that sterilization conditions have been achieved can be obtained only through a biologic control test. The biologic indicator detects nonsterilizing conditions in the sterilizer. A biologic indicator is a preparation of living spores resistant to the sterilizing agent. These may be supplied in a self-contained system, in dry spore strips or discs in envelopes, or sealed vials or ampoules of spores to be sterilized and a control that is not sterilized. Some incorporate a chemical indicator also. The sterilized units and the control are incubated for 24 hours for Bacillus stearothermophilis at 131 to 141 F (55 to 66 C) to test steam under pressure, for 48 hours for Bacillus Subtilis at 95 to 98.6 F (35 to 37 C) to test ethylene oxide. A biologic indicator must conform with USP testing standards. A control test must be performed at least weekly in each sterilizer. Many hospitals monitor on a daily basis; others test each cycle. Very load of implantable devices must be monitored and the implant should not be used until negative test results are known. Biological indicators also are used as a challenge test before introducing new products or packaging materials, after major repairs on the sterilizer, or after a sterilization failure. All test results are filled as a permanent record for each sterilizer.

Fig.16 Biological Indicator

3.5 Administrative Monitoring

Work practices must be supervised. Written policies and procedures must be strictly followed by all personnel responsible and accountable for sterilizing and disinfecting items, and for handling sterile supplies. If sterility cannot be achieved or maintained, the system has failed. Policies and procedures pertain to;

1. Decontaminating, terminally sterilizing, and cleaning all reusable items; disposing of disposable items.
2. Packaging and labeling of items.
3. Loading and unloading the sterilizer.
4. Operating the sterilizer.
5. Monitoring and maintaining records of each cycle.
6. Adhering to safety precautions and preventive maintenance protocol.
7. Storing of sterile items.
8. Handling sterile items ready for use.
9. Making sterile transfer to a sterile field.

Chapter 4

Research Methodology

Research nature urges to follow applied research methodology which tries to solve the practical problem rather than sake of knowledge and is considered to be moral fibre of the project. It is carried on to find a solution to a real-life problem requiring an action or policy decision. It is thus problem-oriented and action-directed. It seeks an immediate and practical result, e.g., marketing research carried on for developing a new market or for studying the post-purchase experience of customers. It can put theory to the test. It may aid in conceptual clarification. It may integrate previously existing theories. Purposes of the research are to seek effective way to organize and run the CSSD. Since CSSD functions like a manufacturing plant, PDCA methodology will suit for the study.

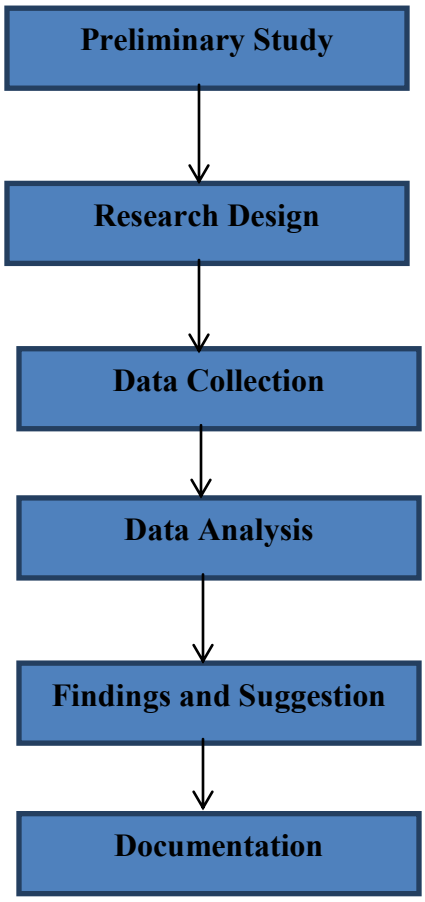


Fig 17. Research Workflow

4.1) PRELIMINARY STUDY

In this phase, Researcher performed literature review by collecting information through secondary sources such as journals supporting the research, Hospital website and healthcare Industry analysis .Through this phase, Researcher gained subject knowledge and analysed the possibility to identify and solve problems through research. Researcher cross related similar industry and determined methodology applied in other industry to solve problem in CSSD.

4.2) RESEARCH DESIGN

In this phase, Researcher prepares framework of the project and also necessary tools and data collection methodologies to be applied in research. Research design phase gives clarity about the objective of the project. Research Hypothesis is formulated in this stage of study. Researcher uses Descriptive or Survey Research Design where researcher attempts to describe and explain conditions of the present by using many subjects and questionnaires to fully describe a phenomenon. Survey research design /survey methodology is one of the most popular for dissertation research.

a) Research Hypothesis

By definition, a hypothesis is a proposed statement made on the basis of limited evidence that can be proved or disproved and is used as a starting point for further investigation.

Null Hypothesis of the study: CSSD department is working efficiently and meets day to day challenges demanded by the hospital.

b) Sample size

In this study, researcher uses cluster sampling where the total population is divided into recognizable sub-divisions, known as clusters such that within each cluster they are homogenous. The units are selected from each cluster by suitable sampling techniques and Judgment sampling where the choice of sampling items depends exclusively on the judgment of the investigator. The investigator's experience and knowledge about the population will help to select the sample units. It is the most suitable method if the population size is less. This study discusses various angles towards determining solution to the problem. Hence, three types of survey is conducted during whole research. First study focuses on CSSD users and LLH hospital has 3 staff in CSSD. Hence, sample size is 3.Second study focuses on CSSD customers' point of view about CSSD

operation. Hence, Researcher had interviewed 14 staff among various departments of LLH Abu Dhabi. Last study is used to measure the efficiency of CSSD by determining their output and defects in it. For this study, 3 departments are selected based on amount of instruments and frequency of interaction with CSSD.

c) Universe:

The study will be conducted in CSSD department, Quality Department ,Infection control department and other clinical departments of LLH hospital, Abu Dhabi .Other non-clinical departments such as finance, HR, etc. and other LLH hospital branches will be excluded from the study.

4.3) DATA COLLECTION

During this phase Researcher observes the work environment, work practice and workflow to determine the research objective and conclude findings. Research also urges to conduct interviews with the Quality in charge, CSSD staff and all other CSSD customers will be carried out and the final conclusion will be drawn out of it. Also, a questionnaire is to be created for evaluating what customer expects and what they receive. After this phase, process flow chart is prepared to identify factors affecting the variability in the process. In order to measure efficiency of the CSSD, after the preliminary evaluation of the questionnaire result, various parameters affecting CSSD operation is measured to determine the sigma level in which department is currently running by conducting a basic survey among CSSD customers.

Primary source of Data: Primary sources are original sources from which the researcher directly collects data that have not been previously collected.

Primary source data collection methods used in this study are:

1) **Moderate Participant Observation**

   Researcher maintains a balance between "insider" and "outsider" roles which allows a good combination of involvement and necessary detachment to remain objective. Various phases of this type of observation are establishing rapport, in the field, recording the observation and data & analysing data.

2) **Focused Interview**

   This technique is used to collect qualitative data by setting up a situation (the interview) that allows a respondent the time and scope to talk about their opinions on a particular subject. The focus of the interview is decided by the researcher and there may be areas

the researcher is interested in exploring. The objective is to understand the respondent's point of view rather than make generalisations about behaviour. It uses open-ended questions. The researcher tries to build a rapport with the respondent and the interview is like a conversation. Questions are asked when the interviewer feels it is appropriate to ask them. They may be prepared questions or questions that occur to the researcher during the interview. The wording of questions will not necessarily be the same for all respondents.

3) **Action Research**

   Action research involves the process of actively participating in an organization change situation whilst conducting research. Action research can also be undertaken by larger organizations or institutions, assisted or guided by professional researchers, with the aim of improving their strategies, practices and knowledge of the environments within which they practice.

4) **Questionnaire**

   A questionnaire is a research instrument consisting of a series of questions and other prompts for the purpose of gathering information from respondents. Questionnaires have advantages over some other types of surveys in that they are cheap, do not require as much effort from the questioner as verbal or telephone surveys, and often have standardized answers that make it simple to compile data. However, such standardized answers may frustrate users. Questionnaires are also sharply limited by the fact that respondents must be able to read the questions and respond to them. Thus, for some demographic groups conducting a survey by questionnaire may not be practical.

Secondary Sources of Data: Secondary sources are data that already exists

Secondary source data collection methods used in this study are:

1) Internet Websites relating to CSSD and PDCA
2) Journals and Instrument manuals
3) PDCA Case studies
4) Hospital Policies and Best Practice documents
5) Hospital website
6) Hospital Log Book

4.4) DATA ANALYSIS:

In this phase, detailed analysis of the questionnaire will be performed and project into various data representing tools. Also, external measurement after the customer feedback is performed in this phase fishbone analysis, FMEA, PDCA etc. In this phase, detailed analysis of workflow will also take place which help researcher to identify unwanted/non value added process. After data analysis, necessary recommendation will be suggested to improve the process and increase the throughput.

Research tools applied:

1) Fishbone Diagram

A fishbone diagram, also called a cause and effect diagram or Ishikawa diagram, is a visualization tool for categorizing the potential causes of a problem in order to identify its root causes.

2) FMEA

Failure Modes and Effects Analysis (FMEA) is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.

3) ANOVA

Analysis of variance (ANOVA) is a collection of statistical models used to analyse the differences between group means and their associated procedures (such as "variation" among and between groups). In ANOVA setting, the observed variance in a particular variable is partitioned into components attributable to different sources of variation. In its simplest form, ANOVA provides a statistical test of whether or not the means of several groups are equal, and therefore generalizes the *t*-test to more than two groups. Doing multiple two-sample t-tests would result in an increased chance of committing a type I error. For this reason, ANOVAs are useful in comparing (testing) three or more means (groups or variables) for statistical significance.

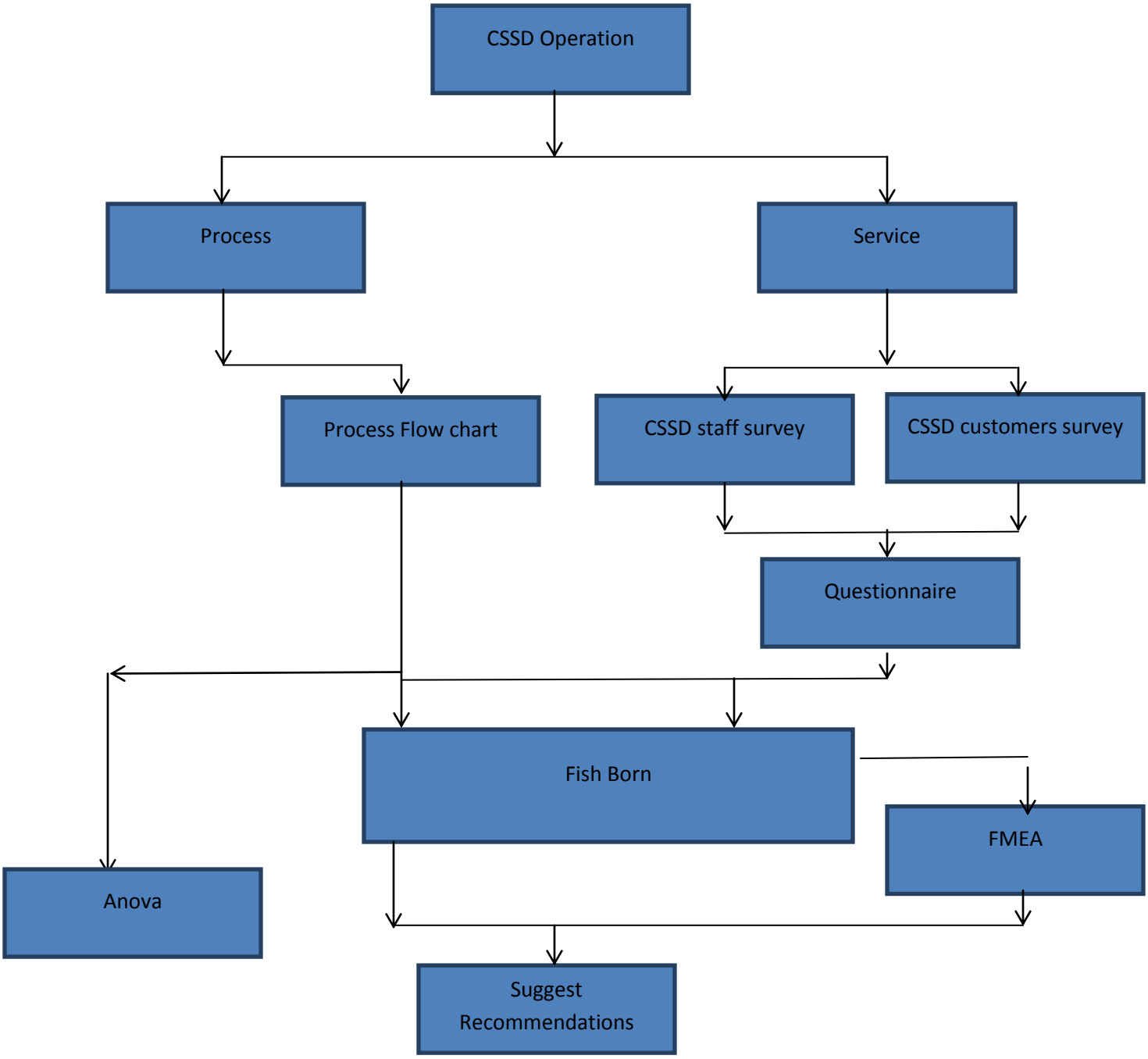


Fig 18. Data Analysis Flowchart

4.5) Documentation and Submission: In this phase, Final report is prepared for submitting to the project coordinator for approval.

Chapter 5

Data Representation and Analysis

5.1 Objective 1: To perform voice of customer survey on all departments depended on CSSD operation.

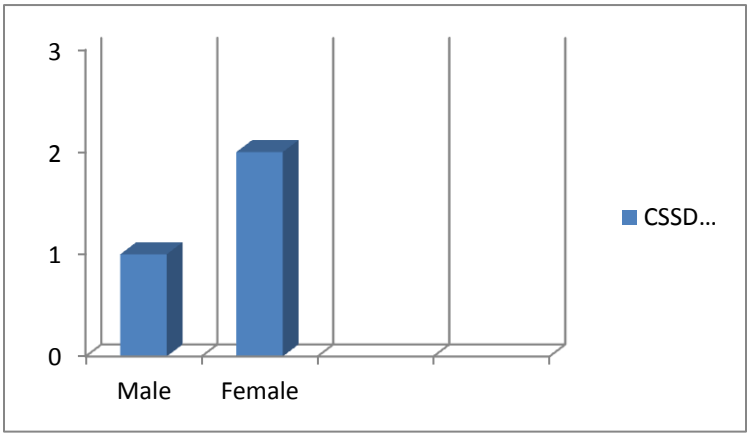
a) CSSD staff questionnaire Result:

Sample size: 3

Universe: CSSD Department, LLH Hospital, Abu Dhabi

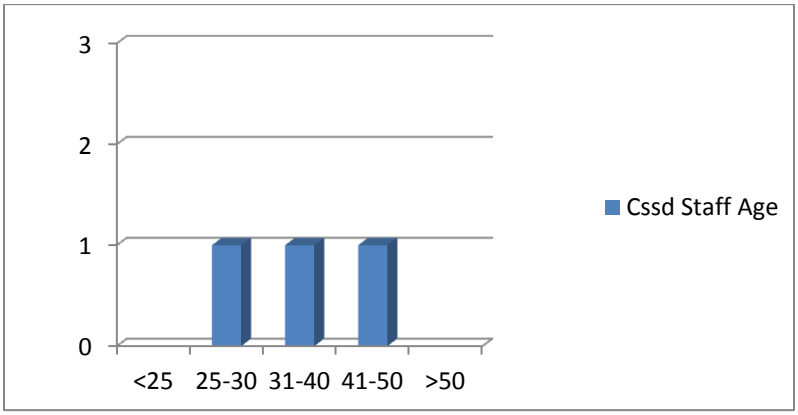
User Details:

1) **Gender**



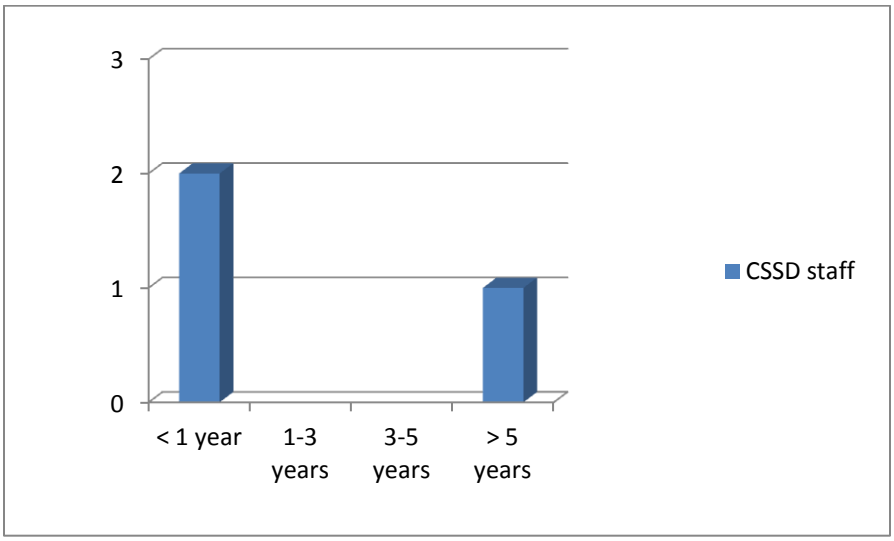
Analysis: Out of 3 respondents, two of them were female and one male.

2) **Age Group**



Analysis: All of the respondents were in different age group ranging from 25 to 50 years.

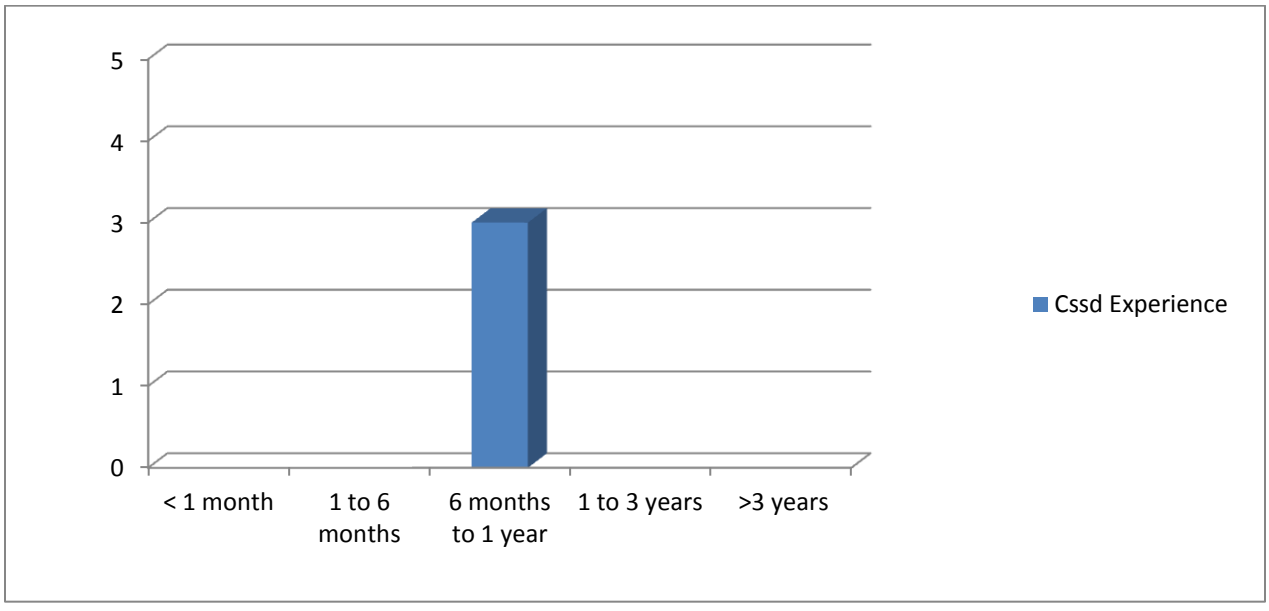
3) How long have you been working in CSSD Industry?



Analysis: Except the CSSD Technician who has 10 years of experience, all other staff is new to CSSD industry and presently building up experience in this field.

CSSD Efficiency Survey

4) How long have you been working in LLH's CSSD Department?



Analysis: All staffs are new to the LLH Hospital and now familiarizing the environment and challenges of the hospital.

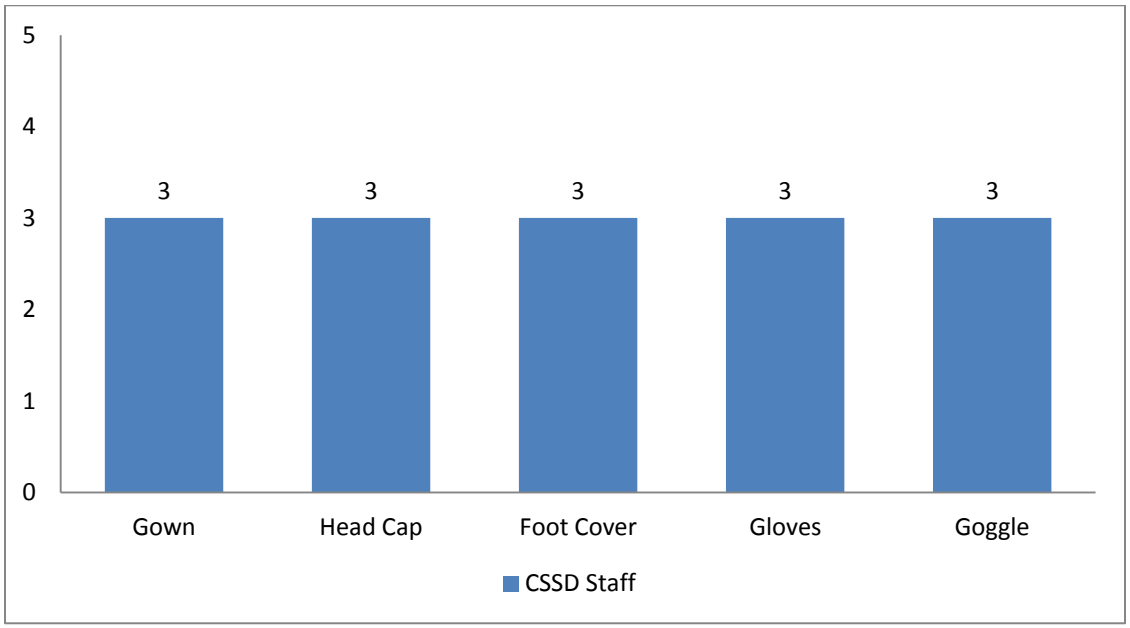
5) What are strengths of CSSD Department?

According to CSSD staff, teamwork, dedication and time management are strengths of their Department. This factors show positive trend of cooperation and dedication among the CSSD staff to manage day to day challenge. From management perspective, these factors will help the organisation to utilize available resource.

6) What are weaknesses of CSSD Department?

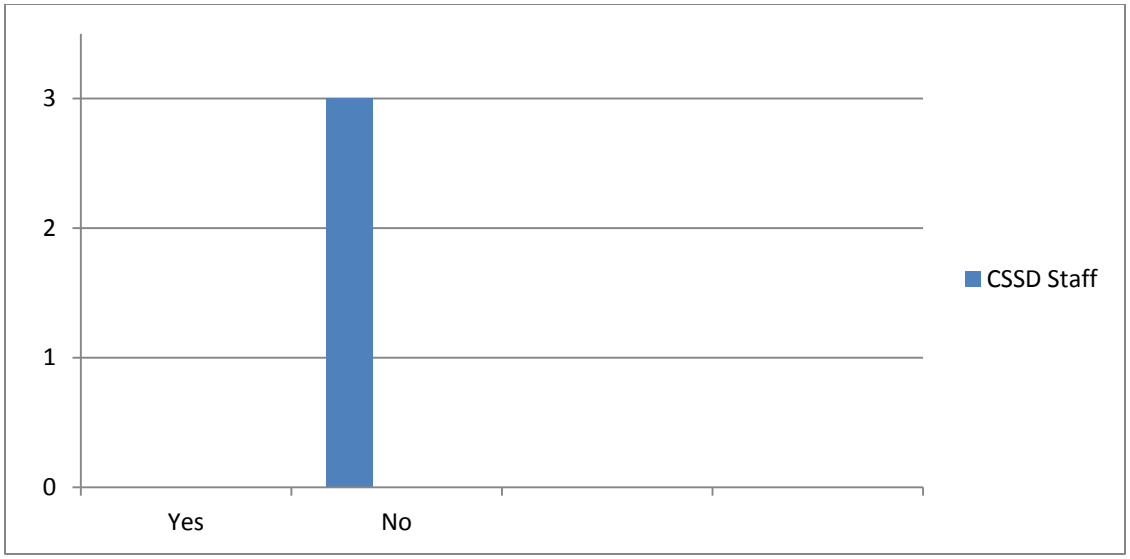
According to CSSD staff, Lack of staff number and education are weakness of CSSD Department. These factors show there is a drastic shift in the work load and recent changes in the CSSD staff finds difficulty in handling because lack of experience and education.

7) What kind of Personal Protective Equipment's are worn during CSSD operation?



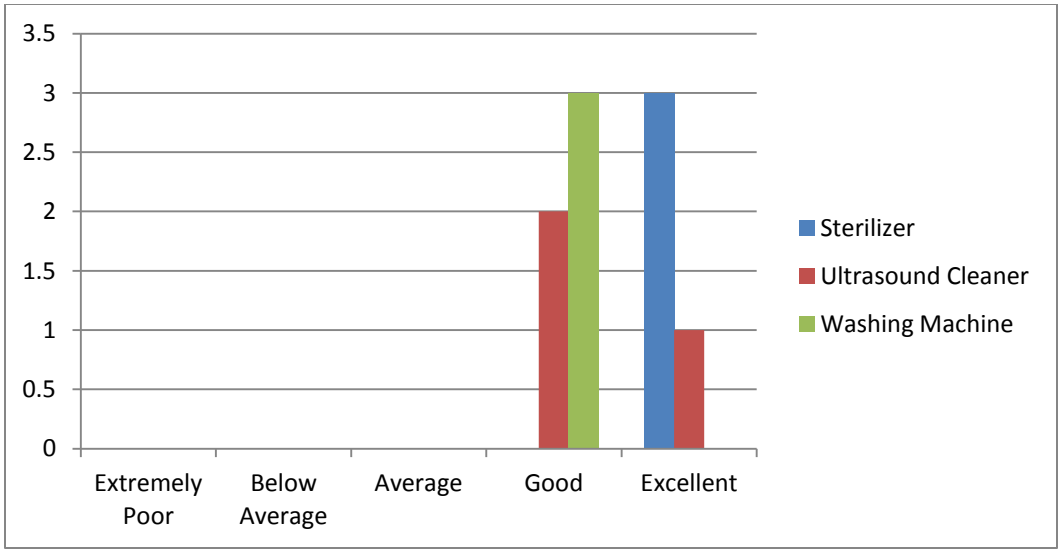
Analysis: Since, all are using necessary safety gadgets; the risk for accidents due to sharp instrument injury/chemical spilling is low. These points help management to reduce risk of occupational hazard and accidents during CSSD operation.

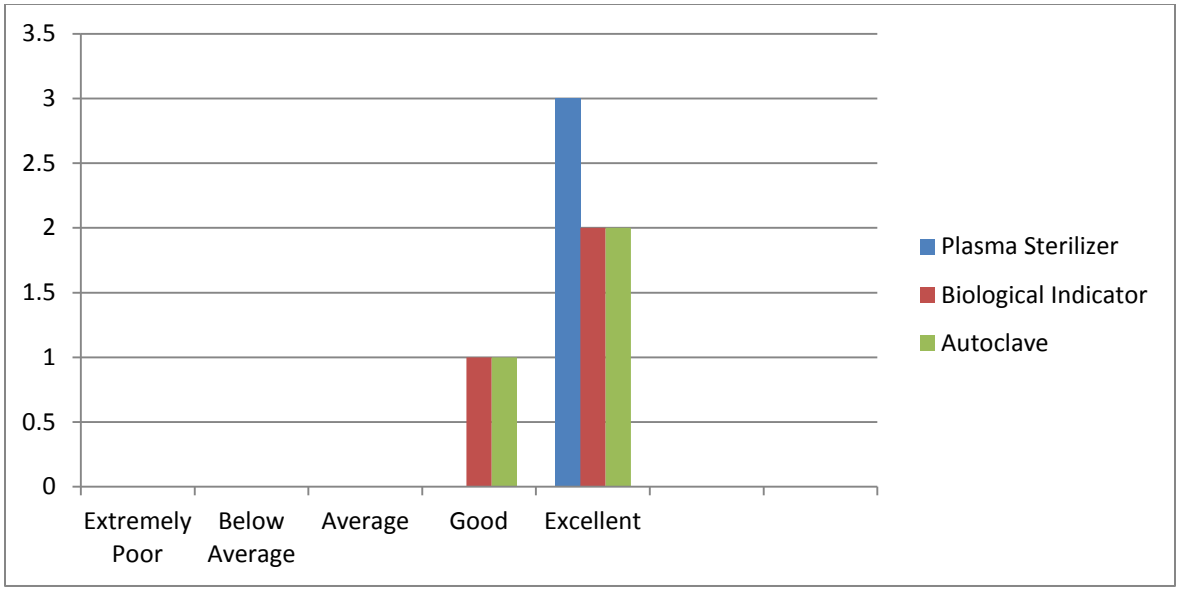
8) Do you believe your department has enough staff to meet day to day challenges?



Analysis: Since, all respondents stated they lack enough staff; there is an urgent requirement for a staff with respect to the workload. This point will be taken for further analysis and will be discussed in the next stages of data collection to verify its credibility. They have recommended at least one staff additional to carry out the present work. One of the respondents also stated that they are lacking a messenger to transport instruments after and before sterilisation to the various departments.

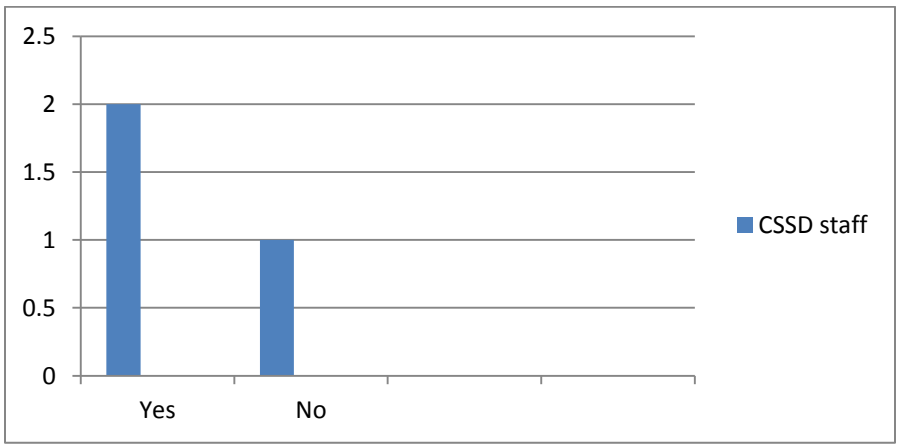
9) How do you rate machinery performance?





Analysis: All staff rated machine performance above average which shows the instruments installed in the facility are of right capacity to meet the workload and user friendly to operate. Some of the suggestion from staff was need for a double door disinfector, latest ultrasound cleaner and class 6 integrator for quality assurance.

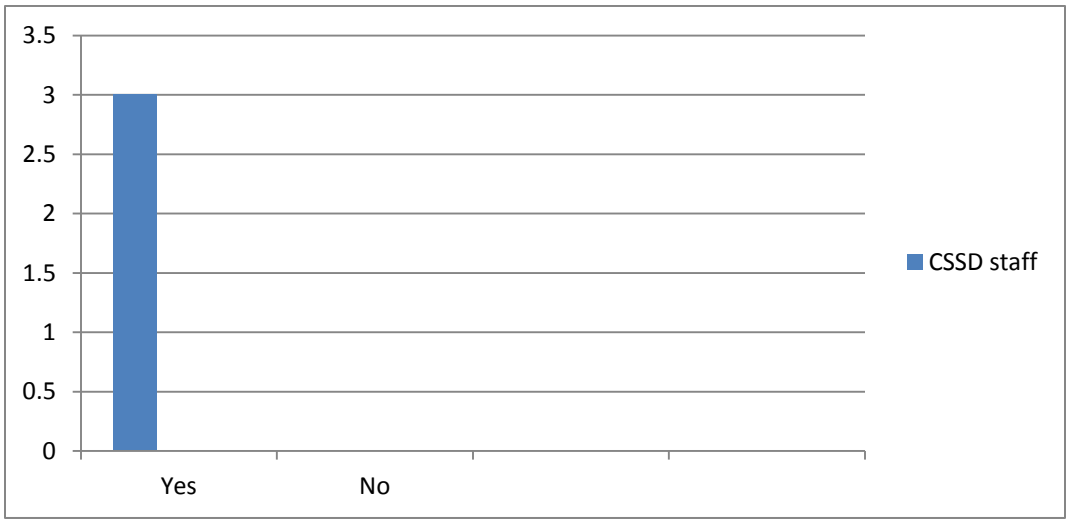
10) Whether you require any other additional tools /machinery for improving speed?



Analysis: Two of the respondents suggested they need additional tools to improve speed such as brushes used in the pre-cleaning process. Magnifying lamp for detailed inspection of instruments before processing, double door Washer Disinfector which reduces turnaround time of CSSD staff

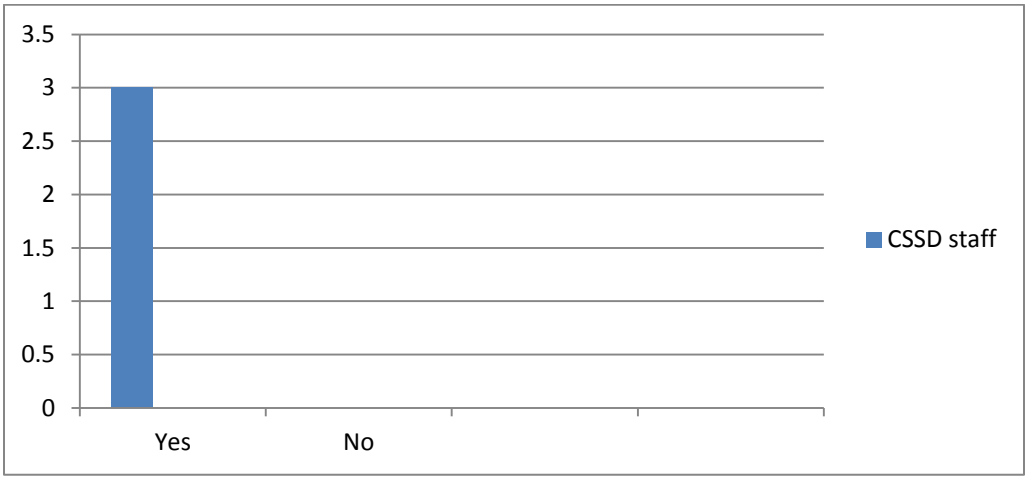
between decontamination area and sterile area. These points will be considered for future studies and will analyze the requirement.

11) If you receive OT schedules will it help you to organize your work?



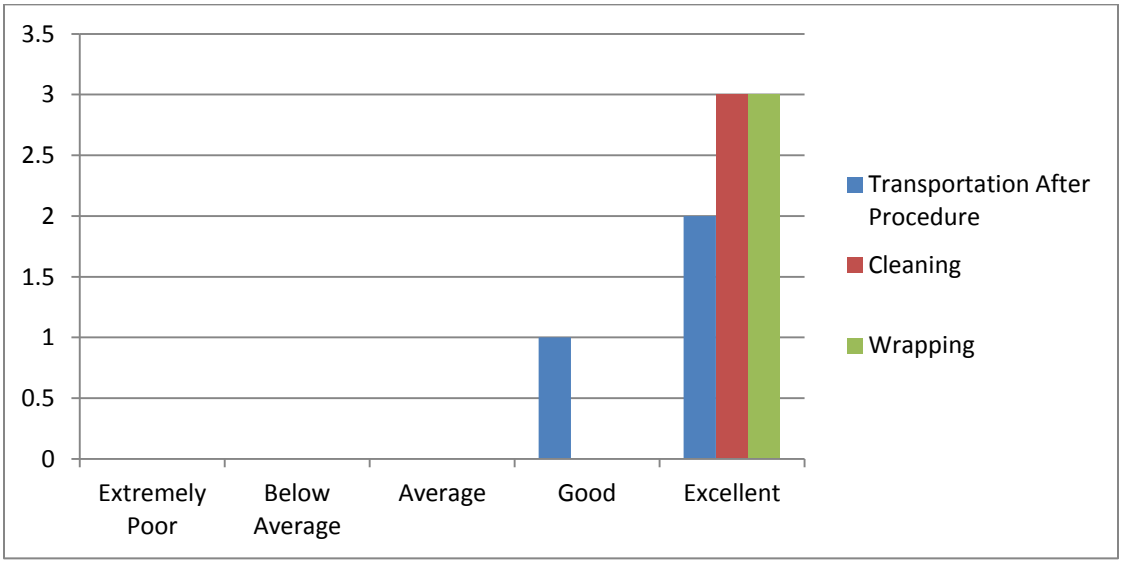
Analysis: All respondents responded positively and will check further methods which will improve the communication among department with CSSD and avoid delays in late receiving and dispatch.

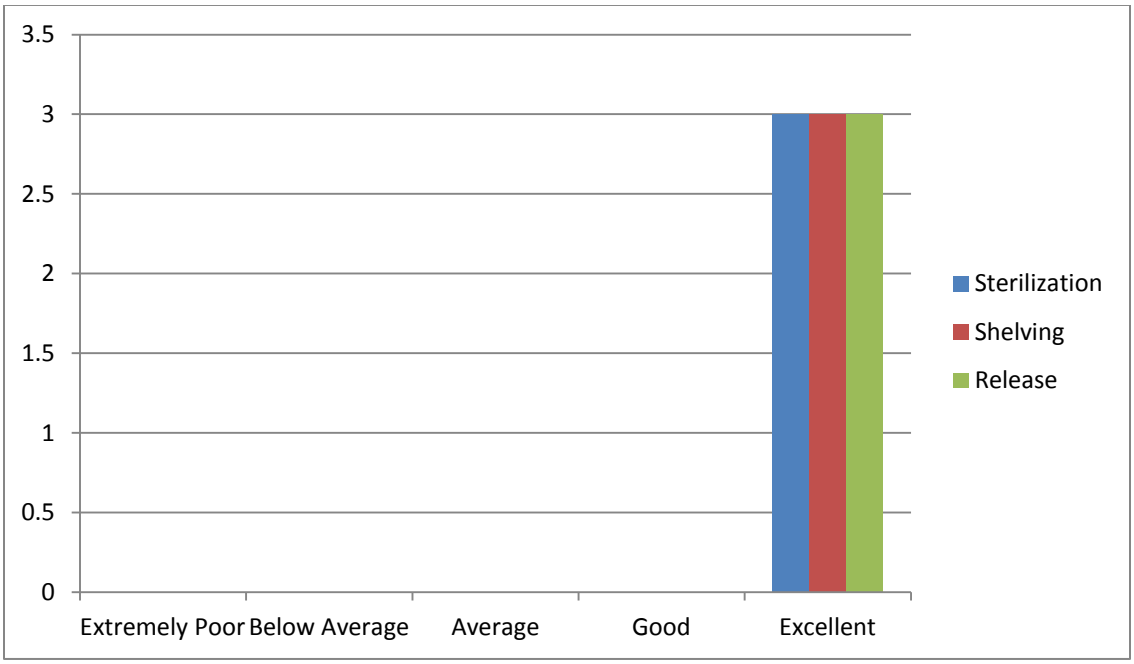
12) Are you satisfied with existing quality control procedure practiced by CSSD?



Analysis: All the respondents are satisfied with the existing quality assurance practice they are following which ensures the operation of the department is in compliance with the international standards. This enhances patient safety and avoids unnecessary risk due to unhealthy practices for the management.

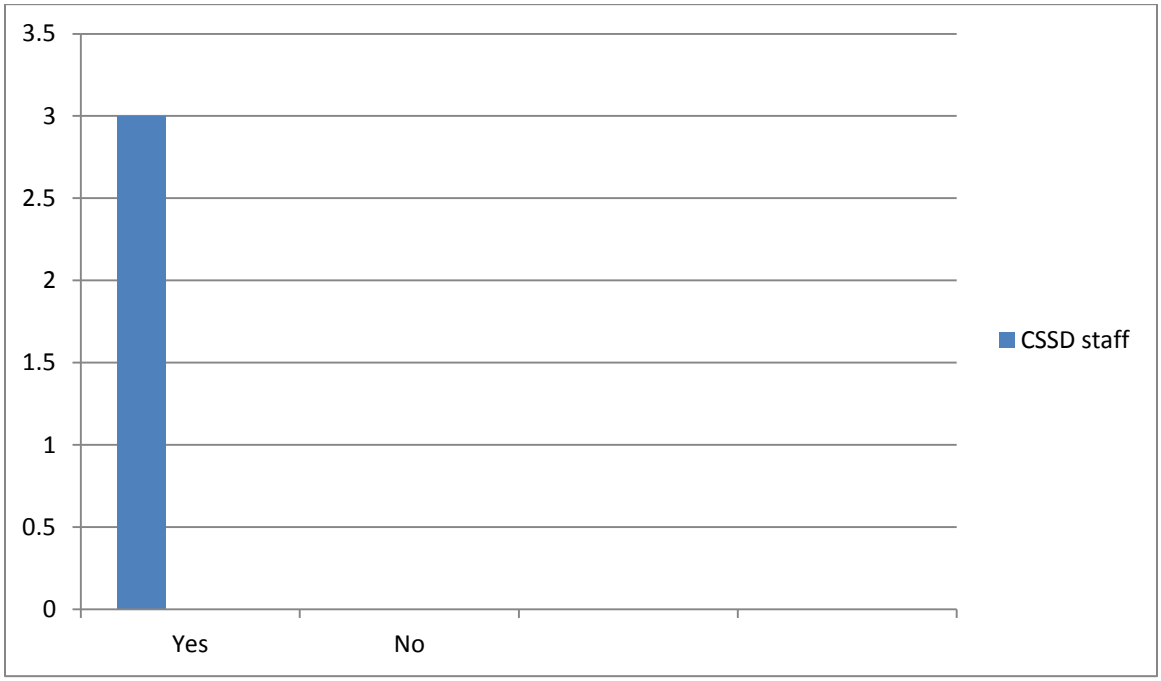
13) How would you rate CSSD performance?





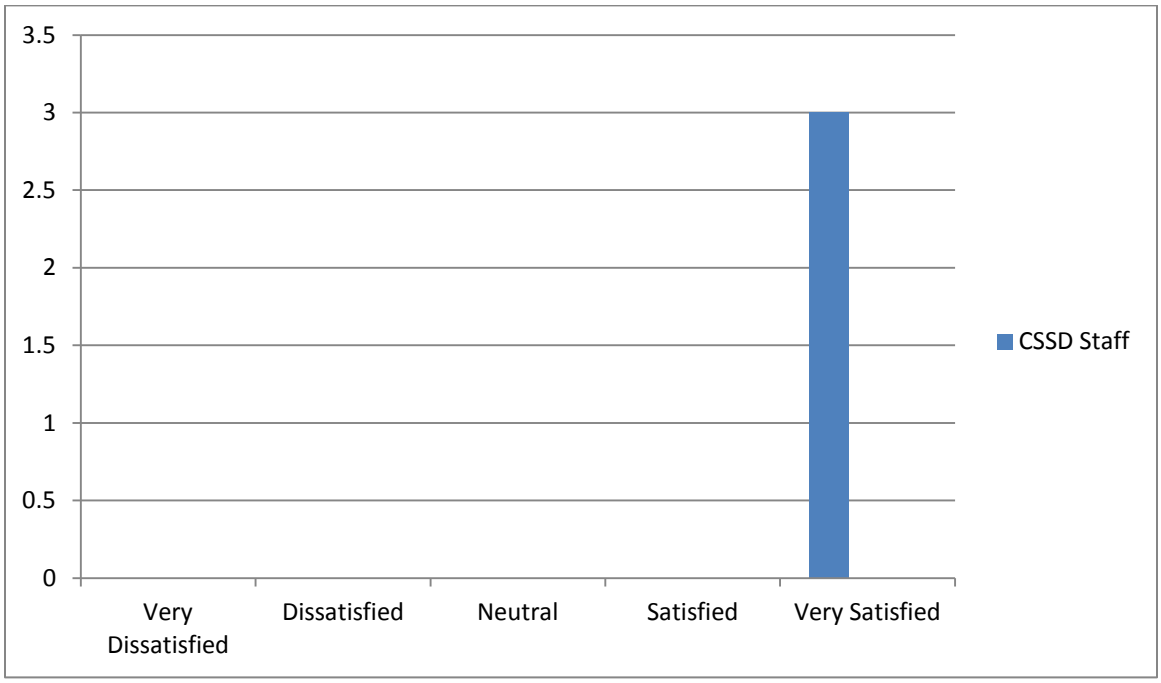
Analysis: According to the CSSD staff, all processes are maintaining excellent standard, except transportation to the CSSD. This is due to delay in receiving instrument or lack of a messenger / transporter to bring contaminated instruments from the department. This will be taken for further analysis in future studies.

14) Have you ever observed any defects on the sterilized instruments after processing?



Analysis: All respondents stated yes to this question. They stated sometimes due to improper drying the instruments will remain wet which makes it unsterile and will make reprocessing of instruments again. This causes additional delays and unnecessary loss of manpower, time and resources which must be prevented.

15) Overall, how satisfied are you, with CSSD operation?



Analysis: This response show positive outlook of the staff and help the management to evaluate the dedication and passion for the job.

16) What recommendation would you offer for improving CSSD performance?

Analysis: Respondents demanded new kind of brushes for accessing dirt from various instruments with complex design. This suggestion seems to be genuine at this point and will be put in the recommendations for the management. Also, lack of a toilet inside the CSSD will cause unnecessary delays because staff has to change from sterile dress to civilian dress to move from CSSD sterile area to outside. This causes delay in operation and degrades performance

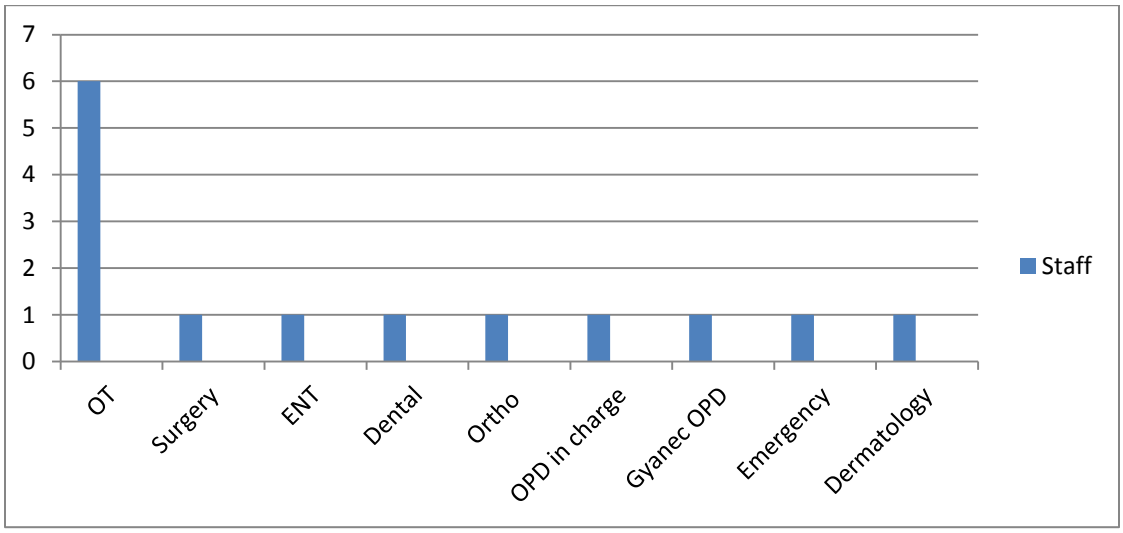
b) CSSD Customer questionnaire result:

Sample size: 14

Universe: Clinical Departments, LLH Hospital, Abu Dhabi

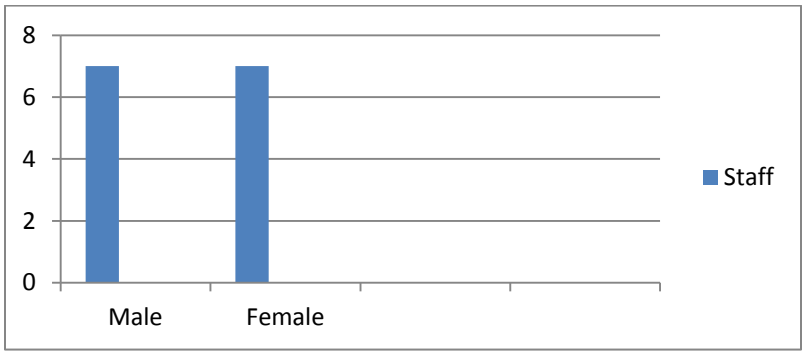
User Details:

1) Department



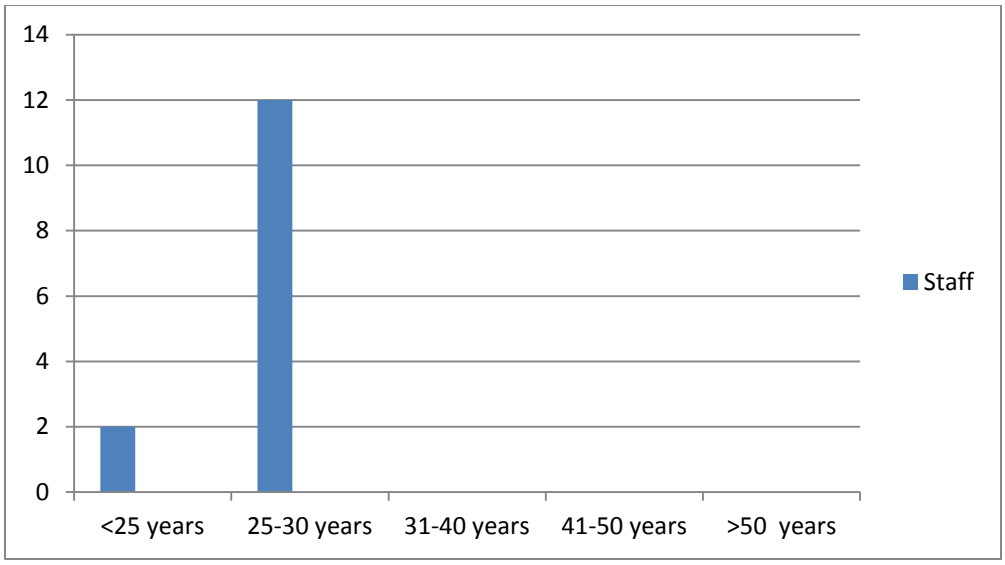
Analysis: Among the respondents, majorities are from Operation theatre dept. and they are the most prominent users of the CSSD. Hence, there participation in this study is useful.

2) Gender



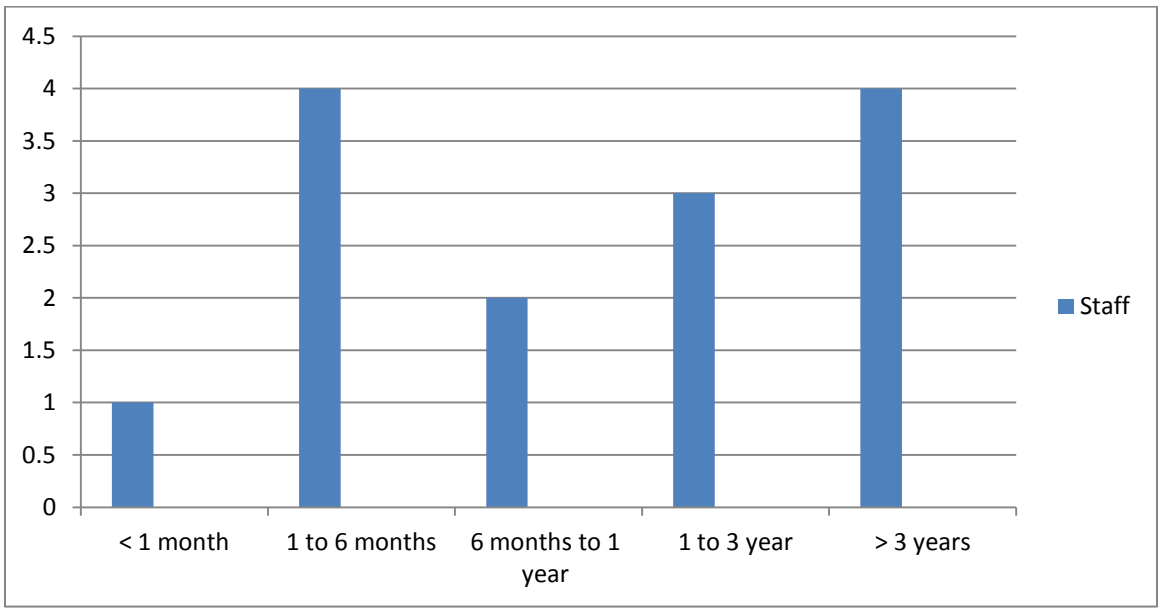
Analysis: Out of the total respondents, there was equal participation from both gender groups which will give more unbiased result.

3) Age



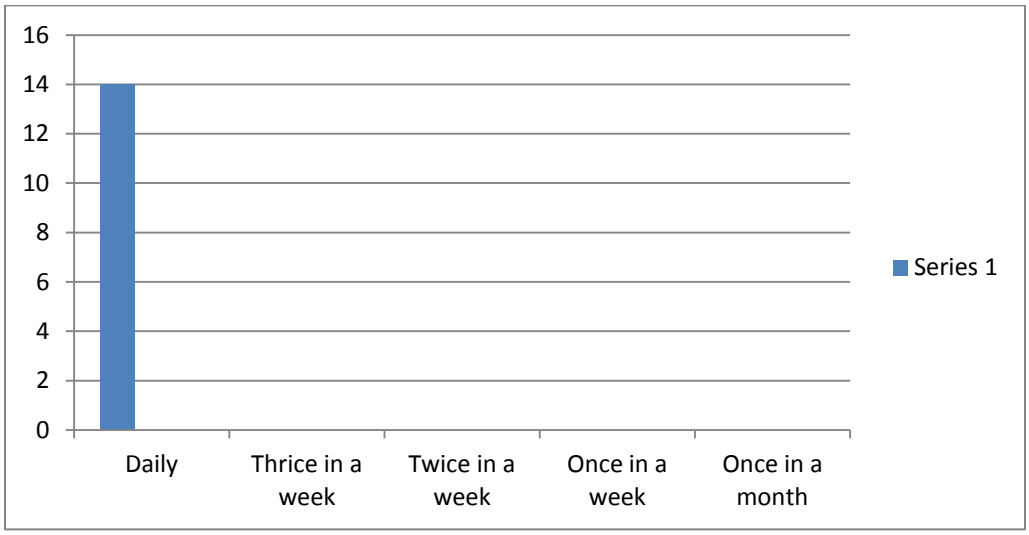
Analysis: Out of the total respondents, all of them are below 30 years which shows they are young and have approx. less than 5 years' experience in healthcare industry.

4) How long have you been using CSSD service?



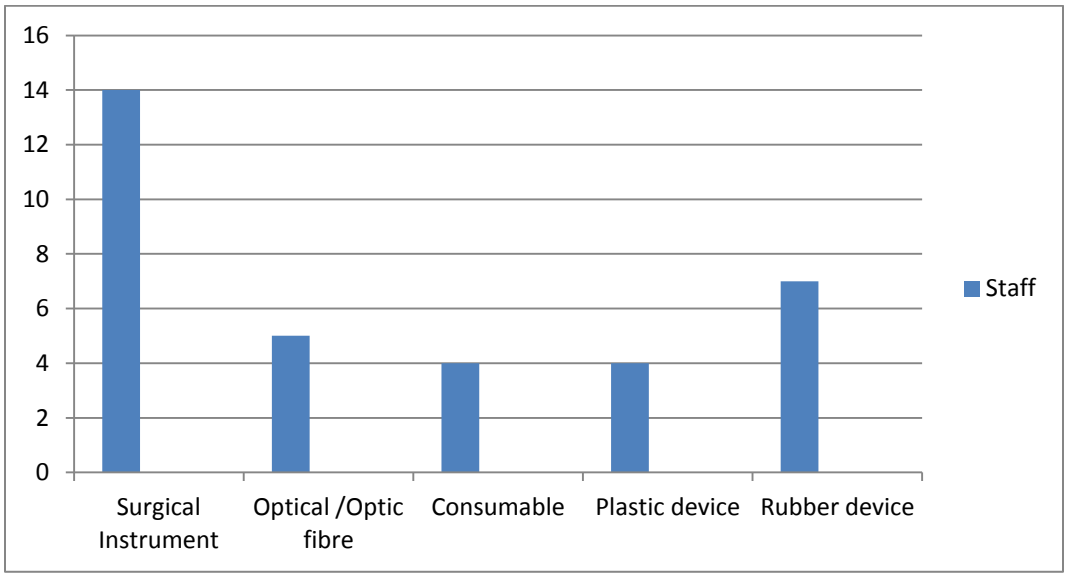
Analysis: This question is considered to be important to relate all other data because if they are not proper user of the service. There is a chance of providing wrong information which leads to wrong decision making by the researcher.

5) How often do you use CSSD?



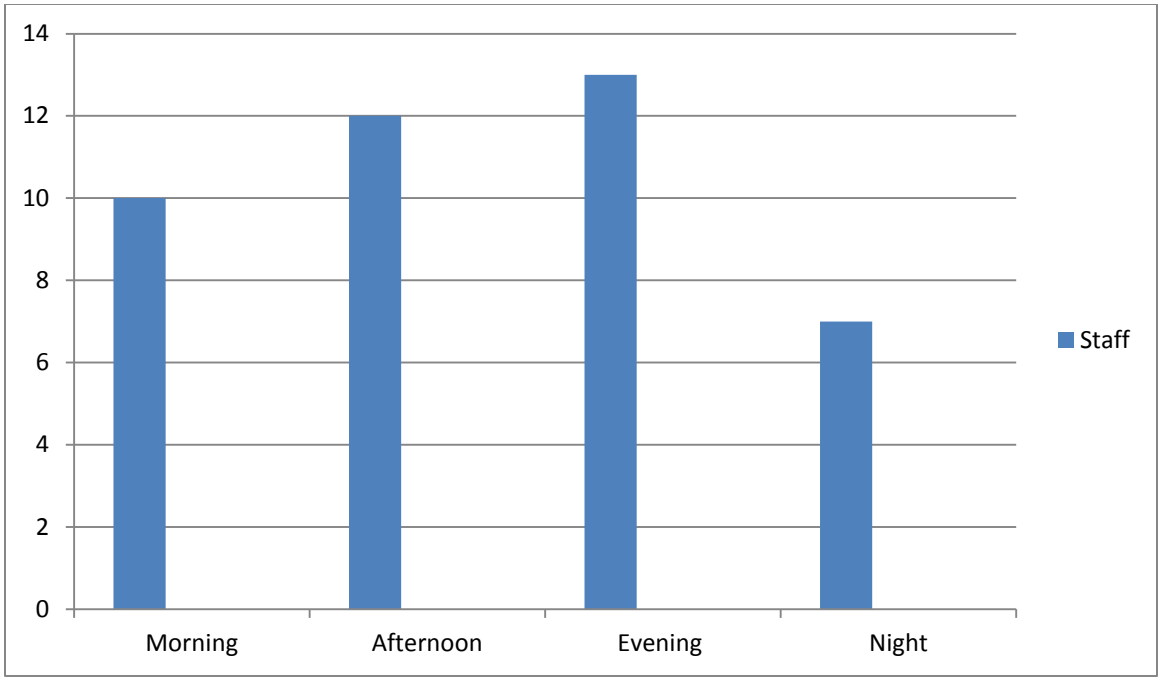
Analysis: Through this data, researcher understands the CSSD service is a critical department. If there is any halt in the CSSD operation, it will affect the whole hospital operation because of its link between almost all departments.

6) What kind of items do you give for sterilization?



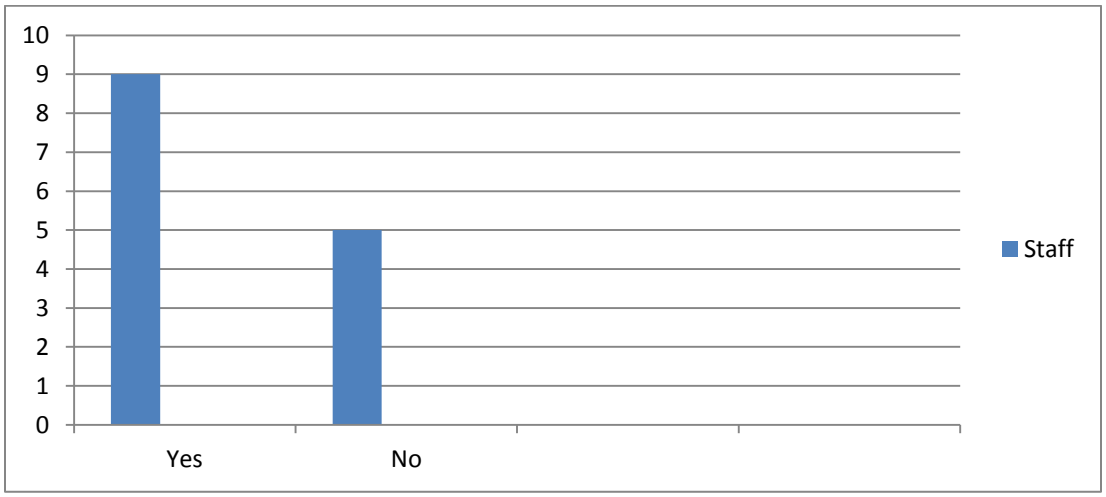
Analysis: This result shows the purpose of the user to depend on CSSD service. From the result, every department uses CSSD service for surgical instrument reprocessing and surgical instrument will be used daily for patient diagnosis.

7) When do you give items for sterilization?



Analysis: Researcher uses this data to analyse the peak hours of CSSD service. This will help to schedule less priority departments in off –peak hours and improve time management of the department.

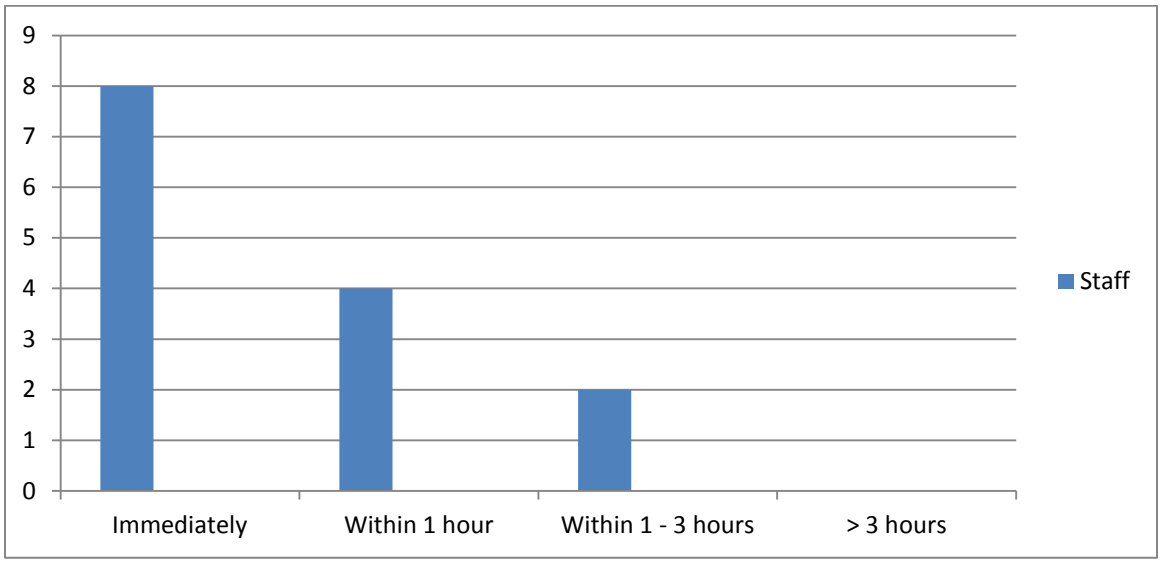
8) Whether blood stains will be present on the instruments?



Analysis: These data helps researcher to analyse depts. That gives blood stained instruments for reprocessing. These departments must bring the instrument immediately because as time after procedure increases blood will become harder and his will affect pre cleaning phase. In this

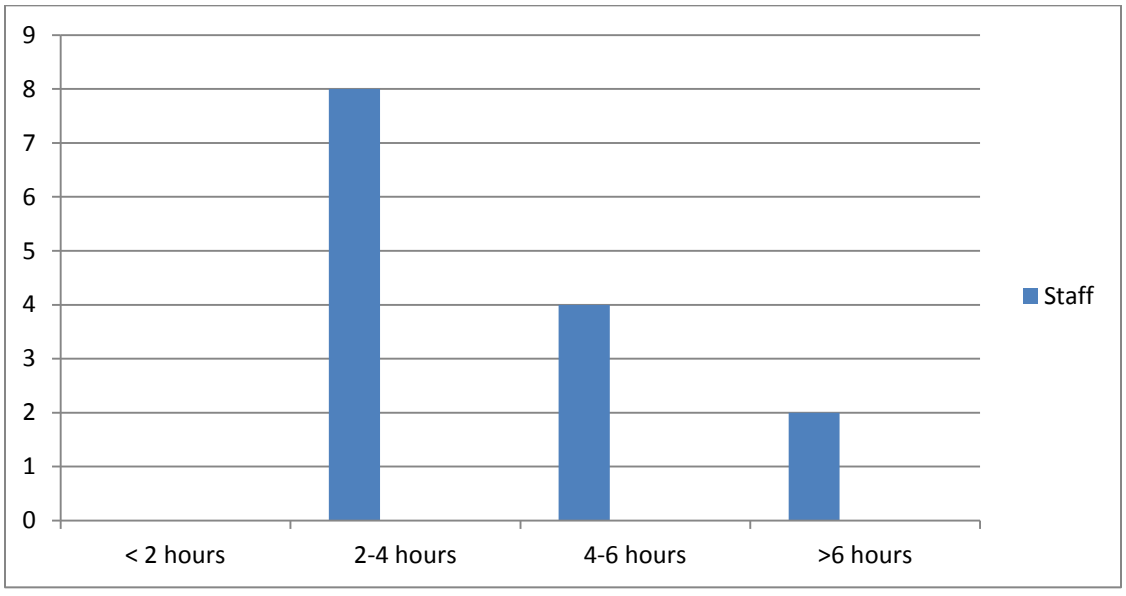
phase, CSSD staff will find difficult to remove hardened blood stains which may result in time lag.

9) When will you sent the contaminated instruments after procedure?



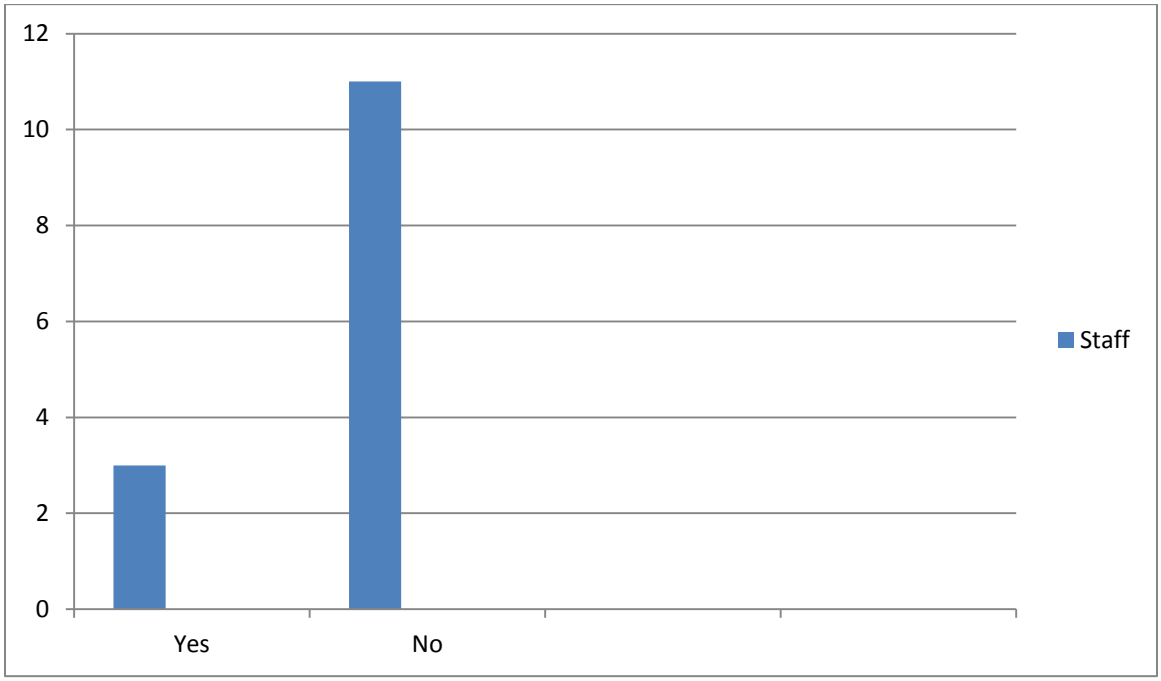
Analysis: This result helps researcher to identify delay in sending instruments by each departments. Some of departments delay because of high volumes of patients and lack of time. Hence, researcher will use this data to recommend suggestion for the management to implement proper transportation channel between all departments and CSSD.

10) When will you receive the items return?



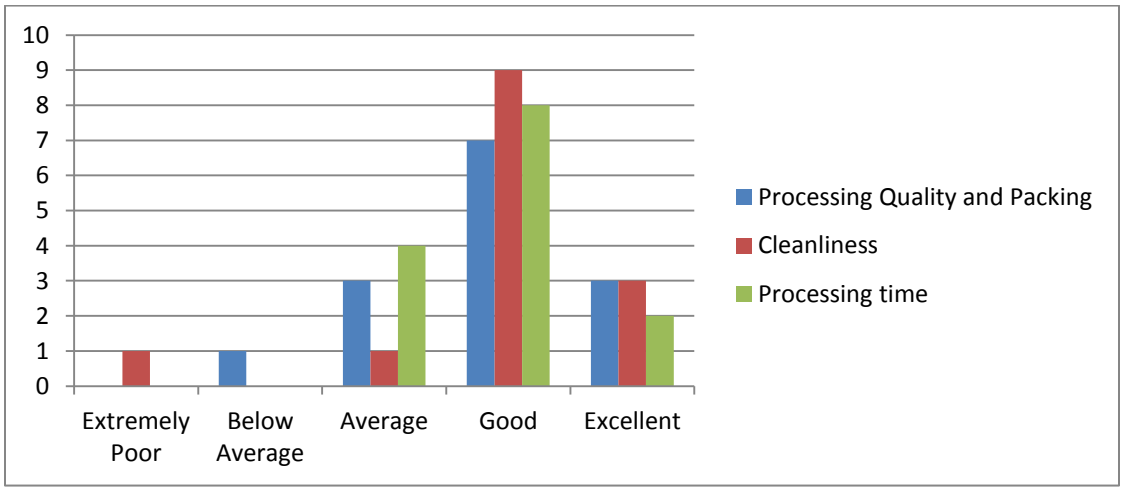
Analysis: CSSD process normally takes 2 – 3 hours. Since, nearly 60% of the customers receive instrument between 2- 4 hours shows CSSD department is working efficiently. But, few customers states it takes more than 6 hours which shows there is a scope of improvement.

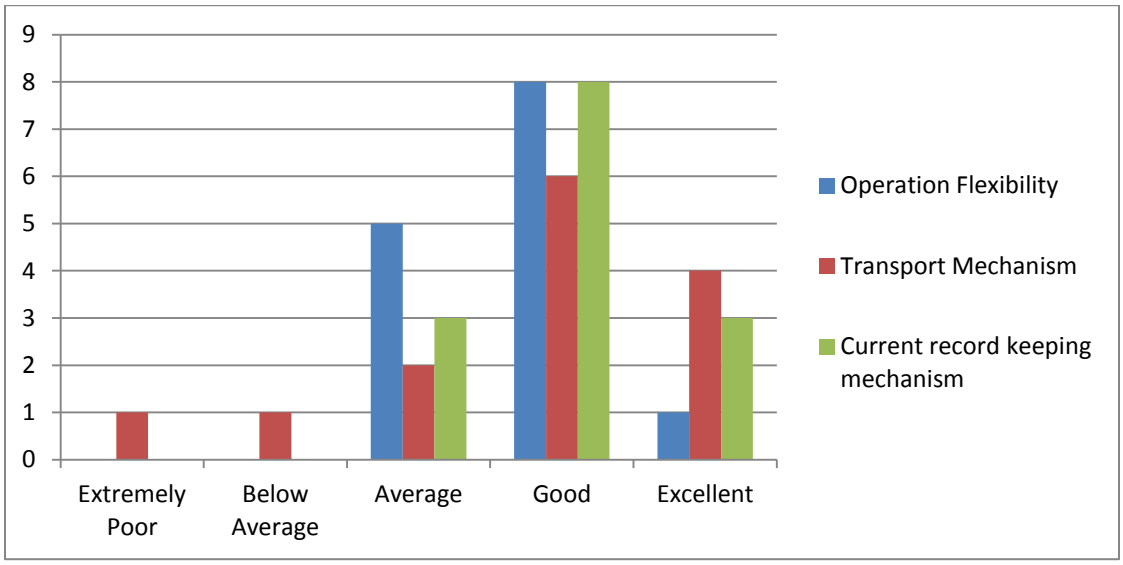
11) Have you ever observed any defect on the sterilized instruments after processing?



Analysis: Researcher attempts to find out the defects in instrument after processing. Defects can be discoloration, improper dirt removal, functional damage etc.3 out of 14 has replied as there was a defect before. Hence, researcher will take this point into consideration in future studies.

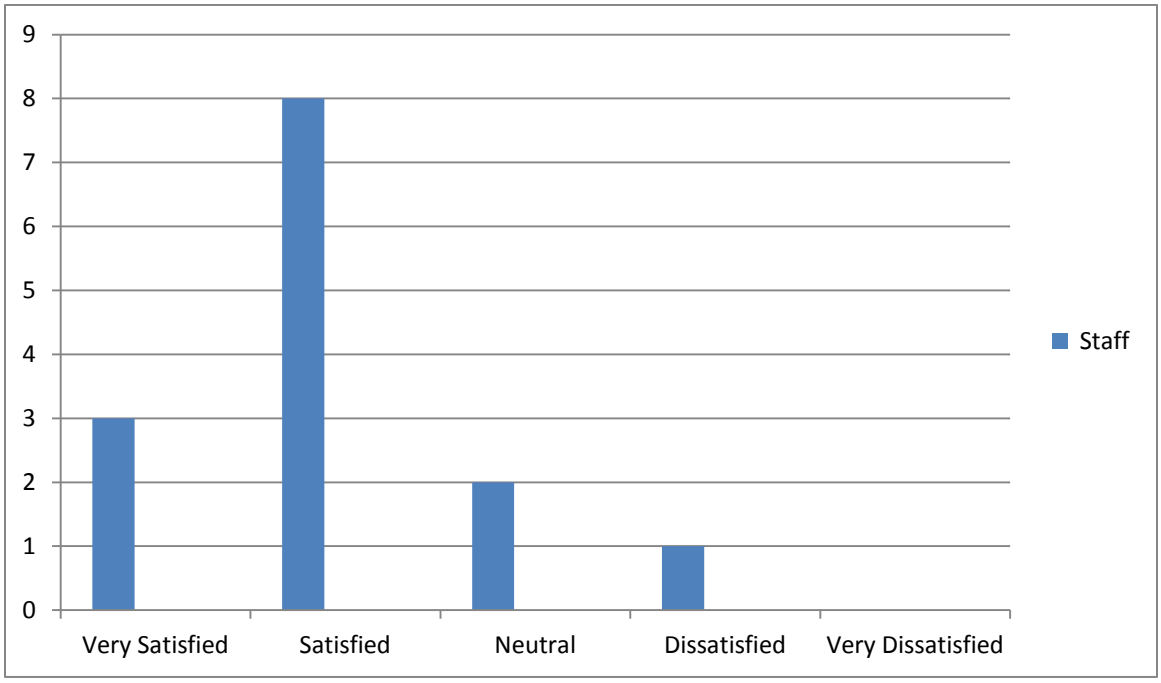
12) How would you rate CSSD performance?





Analysis: These are the factors judging the CSSD efficiency. These data will be further analyzed using Anova to study dependent factors for the efficiency and prove the hypothesis.

18) Overall, how satisfied are you, with CSSD Service?



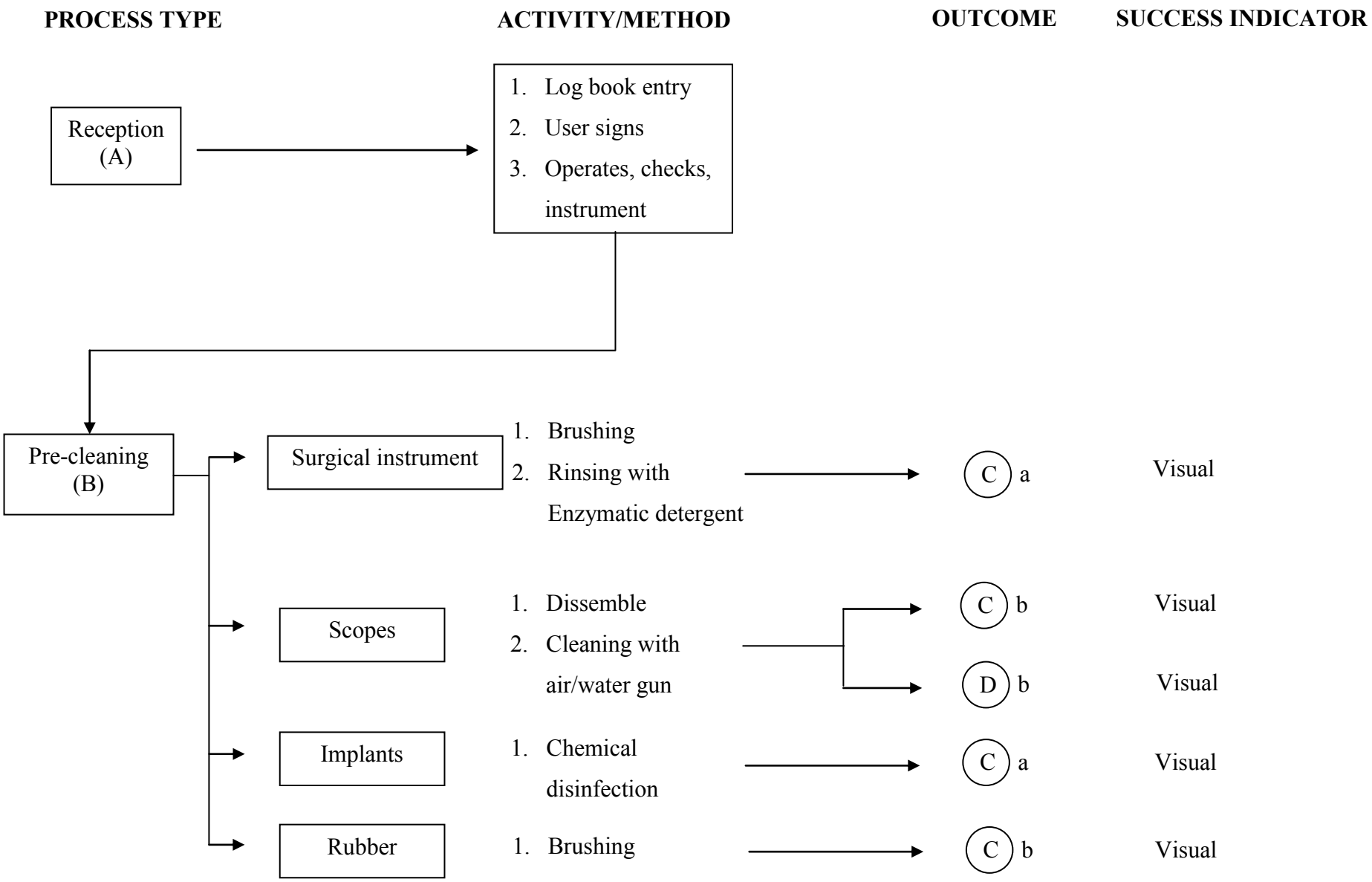
Analysis: Nearly 79 % of respondents are satisfied with the performance of the CSSD service. This is a positive trend for the management and as a researcher it strengthens the study is moving in the right direction.

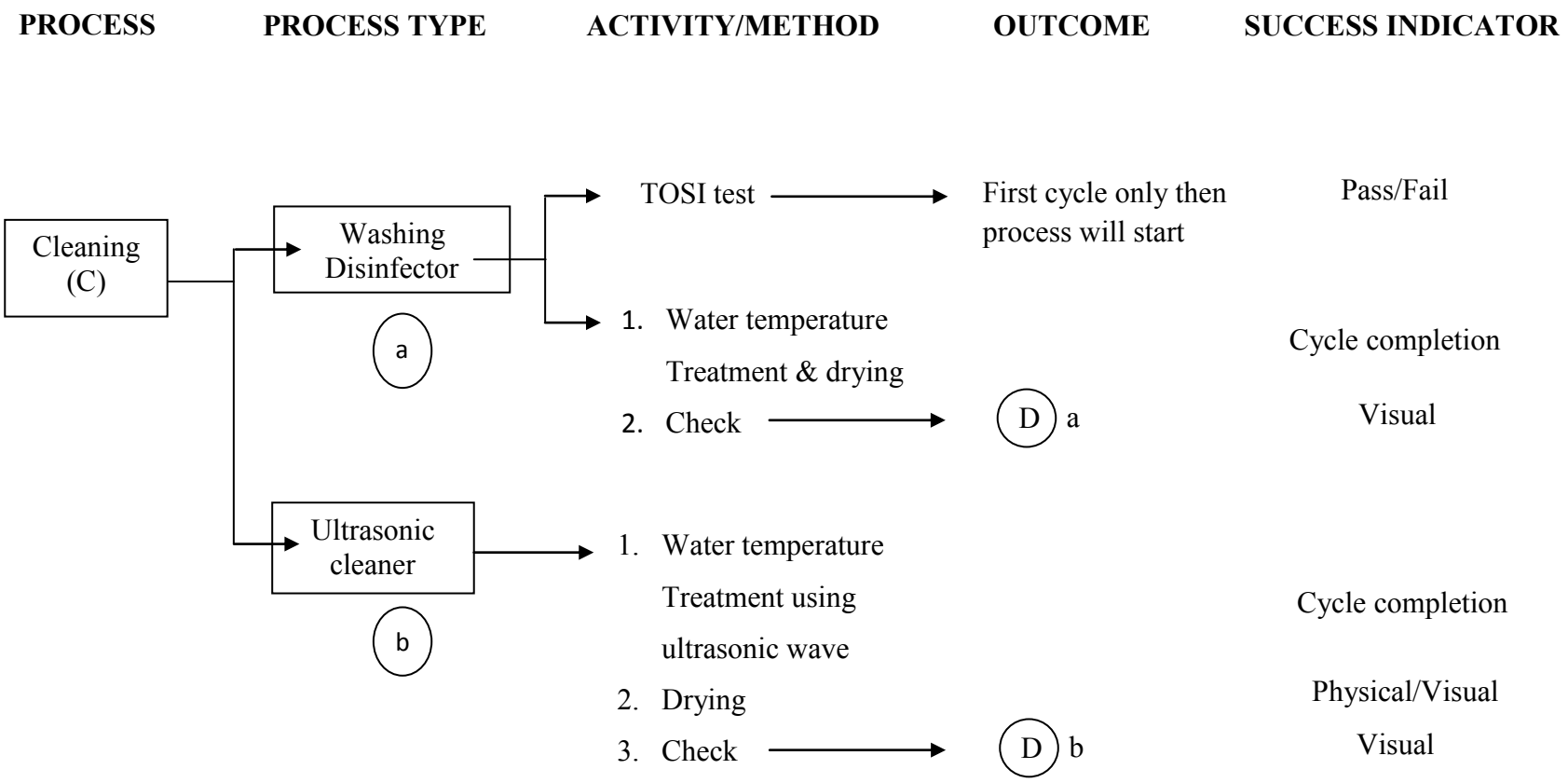
19) What recommendations would you offer for improving CSSD performance?

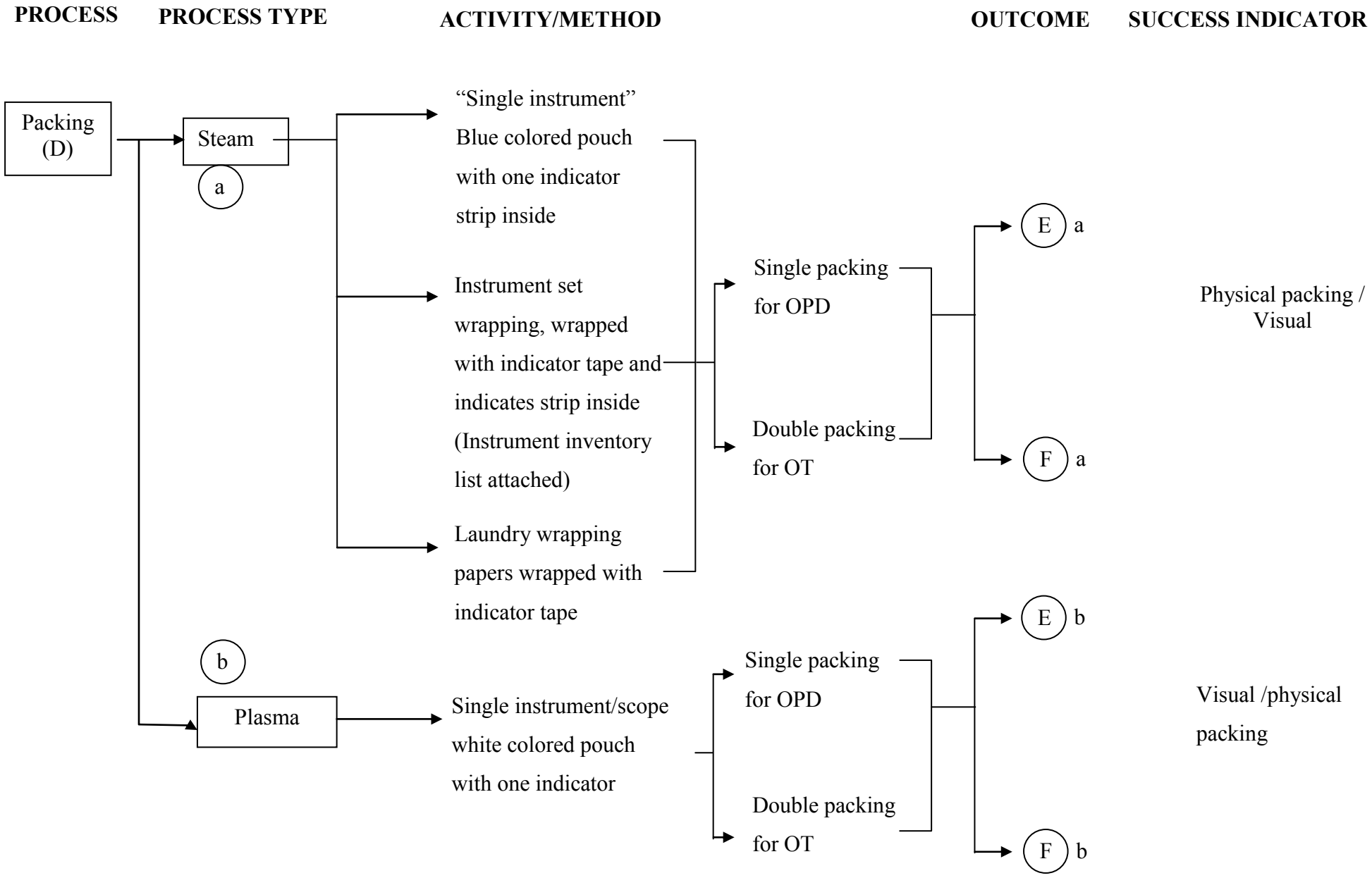
Analysis: Some of the suggestions given by the users are

- Improve handling of dislocated instruments
- Direct communication and transfer channel between OT and CSSD.
- Perform proper disinfection and ensure debris like dental cement from the instrument is removed.
- Maintain packing styles specific to particular department requirement like dental endodontic instruments.

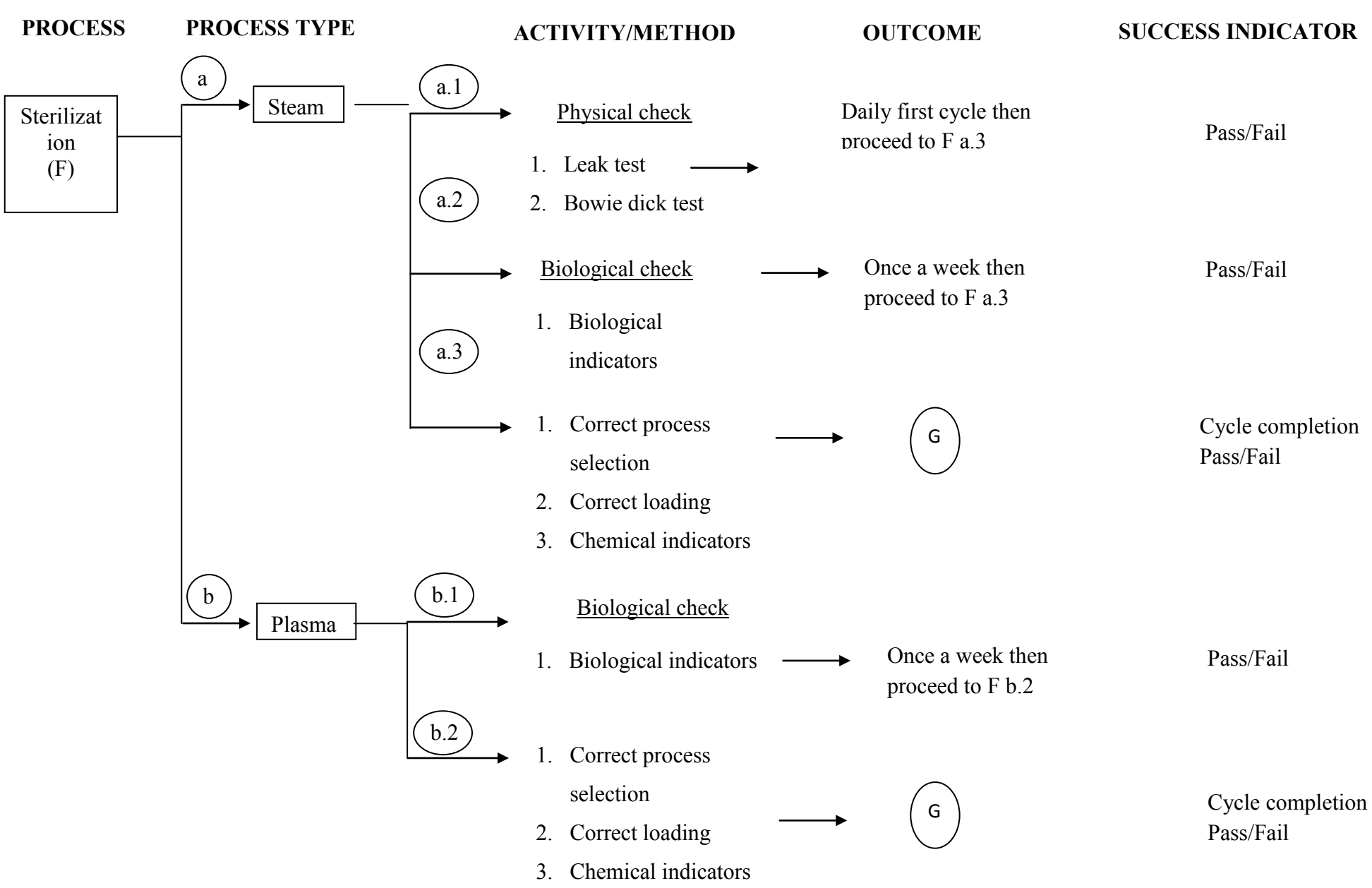
5.2 Objective 2: To determine process map (Value stream) and identify factors affecting each process.




PROCESS
PROCESS TYPE
ACTIVITY/METHOD
OUTCOME
SUCCESS INDICATOR
Cleaning (C)
Washing Disinfector
a
Ultrasonic cleaner
b
TOSI test
First cycle only then process will start
Pass/Fail
1. Water temperature
Treatment & drying
2. Check
D a
Cycle completion
Visual
1. Water temperature
Treatment using ultrasonic wave
2. Drying
3. Check
D b
Cycle completion
Physical/Visual
Visual


PROCESS
PROCESS TYPE
ACTIVITY/METHOD
OUTCOME
SUCCESS INDICATOR
Packing (D)
Steam
a
"Single instrument" Blue colored pouch with one indicator strip inside
Instrument set wrapping, wrapped with indicator tape and indicates strip inside (Instrument inventory list attached)
Laundry wrapping papers wrapped with indicator tape
Single packing for OPD
Double packing for OT
E a
F a
Physical packing / Visual
b
Plasma
Single instrument/scope white colored pouch with one indicator
Single packing for OPD
Double packing for OT
E b
F b
Visual /physical packing

PROCESS	PROCESS TYPE	ACTIVITY/METHOD	OUTCOME	SUCCESS INDICATOR
Sealing (E)	a Steam	Single instrument blue colored pouch sealed at 180 °C and painted with number, packing date and expiry date	F a	Visual/physical packing
	b Plasma	Single instrument blue colored pouch sealed at 130 °C and painted with number, packing date and expiry date	F b	Visual/physical packing


PROCESS
PROCESS TYPE
ACTIVITY/METHOD
OUTCOME
SUCCESS INDICATOR
Sterilization (F)
a
Steam
a.1
Physical check
1. Leak test
2. Bowie dick test
Daily first cycle then proceed to F a.3
Pass/Fail
a.2
Biological check
Once a week then proceed to F a.3
Pass/Fail
a.3
1. Biological indicators
1. Correct process selection
2. Correct loading
3. Chemical indicators
G
Cycle completion Pass/Fail
b
Plasma
b.1
Biological check
1. Biological indicators
Once a week then proceed to F b.2
Pass/Fail
b.2
1. Correct process selection
2. Correct loading
3. Chemical indicators
G
Cycle completion Pass/Fail

PROCESS	PROCESS TYPE	ACTIVITY/METHOD	OUTCOME	SUCCESS INDICATOR
Shelving (G)	Storage system	Store sterilized products department wise	H	Physical/ Visual
Dispatch (H)		1. Data log entry 2. Released to concern departments	END	

Analysis:

Ishikawa diagrams

Ishikawa diagrams (also called fishbone diagrams, herringbone diagrams, cause-and-effect diagrams, or Fishikawa) are causal diagrams created by Kaoru Ishikawa (1968) that show the causes of a specific event. Common uses of the Ishikawa diagram are product design and quality defect prevention, to identify potential factors causing an overall effect. Each cause or reason for imperfection is a source of variation. Causes are usually grouped into major categories to identify these sources of variation.

Brainstorm the major categories of causes of the problem. If this is difficult use generic headings:

- People: Anyone involved with the process
- Methods: How the process is performed and the specific requirements for doing it, such as policies, procedures, rules, regulations and laws
- Machines: Any equipment, computers, tools, etc. required to accomplish the job
- Materials: Raw materials, parts, pens, paper, etc. used to produce the final product
- Measurements: Data generated from the process that are used to evaluate its quality
- Environment: The conditions, such as location, time, temperature, and culture in which the process operates

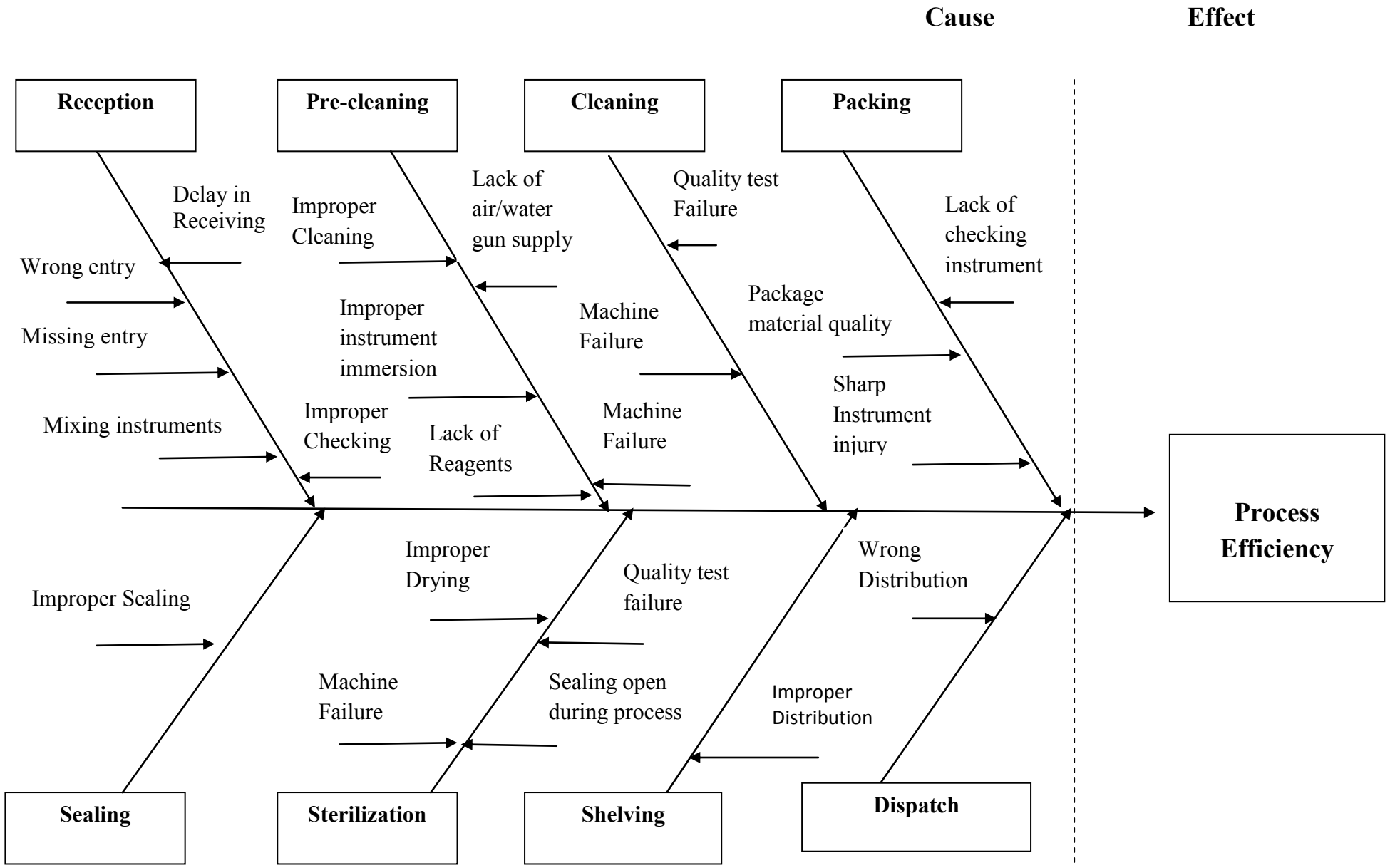


Fig 19 Ishikawa Diagram

5.3 Objective 3: To measure efficiency of the entire process

CSSD efficiency can be measured by CSSD user review regarding following 6 parameters

Processing Quality and Packaging
Cleanliness
Processing time
Operation Flexibility
Transportation mechanism
Current Record Keeping mechanism

Data collected from the CSSD user Questionnaire:

Staff	Process Quality and Packing	Cleanliness	Processing time	Operation Flexibility	Transportation mechanism	Current Record Keeping mechanism
1	4	4	3	3	5	4
2	4	4	5	4	5	5
3	4	4	4	4	3	3
4	5	5	5	5	5	5
5	4	4	4	4	4	4
6	2	3	4	3	2	3
7	4	4	3	4	3	4
8	4	4	4	4	4	4
9	3	4	4	3	4	4
10	4	4	4	4	4	4
11	5	5	3	3	4	4
12	3	1	3	3	1	3
13	3	4	4	4	4	4
14	5	5	4	4	5	5

Analysis:

Null hypothesis for the study (H_0): CSSD department is working efficiently and meets day to day challenges demanded by the hospital.

Alternate Null Hypothesis: CSSD Department is not efficient.

To prove CSSD department is working efficient, all the 6 factors contributing to the efficiency must be efficient .To consider CSSD as efficient we are considering rating 4 (equivalent to good) as references for efficiency. Hence, to prove CSSD as efficient mean of all variables must be equal to 4.

Hence, **Null Hypothesis, H_0** : $\mu_{pq} = \mu_{cl} = \mu_{pt} = \mu_{of} = \mu_{tm} = \mu_{cr} = 4$

And Alternate Hypothesis, **H_1** : Not all mean are equal to 4

Analysis of variance (ANOVA)

ANOVA is a particular form of statistical hypothesis testing heavily used in the analysis of experimental data. A statistical hypothesis test is a method of making decisions using data. A test result (calculated from the null hypothesis and the sample) is called statistically significant if it is deemed unlikely to have occurred by chance, assuming the truth of the null hypothesis. A statistically significant result (when a probability (p-value) is less than a threshold (significance level)) justifies the rejection of the null hypothesis, but only if the a priori probability of the null hypothesis is not high. In the typical application of ANOVA, the null hypothesis is that all groups are simply random samples of the same population. This implies that all treatments have the same effect (perhaps none). Rejecting the null hypothesis implies that different treatments result in altered effects. ANOVA provides a statistical test of whether or not the means of several groups are equal, and therefore generalizes the t-test to more than two groups. Doing multiple two-sample t-tests would result in an increased chance of committing a type I error. For this reason, ANOVAs are useful in comparing (testing) three or more means (groups or variables) for statistical significance.

ANOVA is based on comparing the variance (or variation) between the data samples to variation within each particular sample. If the between variation is much larger than the within variation, the means of different samples will not be equal. If the between and within variations are approximately the same size, then there will be no significant difference between sample means.

Assumptions of ANOVA:

(i) All populations involved follow a normal distribution.

(ii) All populations have the same variance (or standard deviation).

(iii) The samples are randomly selected and independent of one another.

Step 1: Calculation of Sample Mean and Standard Deviation of all variables.

Sample Mean:

Let x_{ij} be the i^{th} independently drawn observation ($i=1,...,N$) on the j^{th} random variable ($j=1,...,K$). These observations can be arranged into N column vectors, each with K entries, with the $K \times 1$ column vector giving the i^{th} observations of all variables being denoted $\mathbf{x}_i$ ($i=1,...,N$). The sample mean vector $\bar{\mathbf{x}}$ is a column vector whose j^{th} element $\bar{x}_j$ is the average value of the N observations of the j^{th} variable:

$$\bar{x}_j = \frac{1}{N}\sum_{i=1}^{N} x_{ij}, \quad j = 1, \ldots, K.$$

Thus, the sample mean vector contains the average of the observations for each variable, and is written

$$\bar{\mathbf{x}} = \frac{1}{N}\sum_{i=1}^{N} \mathbf{x}_i.$$

For instance, Mean of Current Record Keeping mechanism

$$\bar{\mathbf{x}} = (4 + 5 + 3 + 5 + 4 + 3 + 4 + 4 + 4 + 4 + 4 + 3 + 4 + 5) \,/\, 14 = \mathbf{4}$$

Sample Variance

The Variance is defined as the average of the squared differences from the Mean. But if the data is a Sample (a selection taken from a bigger Population), then the calculation changes .When you have "N" data values that are:

- **Population Variance**: divide by **N** when calculating Variance (like we did)

- **Sample Variance**: divide by **N-1** when calculating Variance

  Sample Variance =

For instance, Variance of Current Record Keeping mechanism

Sample Variance = ((4-4) +(5-4) +(3-4)+(5-4)+(4-4)+(3-4)+(4-4)+(4-4)+(4-4)+(4-4)+(4-4)+(3-4)+(4-4)+(5-4)) / (14-1) = **0.461538**

$$\frac{1}{N-1}\sum_{i=1}^{N}(x_i-\overline{x})^2$$

Groups	*Count*	*Sum*	Mean	*Variance*
Processing Quality and Packaging	14	54	3.857143	0.747253
Cleanliness	14	55	3.928571	0.994505
Processing time	14	54	3.857143	0.43956
Operation Flexibility	14	52	3.714286	0.373626
Transportation mechanism	14	53	3.785714	1.412088
Current Record Keeping mechanism	14	56	4	0.461538

Step 2: Calculate the appropriate test statistic

The test statistic in ANOVA is the ratio of the *between* and *within* variation in the data. It follows a F distribution.

Step 3: Calculate the SST

Total Sum of Squares (SST) : It is the total variation in the data. It is the sum of the between and within variation.

Total Sum of Squares = $\sum_{i=1}^{r}\sum_{j=1}^{c}(X_{ij}-\overline{\overline{X}})^2$

Where r is the number of rows in the table, c is the number of columns, $\overline{\overline{X}}$ is the grand mean, and Xij is the i th observation in the j th column

$\overline{\overline{X}}$ = (sum $_{pq}$ + sum $_{cl}$ + sum $_{pt}$ + sum $_{of}$ + sum $_{tm}$ + sum $_{cr}$) / (n $_{pq}$ + n $_{cl}$ + n $_{pt}$ + n $_{of}$ + n $_{tm}$ + n $_{cr}$)

= (54+55+54+52+53+56) / (14 * 6)

= **3.857**

Hence, **SST** = ((4-3.857)^2 + (4-3.857)^2 + ……. + (4-3.857)^2 + (5-3.857)^2) = **58.28571**

Step 4: Calculate the SSTR

Between Sum of Squares (Treatment Sum of Squares**)** – It is the variation in the data between the different samples (or treatments).

Treatment Sum of Squares (SSTR) = $\sum r_j (\overline{X}_j - \overline{\overline{X}})^2$ where r_j is the number of rows in the j th treatment and $\overline{X}_j$ is the mean of the j th treatment.

SSTR = ((14*($\overline{\mathbf{X}}_{pq}$ - $\overline{\overline{X}}$)^2) + (14*($\overline{\mathbf{X}}_{cl}$ - $\overline{\overline{X}}$)^2) +(14*($\overline{\mathbf{X}}_{pt}$ - $\overline{\overline{X}}$)^2) +(14*($\overline{\mathbf{X}}_{of}$ - $\overline{\overline{X}}$)^2) + (14*($\overline{\mathbf{X}}_{tm}$ - $\overline{\overline{X}}$)^2) +(14*($\overline{\mathbf{X}}_{cr}$ - $\overline{\overline{X}}$)^2))

= ((14*(3.857 - 3.857)^2) + (14*(3.928 - 3.857)^2) +(14*(3.857 - 3.857)^2) +(14*(3.714 - 3.857)^2) + (14*(3.785 - 3.857)^2) + (14*(4 - 3.857)^2))

SSTR = 0.714286

Step 5: Calculate the SSE

Within variation (or Error Sum of Squares) :It is the variation in the data from each individual treatment.

Error Sum of Squares (SSE) = $\sum\sum (X_{ij} - \overline{X}_j)^2$

SSE= [$((4-3.857)^2 + (4-3.857)^2+\ldots\ldots\ldots\ldots+(5-3.857)^2) + ((4-3.928)^2+(4-3.928)^2+\ldots+(5-3.928)^2) + ((3-3.857)^2+(5-3.857)^2+\ldots..+(4-3.857)^2) + ((3-3.714)^2+(4-3.714)^2+\ldots..+(4-3.714)^2)$

$+ ((5-3.785)^2+(5-3.785)^2+\ldots\ldots\ldots\ldots+ (5-3.785)^2) + ((4-4)^2+(5-4)^2+(5-4)^2)]$

SSE = 57.57143

Note : SST= SSTR + SSE

= 0.714286 + 57.57143

= 58.28571

Step 6 : To compute the "average" sources of variation in the data using SST, SSTR, and SSE.

a) Total Mean Squares (MST) :

MST is the average total variation in the data, where N is the total number of observations

MST = SST / (N-1)

= 58.2851 / (84 - 1)

= **0.7022301**

b) Mean Square Treatment (MSTR)

MSTR is the average between variations, where c is the number of columns in the data table

MSTR = SSTR / (c-1)

= 0.714286 / (6-1)

= 0.1428572

c) Mean Square Error (MSE)

MSE is the average within variation.

MSE = SSE / (N-c)

=57.57143 / (84 - 6)

= **0.73809525**

Note: MST ≠ MSTR + MSE

Step 7: Calculate F
The test statistic may now be calculated. For a one-way ANOVA the test statistic is equal to the ratio of MSTR and MSE. This is the ratio of the "average between variation" to the "average within variation." In addition, this ratio is known to follow an F distribution.
Hence, F = MSTR / MSE

= 0.1428572 / 0.73809525

= **0.193548**

The intuition here is relatively straightforward. If the average between variation lowers relative to the average within variation, the F statistic will decrease and so will our chance of accepting the null hypothesis.

Step 8: Obtain the critical value

To find the critical value from an F distribution you must know the numerator (MSTR) and denominator (MSE) degrees of freedom, along with the significance level. F_{CV} has df1 and df2 degrees of freedom, where df1 is the numerator degrees of freedom equal to c-1 and df2 is the denominator degrees of freedom equal to N-c.

In this case, df1 = 6 - 1 = 5 and df2 = 84 - 6 = 78. Hence value for $F_{CV}\ 5,78$ corresponding to α= 5%. Using the F tables in your text we determine that $F_{CV}\ 5,78$ = **2.331**

Step 9 : Decision Rule:

The null hypothesis will be accepted if: F (observed value) < F_{CV} (critical value). In this case, **0.193548 < 2.331**. So, **Researcher accepts the null hypothesis.**

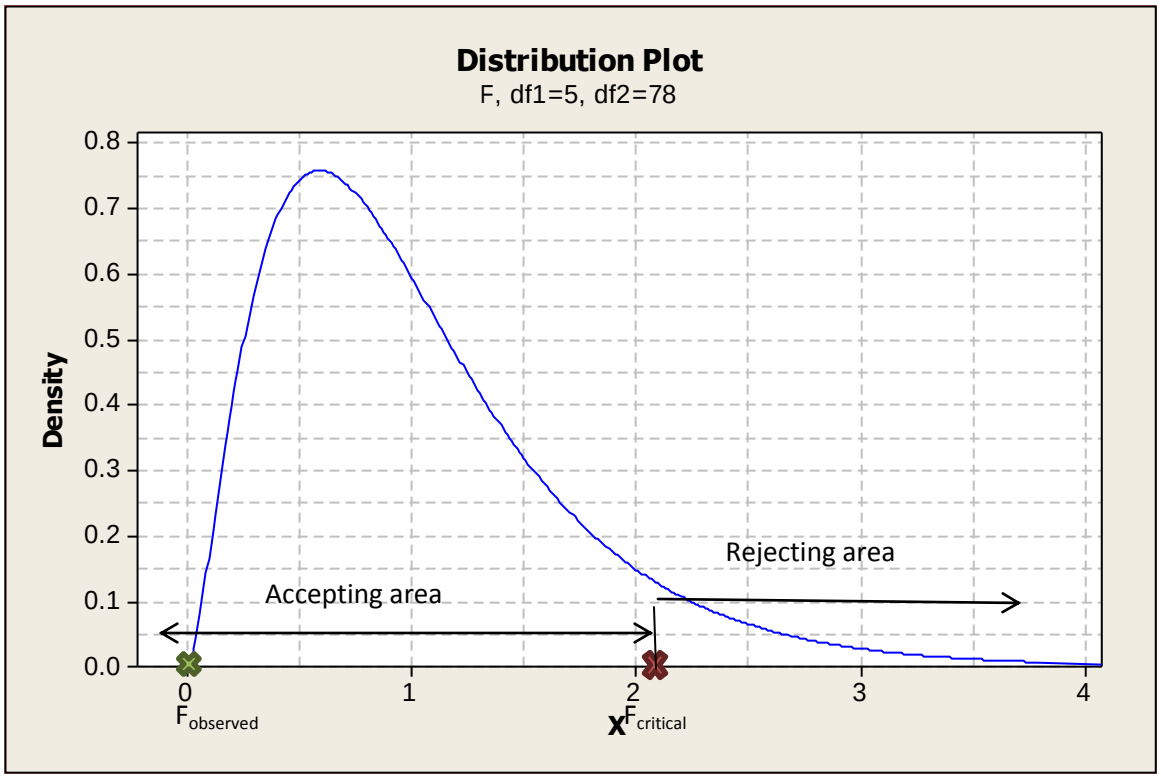


Fig 20: F-test graph

Individual value Plot representation of data

Individual Value plots are graphs that are useful for comparing groups of data. Individual Value plots are very similar to Dot Plots except that data points are displayed vertically instead of horizontally as in a dot plot. Individual Value Plots can help visualize which data values occur the most often and give us an idea of the minimum and maximum values.

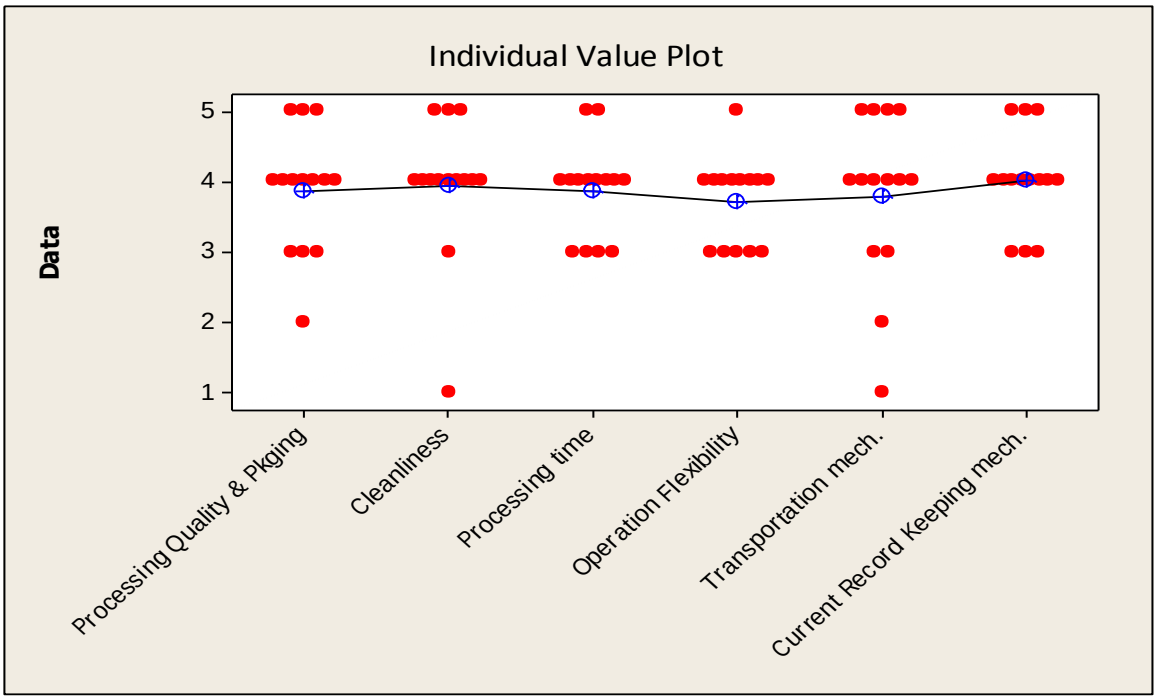


Fig 21: Individual Value plot representation of the data

Interpretation and Discussion:

A one-way between subjects ANOVA was conducted to compare the mean of CSSD user ratings for individual variables which constitute efficiency of CSSD. One-way ANOVA compares 6 unmatched groups, based on the assumption that the populations are Gaussian.

Result Summary:

SUMMARY

Groups	*Count*	*Sum*	*Average*	*Variance*
Processing Quality and Packaging	14	54	3.85714	0.74725
Cleanliness	14	55	3.92857	0.99451
Processing time	14	54	3.85714	0.43956
Operation Flexibility	14	52	3.71429	0.37363
Transportation mechanism	14	53	3.78571	1.41209
Current Record Keeping mechanism	14	56	4	0.46154

ANOVA

Source of Variation	*SS*	*df*	*MS*	*F*	*F crit*
Between Groups	0.714286	5	0.142857	0.193548	2.331739
Within Groups	57.57143	78	0.738095		
Total	58.28571	83			

ANOVA partitions the variability among all the values into one component that is due to variability among group means (due to the treatment) and another component that is due to variability within the groups (also called residual variation).

Variability within groups (within the columns) is quantified as the sum of squares of the differences between each value and its group mean. This is the residual sum-of-squares. In this case, SSE = 57.57143 .Variation among groups (due to treatment) is quantified as the sum of the squares of the differences between the group means and the grand mean (the mean of all values in all groups).In this case, SSTR=0.714286.Since, this value is small, it shows sample means are closer to each other.

Each sum-of-squares is associated with a certain number of degrees of freedom (df, computed from number of subjects and number of groups), and the mean square (MS) is computed by dividing the sum-of-squares by the appropriate number of degrees of freedom. Under the null hypothesis of no difference between population means (and assuming that standard ANOVA regularity assumptions are satisfied) the sums of squares have scaled chi-squared distributions, with the corresponding degrees of freedom. In this case, Degree of freedom for between groups, df1 is 5 and degree of freedom for within group, df2 is 78.

The F-test statistic is the ratio, after scaling by the degrees of freedom. The F ratio is the ratio of two mean square values. In this case ratio is 0.19358. This value gives probability of accepting null hypothesis is more and basic assumption put forward by researcher during initial stage is true. A large F ratio means that the variation among group means is more than you'd expect to see by chance. Large F ratio is obtained when the null hypothesis is wrong (the data are not sampled from populations with the same mean) and when random sampling happened to end up with large values in some groups and small values in others. In this case, df1 = 6 - 1 = 5 and df2 = 84 - 6 = 78. Hence value for F_{CV} 5,78 corresponding to α= 5%. Using the F tables in your text we determine that F_{CV} 5,78 = 2.331.Since, F (observed value) < F_{CV} (critical value) statistically it is proved that mean of all variables are equal to 4.

To further analyze Anova result, the coefficient of determination, denoted R^2 is used which indicates how well data points fits a statistical model. It is a statistic used in the context of statistical models whose main purpose is either the prediction of future outcomes or the testing of hypotheses, on the basis of other related information. It provides a measure of how well observed outcomes are replicated by the model, as the proportion of total variation of outcomes explained by the model

R^2 =1- (SSTR/SST) = 1-(0.714286/58.28571)

=1-0.0122

= **98.78%**

In general, the higher the R-squared, the better the model fits your data. Since, R^2 value closer to 100% indicates that the model explains all the variability of the response data around its mean. The more variance that is accounted for by the regression model the closer the data points will fall to the fitted regression line. Theoretically, if a model could explain 98.78% of the variance, the fitted values would nearly equal the observed values and, therefore, all the data points would fall on the fitted regression line. Hence, It supports the data from Anova, that result from one factor of efficiency is closely related to the other factors.

Result:

CSSD is working efficiently based on the data obtained from the CSSD users

5.4 Objective 4: To recommend process improvement suggestion using PDCA methodologies

FMEA

Failure modes and effects analysis (FMEA) [10] is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service. "Failure modes" means the ways, or modes, in which something might fail. Failures are any errors or defects, especially ones that affect the customer, and can be potential or actual. "Effects analysis" refers to studying the consequences of those failures. Failures are prioritized according to how serious their consequences are, how frequently they occur and how easily they can be detected. The purpose of the FMEA is to take actions to eliminate or reduce failures, starting with the highest-priority ones.

Failure modes and effects analysis also documents current knowledge and actions about the risks of failures, for use in continuous improvement. FMEA is used during design to prevent failures. Later it's used for control, before and during ongoing operation of the process. Ideally, FMEA begins during the earliest conceptual stages of design and continues throughout the life of the product or service.

Begun in the 1940s by the U.S. military, FMEA was further developed by the aerospace and automotive industries. Several industries maintain formal FMEA standards.

Application of FMEA:

- When a process, product or service is being designed or redesigned, after quality function deployment.
- When an existing process, product or service is being applied in a new way.
- Before developing control plans for a new or modified process.
- When improvement goals are planned for an existing process, product or service.

- When analyzing failures of an existing process, product or service.
- Periodically throughout the life of the process, product or service

Steps involved in preparing FMEA:

A typical FMEA consists of the following steps:

1. Identify the process to be analyzed. Typically, this is a main process for the organization.

2. Assemble and train the team. Processes usually cross functional boundaries and, therefore, the analysis should be performed by a team of relevant personnel. No one person or persons from a single functional area will have the knowledge needed to perform the analysis.

3. Develop a detailed process flowchart, including all steps in the process.

4. Identify each step (or function) in the process.

5. Identify potential failures (or failure modes) at each step in the process. Note that there may be more than one potential failure at each step.

6. Determine the worst potential consequence (or effect) of each possible failure.

7. Identify the cause(s) (contributory factors) of each potential failure. A root cause analysis can be helpful in this step. Note that there may be more than one cause for each potential failure.

8. Identify any failure "controls" currently present. A control reduces the likelihood of causes or failure occurring, reduces the severity of an effect, or enables the detection of the occurrence of a cause or failure before it leads to the adverse effect.

9. Rate the severity of each effect (on a scale of 1-10, with 10 being the most severe). This rating should reflect the impact of any controls that reduce the severity of the effect.

10. Rate the likelihood (occurrence score) of each cause occurring (on a scale of 1-10, with 10 being certain to occur). This rating should reflect the impact of any controls that reduce the likelihood of occurrence.

11. Rate the effectiveness of each control (on a scale of 1-10, with 1 being an error free detection system).

12. Multiply the three ratings by one another to obtain the Risk Priority Number (RPN) for each cause or contributory factor.

13. Use the RPNs to prioritize problems for corrective action. All causes which result in an effect with a severity of 10 should be high on the priority list, regardless of RPN.

14. Develop an improvement plan to address the targeted causes (who, when, how assessed, etc.)

FMEA PROJECT: Improve Efficiency of CSSD Service

FMEA goal:	To decrease failures in CSSD processes
Project leader:	Mr. Moh'd Hamad
Team members:	Mrs.Hodan,Mrs.Julian,Mr.Faiz and Ms Shiji
Date prepared:	15TH May 2014

#	Process Function (Step)	Potential Failure Modes (process defects)	Potential Failure Effects (KPOVs)	Potential Causes of Failure (KPIVs)	SEV	OCC	Current Process Controls	DET	RPN	Recommend Actions	Responsible Person & Target Date	SEV	OCC	DET	RPN
1	Reception	Wrong / Missing Entry	Loss of instrument tracking	Customer carelessness and lack of time	6.25	5.25	Log book Entry	4	131.25	Check during receiving and sending	CSSD head	6	4	2	50
2	Reception	Mixing	Loss of instrument tracking	More than two customers come and left instruments in hurry	5	5.25	Log book Entry	4	105	Count loud and write by the customer /introduce inventory management system	CSSD head	5	4	2	40
3	Reception	Improper Checking of defects in instrument	Customer and CSSD staff will blame on each other if any defects found after sterilization	Lack of detailed instrument checking or due to lack of time	6.75	5.25	Visual inspection	4.75	168.33	Introduce magnifying lamp for detailed instrument check	CSSD head	6.75	4	2	54
4	Reception	Receiving instrument without Personal protective equipments	Lack of staff	Possibility of staff infection from contaminated instruments	10	2.25	N/a	3.25	73.13	Strict monitoring of plastic apron and gloves	Infection Control in charge	10	2.25	3	67.5
5	Reception	Delay in receiving instrument	Delay in pre-cleaning	Stains harden due to delay	3.5	6.25	N/a	2.75	60.16	Implement time schedule	Dept. head	2	4	2.75	22
6	Pre-cleaning	Improper cleaning	Ineffective dirt removal	Improper technique/old brushes/improper brush size	6	5.75	N/a	4.25	146.63	Intend & store the required brushes	Stores & CSSD head	5	5	4.5	112.5

7	Pre-cleaning	Unavailability of reagent	Cant process	Ineffective cleaning	8	6	Stock replenish every 10 days	3.75	157.50	Intend & store before stock depletes	Stores & CSSD head	6	5	3	90
8	Pre-cleaning	Ineffective pre cleaning	Ineffective dirt removal	Not maintaining minimum time of instrument immersion in reagent/improper dilution rate	6	5.75	N/a	4.5	155.25	Strict use of measuring cup to maintain proper dilution rate	CSSD head & Infection control	5	5	3	75
9	Pre-cleaning	Presence of dental cement after sterilization	Ineffective dirt removal	Staff finds difficulty removing cement because of its chemical properties.	6.25	5.75	N/a	4.75	170.70	Visual inspection and use of effective chemicals	CSSD head & Infection control	6	5	3	90
10	Pre-cleaning	Scope Instrument disassembly and reassembling lag	Increases process time	Wrong reassembling /parts missing/parts damage	4	4.25	N/a	3.5	59.50	Conduct manufacturer training by the suppliers about cleaning	CSSD Head	4	3	2	24
11	Pre-cleaning	Lack of air/water gun cleaning	Ineffective cleaning	Lack of air/water supply/gadget malfunction	6.5	3.5	Inform to maintenanc e department	2.5	56.88	Daily check before operation	CSSD Head and staff	6	3.5	2	42
12	Pre-cleaning	Ultrasound cleaner not working	Ineffective cleaning	Machine error	5.75	3.5	Inform to biomedical/ supplier	2	40.25	Daily check before operation	CSSD Head and staff	5	3	2	30
13	Cleaning	Quality test failure	Can't process	Failure of tosi test	8.25	4	Inform to biomedical/ supplier	2.75	90.75	Daily monitoring / repeat test	CSSD Head	8	3	2	48
14	Cleaning	Cleaner disinfectant not working/leakin g	Can't process	Machine error/Gasket failure	8	6	Inform to biomedical/ supplier	3.25	156.00	Perform routine checkup	CSSD Head and staff	8	5	2	80
15	Cleaning	Cleaner disinfector not drying	Ineffective cleaning	Improper drying	7.25	6.25	Manual drying by staff	2.5	113.28	Check instrument before proceeding to next process	CSSD Head and staff	7	5	2	70
16	Cleaning	Instrument missing inside Cleaner disinfectant	Instrument tracking loss	Instrument will get trapped inside machine	4.75	3.5	Manual searching inside machine	4.5	74.81	Check while unloading for trapped instrument	CSSD Head and staff	4.5	3	3	40.5

17	Packing	Sharp Instrument injury without PPE	Lack of staff	Possibility of staff infection from contaminated instruments due to injury	10	2.25	N/a	3.25	73.13	Use of Heavy duty gloves	Infection Control	10	2	3	60
18	Packing	Absence of Quality indicator strip in the pouch	Uncertainty about instrument status	Staff accidently skips strip insertion	6	4	N/a	4.5	108.00	Monitoring and checking	CSSD Head and staff / Infection control	6	4	4	96
19	Packing	Lack of double packing for OT instruments	Easily contaminated	Staff accidently skips double packing	7.25	4	N/a	4	116.00	Monitoring and checking	CSSD Head and staff/ infection control	7	3	4	84
20	Packing	Lack of checking instrument	Loss of instrument tracking	Small /minor Instrument may get miss after cleaning process	5	4.5	N/a	4.75	106.88	Log book comparison before packing	CSSD Head and staff	5	3	3	45
21	Sealing	Improper sealing	Will affect sterilization process	Machine or packing material problem	5.25	4	Inform biomedical/ supplier	4	84	Check user settings / Biomedical action	CSSD Head and staff	5	3	3	45
22	Sterilization	Can't process	Machine error	Gasket failure/improper vacuum/lack of water supply	7	5.25	Inform biomedical/ supplier	1.75	64.31	Check user settings / Biomedical action	CSSD head	7	4	1	28
23	Sterilization	Improper drying	Instrument s will be wet	Sterilizer error	7	4.25	Inform biomedical/ supplier	3.75	111.56	Check user settings / Biomedical action	CSSD Head	7	4	3	84
24	Sterilization	Quality test failure	Cant process	Failure of bowie dick or Biological indicator test	7.75	3.5	Inform biomedical/ supplier	2.25	61.03	Monitoring and checking	CSSD Head and staff/ infection control	7	3	2	42
25	Sterilization	Packing will get opened during sterilization	Generates uncertainty about quality of instrument processed	Low quality of the pouches or improper sealing	6.5	3.5	Reprocessing	3	68.25	Inspection before transferring	CSSD Head and staff	6	3	3	54

26	Shelving	Wrong placement of instruments	Loss of instrument tracking	Staff Carelessness / lack of time	5.5	5.25	N/a	5	144.38	Proper labeling and partition should be made	CSSD Head and staff	5	5	4	100
27	Dispatching	Improper distribution	Loss of instrument tracking /delay in receiving	Lack of proper communication / lack of messenger /lack of cross checking by user as well as staff	6	5.25	N/a	5	157.50	Perform cross checking by messenger and cssd staff before dispatch	CSSD Head and staff	6	4	4	96
28	CSSD staff	Absence of staff	Process delay / reduction in efficiency	Increased number of OR cases	6.25	4.25	N/a	2	53.13	Redesign workflow to suit demand	Quality dept.	6	4	2	48
					Total				**2908**		Total				**1718**

AIAG Compelled Rating			
Rating	Severity of Effect	Likelihood of Occurrence	Ability to Detect
10	Hazardous without Warning	Very high; Failure is almost inevitable	Can not detect
9	Hazardous with Warning	Very high; Failure is almost inevitable	Very remote chances of detection
8	Lose of primary function	High; Repeated failures	Remote chances of detection
7	Reduced primary function performance	High; Repeated failures	Very low chances of detection
6	Lose of secondary function	Moderate; Occasional failures	Low chances of detection
5	Reduced secondary function performance	Moderate; Occasional failures	Moderate chances of detection
4	Minor defect noticed by most customers	Moderate; Occasional failures	Moderate high chances of detection
3	Minor defect noticed by some customers	Low; Relatively low failures	High chances of detection
2	Minor defect noticed by discriminating customers	Low; Relatively low failures	Very high chances of detection
1	No effect unlikely	Remote; Failure is unlikely	Almost certain

Participant data:

Shiji	Hodan	Julian	fiaz	SEVERITY	Shiji	Hodan	Julian	fiaz	Occurrence	Shiji	Hodan	Julian	fiaz	Detectability	RPN
7	6	7	5	6.25	7	7	4	3	5.25	5	4	4	3	4	131.25
7	6	5	2	5	6	7	5	3	5.25	5	5	3	3	4	105.00
8	7	7	5	6.75	6	4	6	5	5.25	5	3	8	3	4.75	168.33
10	10	10	10	10	2	3	2	2	2.25	2	6	3	2	3.25	73.13
4	3	5	2	3.5	7	6	6	6	6.25	4	3	2	2	2.75	60.16
5	5	7	7	6	6	6	6	5	5.75	4	4	6	3	4.25	146.63
8	9	7	8	8	5	7	4	5	5.25	5	4	4	2	3.75	157.50
6	9	7	2	6	7	6	5	5	5.75	5	5	6	2	4.5	155.25
7	8	5	5	6.25	7	6	5	5	5.75	7	4	6	2	4.75	170.70
2	6	3	5	4	6	4	2	5	4.25	6	5	2	1	3.5	59.50
6	6	7	7	6.5	5	4	2	3	3.5	4	3	2	1	2.5	56.88
8	8	3	4	5.75	4	5	2	3	3.5	3	2	2	1	2	40.25
8	9	8	8	8.25	6	6	2	2	4	2	6	2	1	2.75	90.75
8	9	8	7	8	7	6	6	5	6	3	5	3	2	3.25	156.00
8	9	4	8	7.25	7	3	10	5	6.25	4	4	1	1	2.5	113.28
2	6	4	7	4.75	6	2	4	2	3.5	5	7	5	1	4.5	74.81
10	10	10	10	10	2	3	2	2	2.25	2	8	2	1	3.25	73.13
5	9	5	5	6	5	5	2	4	4	7	2	8	1	4.5	108.00
7	8	7	7	7.25	6	5	4	1	4	6	2	7	1	4	116.00
3	6	6	5	5	6	6	4	2	4.5	5	7	5	2	4.75	106.88
4	6	6	5	5.25	5	5	5	1	4	5	6	4	1	4	84.00
6	6	8	8	7	7	4	5	5	5.25	3	1	2	1	1.75	64.31
8	8	6	6	7	4	4	3	6	4.25	4	2	8	1	3.75	111.56
8	9	8	6	7.75	5	3	4	2	3.5	3	3	2	1	2.25	61.03
4	8	7	7	6.5	5	3	4	2	3.5	7	2	2	1	3	68.25
5	7	7	3	5.5	5	8	6	2	5.25	7	7	5	1	5	144.38
5	7	9	3	6	6	5	8	2	5.25	7	7	5	1	5	157.50
5	5	7	8	6.25	4	7	5	1	4.25	2	3	2	1	2	53.13

Analysis and Interpretation:

Risk Priority Number

In Risk Management, risk is the combination of severity of the harm and probability that it will occur. For medical device manufacturers, the relevant standard is ISO 14971:2007 which uses this definition of risk. The traditional method develops a two dimensional table in which the cells represent risk acceptability. Risk Management identifies hazards and tracks them through a sequence of events that creates a hazardous situation. This hazardous situation could result in harm to people, property, or the environment. The resulting harm has a severity and a probability of occurrence

One common approach in FMEA calculates a Risk Priority Number (RPN). Each failure (mode) has an assigned severity, probability, and detectability values. This common approach uses the following qualitative scale for ranking.

•The severity score (S) is an integer between 1 and 10, where the most severe is a 10

•The probability score (P) is an integer between1 and 10, where the highest probability is 10

•The detectability score (D) is an integer between 1 and 10 where most difficult to detect is 10.

The RPN is the product of the three ranks. For example, with S = 5, P = 3, D = 6, the RPN is 90 = (5)(3)(6). The RPN is not a measure of risk, but of risk priority. The RPN generates a model to allocate these risk prone resources. Higher numbers are higher priority.

Result:

In this research RPN value before control measures is **2907.56** and RPN value obtained after rating the impact of suggested recommendation for each possible failure in the process it reduced to **1717.5**.This implies a reduction of nearly **41%.**This result will provide a greater insight for the management to understand the risk factor regarding CSSD and take necessary action which will improve the performance better and safer.

Chapter 6

Findings, Suggestion and Conclusion

Findings

Through a deep analysis of the operation of CSSD during course of the research, as a researcher, Researcher learned the complexity and impact of maintaining efficiency of a CSSD department for the proper functioning of the hospital. CSSD works on management principles such as teamwork, dedication and time management. Following are the major findings of the research:

1) CSSD is linked with multiple departments' day to day operation with the service it delivers. Hence, management must give special consideration in the daily operations of the department. During the survey, all the customers are daily users of CSSD and most of them uses 3 times a day. There must be quick mechanism for purchasing and decision making process regarding CSSD.

2) Since, CSSD is a complex system; the research was conducted on two dimension of CSSD operation – Process wise and service wise. This is very important to troubleshoot various aspects of CSSD issues. Researcher found this approach is effective during the course of research and gives valuable insight of CSSD operation.

3) Nearly 79% of CSSD users are satisfied with the performance of CSSD. While rest of them are concerned with lack of proper disinfection and cleaning, improper handling of instruments and lack of proper communication and transport with the department.

4) CSSD process normally takes 2 – 3 hours. Since, nearly 60% of the customers receive instrument between 2- 4 hours shows CSSD department is working efficiently. But, few customers states it takes more than 6 hours which shows there is a scope of improvement. Various factors affecting this issue are due to lack of appropriate staff with respect to the increase in the volume of the work increased during recent period. During survey, all respondents stated they lack enough staff; there is an urgent requirement for a staff with respect to the workload.

5) During the course of the research, process flow chart was prepared to get detailed outlook of the process performed in CSSD, this study helped the researcher deeper understanding of various process and conducting future studies based on this findings.

6) CSSD's efficiency have been measured processing quality and packing, cleanliness, processing time, operation flexibility, transport mechanism and current record keeping mechanism. Through ANOVA analysis done on the CSSD user ratings, CSSD found to be "Good "in all 6 variables of CSSD efficiency. This states that CSSD is running efficiently.

7) FMEA study was also conducted during research to analyse possible failures in each process. This research was useful to evaluate CSSD's preparedness against unfavourable condition and through the research, researcher has attempted to give an insight to various aspects of failure and recommended control action which was rated "Good "by the participants and can reduce failures by 41%.

8) According to the CSSD staff, all processes and quality assurance methods are maintaining excellent standard, except transportation to the CSSD. This is due to delay in receiving instrument or lack of a messenger / transporter to bring contaminated instruments from the department.

Suggestion

1) CSSD faces shortage of manpower to run day to day operation smoothly because of recent increase in the workload. As per study, researcher recommends additional one CSSD staff.

2) Delay in receiving instrument degrades the CSSD performance due to extra effort to remove hardened blood stains. Hence; a quick and efficient transportation mechanism must be implemented to maintain good performance level. Introduction of on demand messenger will help to resolve this problem.

3)Due to introduction of a double doored washer disinfector will help in improving several deficiencies of cleaning process such as frequent machine error due to gasket failure and improper drying, unwanted wastage due to unnecessary motion by CSSD staff to transfer instrument from one process to another.

4) Implementation of software based instrument tracking system which can fully automated sterilization data capture and management in SPD and OR. The advantage of software based instrument tracking instrument are Bar code scans or drop down lists create records for trays or peel packs, reduces OR based sterilization & eliminates manual records and complete record for audits & root cause analysis.

5)Usage of double action reagents for cleaning and disinfection will help in improving instrument cleaning process and maintain zero defects which leads to high quality CSSD operation.

6) Building a toilet inside the CSSD ensures maximum utilization of manpower and can convert more duty time productive.

7) Providing adequate training to the CSSD staff ensures safe and better handling of instruments and can improve performance as well as instrument handling defects.

Conclusion

The Central Sterile Service Department is one of the vital departments of the hospital which performs cleaning and sterilization of used surgical instruments after Operation theatre procedure. Today, CSSD is facing several challenges such as higher surgical volumes, overburdened process capacities, lack of viable sterile process outsourcing alternatives, expensive machineries, etc. Administrators have learned that simply increasing spending on capital equipment, space, instrumentation and human resources has not assured the long-term solutions needed to effectively address these concerns .Hence, hospital management must implement strategies for maximum utilization of available resources without compromising quality and safety. Through this research, researcher attempts to identify possible causes which affect efficiency of the CSSD. Researcher attempts to found the current performance level of the department and suggest necessary improvement recommendation which will help to maintain consistent performance by the CSSD. Research also helped to get deeper understanding about LLH organisation and teamwork which maintains hospitals dignity and success in the healthcare industry. In summary, LLH hospital's CSSD is currently running efficiently and meets day to day challenges demanded by the hospital.

ANNEXURE

Questionnaire
for CSSD customers of LLH Hospital, Abu Dhabi

The information gathered will be used to improve the efficiency of Central Sterile Service Department (CSSD) workflow.

User Profile	
Department:	
Male or female:	☐ Male ☐ Female
Age:	☐ < 25 ☐ 25—30 ☐ 31—40 ☐ 41—50 ☐ > 50
CSSD Efficiency Survey	
How long have you been using CSSD service?	☐ Less than one month ☐ One to six months ☐ Six months to one year ☐ 1 to 3 years ☐ More than 3 years
How often do you use CSSD?	☐ Daily ☐ Thrice in a week ☐ Twice in a week ☐ Once in a week ☐ Monthly
What kind of items do you give for sterilization? *(Customer can tick more than one items)*	☐ Surgical Instrument ☐ Optical/Optical Fiber based Scope ☐ Consumables ☐ Plastic Devices ☐ Rubber Devices

When do you give items for sterilization? *(Customer may tick more than one if they use the service more than once in a day)*	☐ Morning ☐ Afternoon ☐ Evening ☐ Night				
Whether blood stains will be present on the instruments?	☐ Yes ☐ No				
When will you sent the contaminated instruments after procedure?	☐ Immediately ☐ Within One hour ☐ Within one to three hours ☐ More than three hours				
When will you receive the items return?	☐ Less than Two hours ☐ Two to Four hours ☐ Four to Six hours ☐ More than Six hours				
Have you ever observed any defect on the sterilized instruments after processing?	☐ Yes ☐ No If yes , kindly mention _____				
How would you rate CSSD performance? (***1-Extremely Poor ,2-Below Average,3-Average ,4 - Good,5-Excellent)***					
Processing Quality and Packaging	1	2	3	4	5
Cleanliness	1	2	3	4	5
Processing time	1	2	3	4	5
Operation Flexibility	1	2	3	4	5
Transportation mechanism	1	2	3	4	5
Current Record Keeping mechanism	1	2	3	4	5
Overall, how satisfied are you, with CSSD Service?	☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Dissatisfied ☐ Very dissatisfied				
What recommendations would you offer for improving CSSD performance?					

Questionnaire
for CSSD Staff of LLH Hospital, Abu Dhabi

The information gathered will be used to improve the efficiency of Central Sterile Service Department (CSSD) workflow.

User Profile	
Male or female:	☐ Male ☐ Female
Age:	☐ < 25 ☐ 25—30 ☐ 31—40 ☐ 41—50 ☐ > 50
How long have you been working in CSSD Industry?	☐ Less than one year ☐ One to three years ☐ Three to five year ☐ More than five years
CSSD Efficiency Survey	
How long have you been working in LLH's CSSD Department?	☐ Less than one month ☐ One to six months ☐ Six months to one year ☐ 1 to 3 years ☐ More than 3 years
What are strengths of CSSD Department?	
What are weaknesses of CSSD Department?	
What kinds of Personal Protective Equipment are worn during CSSD operation?	☐ Gown ☐ Head cap ☐ Slippers/Foot Cover ☐ Gloves

	☐ Goggles				
Do you believe your department has enough staff to meet day to day challenges	☐ Yes ☐ No If No , kindly mention _____				
How would you rate Machinery performance? (***1-Extremely Poor ,2-Below Average,3-Average ,4 - Above Average,5-Excellent)***					
Sterilizer	1	2	3	4	5
Suggestion					
Ultrasound Cleaner	1	2	3	4	5
Suggestion					
Washing machine	1	2	3	4	5
Suggestion					
Plasma sterilizer	1	2	3	4	5
Suggestion					
Biological Indicator	1	2	3	4	5
Suggestion					
Autoclave	1	2	3	4	5
Suggestions					
Whether you require any other additional tools/machinery for improving speed?	☐ Yes ☐ No If yes , kindly mention _____				
If you receive OT schedules will it help you to organize your work?	☐ Yes ☐ No If yes , kindly mention _____				
Are you satisfied with existing Quality control procedure practiced by CSSD	☐ Yes ☐ No If No , kindly mention _____				
How would you rate CSSD performance? (***1-Extremely Poor ,2-Below Average,3-Average ,4 - Above Average,5-Excellent)***					
Transportation after procedure	1	2	3	4	5
Suggestion					

Cleaning	1	2	3	4	5
Suggestion					
Wrapping	1	2	3	4	5
Suggestion					
Sterilization	1	2	3	4	5
Suggestion					
Release	1	2	3	4	5
Suggestion					
Shelfing	1	2	3	4	5
Suggestions					
Have you ever observed any defect on the sterilized instruments after processing?	☐ Yes ☐ No If yes , kindly mention _____				
Overall, how satisfied are you, with CSSD operation?	☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Dissatisfied ☐ Very dissatisfied				
What recommendations would you offer for improving CSSD performance?					

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