

Emerging Trends in Sterile Supply

CSSD's role lies in receiving, cleaning, packing, disinfecting, sterilising, storing and distributing instruments as per well-delineated protocols and standardised procedures



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The Central Sterile Supply Department (CSSD) in recent times has expanded from a mere support entity which consisted of steam sterilisation units to process instrument and linen packs. Today, CSSD is the heart of hospital infection control and the most important unit of clinical support services.

CSSD's role lies in receiving, cleaning, packing, disinfecting, sterilising, storing and distributing instruments (both multi-use and single-use devices), as per well-delineated protocols and standardised procedures. However, with newer techniques of surgery and subsequent sophisticated instruments, these functions have become critical and specialised. Modern medical technology has thus given a host of transformations, which have helped to ensure that the sterile supply remains—sterile. Broadly, the reflections could be felt in the following points:

New-age Sterilisers & Modalities

Manual sterilisers are now a passe and now fully automated pre-vacuum-assisted sterilisers are replacing them. These sterilisers are generally more efficient and leave very little space for error. Computer-operated sterilisers with automated recording system are also available now-a-days which record vital details like temperature, pressure, etc. Also, they record the load weight, cycle time and other details vital to business analysis.



On the other hand, ETO is now not the preferred choice for sterilising the thermo labile items due to their toxicity and environmental hazards. Hydrogen Peroxide sterilisers and Gamma irradiation have shown a new way to safe and speedy sterilisation.

Process Challenge Devices

With the change and sophistication of surgical sciences, sophisticated minimally invasive instruments (MIS) have also come into picture, which generally have very narrow lumen. Improperly maintained old sterilisers generally cannot put air out of the lumen, which is an essential element for kill kinetics. This could not be detected by normal chemical indicators, rather a process challenge device and PCD Bowie Dick indicator is required to get this checked and corrected. PCD tests the steriliser by simulating worst situations which can happen while sterilisation.

Biological & Chemical Indicators

Biological and chemical indicators remain a preferred choice for testing the sterility. However, with recently launched chemical integrators, it is easy to check for multiple parameters at the same go in every cycle/pack.

Quality & Documentation

A modern CSSD must follow well-established Quality Management System like EN ISO 14937, EN 550, 552. ISO 900:2001 (with reference to ISO 13487), which states the requirements for a quality management system for sterile supply services department.

Batch Processing Label System

Another useful device is the batch monitoring system. In case of sterilisation breakdown, when the entire lot needs to be retrieved from various parts of the hospital, this system comes handy.

The entire lot could be just called back by simply identifying the packets with the label bearing the same lot number. Also, the label gives you the sterilisation and the expiry date, ruling out chances of error while calculating 48 hours or seven days time frame. The presence of autoclave number and the operator code also helps to identify the malfunctioning machine and fix the accountability.

Lubricants & Enzymatic Detergents

Instruments, generally, have a tendency to develop crust or sometimes even rust near the grooves and hinges, which may be a potential source of infection. Also, they decrease the life of the instruments drastically, which could be prevented by using instrument lubricants.

Lubricant generally develops a protective film on the instruments. In addition, some of these lubricants have anti-bacterial property, which prevents pathogenic growth on the instruments. It is true that whatever is not clean cannot be sterilised. This is where the enzymatic detergents come into picture. These enzymatic detergents clean the human enzymes from the tiny instruments and thus decrease the bio burden to ensure proper sterilisation.

Management & Training

CSSD is no longer run by nurses and general technicians, but by hospital management graduates and senior technological officers, who are specially trained in varied techniques of quality management. You will also come across CSSD departments having a MoU with the sterilisation product companies who take steps for complete training and quality assurance of the department.

Re-use

Most Indian hospitals use devices like catheters, balloons, octopaus and tissue stabilisers multiple times in order to minimise cost to the patient. However, if not done properly, this could be a health hazard. Therefore, the sterile supply department must ensure adoption of a standard protocol with non-toxic marking of the items with non-toxic markers. These single use items generally get defected on using for few times and thus it is very important to know their number of use for patient safety.

CSSD is the abbreviation of the Central Sterile Supply Department. The objective of establishing a Central Sterile Supply Department is to make reliably sterilized articles available at the required time and place for any agreed

purpose in the Hospital as economically as possible, having regard to the need to conserve the time of users [especially Doctors And Nurses].

The Sterile Supply Department within a hospital receives stores, sterilizes and distributes to all departments including the wards, outpatient department [OPD] and other special units such as operating theatre [OT]. Major responsibilities of CSSD include processing and sterilization of syringes, rubber goods [catheters, tubing], surgical instruments, treatment trays and sets, dressings etc. it is also responsible for economic and effective utilization of equipment resources of the Hospital under controlled supervision.

The main objectives of the Central Sterile Supply Department are:

- To provide sterilized material from a central department where sterilizing practice is conducted under conditions, which are controlled, thereby contributing to a reduction in the incidence of hospital infection.
- To take some of the work of the Nursing staff so that they can devote more time to their patients.
- To avoid duplication of costly equipment's, which may be infrequently used.
- To maintain record of effectiveness of cleaning, disinfection and sterilization process.
- To monitor and enforce controls necessary to prevent cross infection according to infection control policy.

- To maintain an inventory of supplies and equipment.
- To stay updated regarding developments in the field in the interest of efficiency, economy, accuracy and provision of better patient care.
- To provide a safe environment for the patients and staff.

The CSSD also aims at assuming total responsibility for processing hospital items thereby assuring that all of them receive the same degree of cleaning and sterilization. It also contributes to the educational program within the hospital relating to infection control and develops a cost-effective program by cost analysis of personnel, supplies and equipment.

ORGANISATIONAL STRUCTURE

Central Sterile Supply Department should be under technical supervision of a responsible officer who is concerned with the day management of the unit. The Central Sterile Supply Department

manager will liaise with the infection control team, OT manager and clinical departments. The CSSD manager is administratively responsible to the head of the health care facility



Functional flow of activities in CSSD may be generally specified as follows.

WASHING: -Rinsing of articles after use should not be permitted in patient care areas unless carried out by a trained member of the staff.

CLEANING: - All reusable medical devices should be thoroughly cleaned prior to disinfection or sterilization.

DRYING: - all articles should be dried appropriately

INSPECTION AND ASSEMBLY: - Each item should be inspected for functionality, defects, breakage and then appropriately assembled.

PACKAGING: - Articles should preferably be packed in porous material.

LABELLING: - Each pack should be marked with nomenclature of the article, contents of the pack, initials of the person who packed it, date and initials of the person who carried out the sterilization.

STERILIZATION: - The operation of the sterilizer should be entrusted to a responsible and fully trained person. It should be kept in a state of good maintenance and repair.

STORAGE: - Should be properly managed separately for sterile and non-sterile stores. For sterile goods, clean room conditions should be followed.

RETRIEVAL AND DISTRIBUTION: -Refers to clean and dirty articles exchange system. A program should be established for the collection of used items from patient care areas and distribution of sterilized goods.

Introduction

The Sterile Processing Department (Central Supply, or Sterile Supply as it is also known), comprises that service within the hospital in which medical/surgical supplies and equipment, both sterile and nonsterile, are cleaned, prepared, processed, stored, and issued for patient care.

Until the 1940's, medical/surgical supplies were, for the most part, processed and maintained in the departments and patient care areas in which they were to be used. Under this system, there was considerable duplication of effort and equipment, and it was difficult to maintain consistently high standards for sterilization technique and product quality throughout the health care facility.

As the number and variety of surgical procedures grew and the types of medical devices, equipment, and supplies proliferated, it became apparent that a centralized processing was needed for efficiency, economy, and patient safety. The work of scientists W.B. Underwood and J.J. Perkins (3) was instrumental in encouraging health care facilities to establish a separate and distinct department, the Sterile Processing Department, with specialized expertise and direct responsibility for providing clean and sterile medical/surgical supplies and equipment to patient care areas.

Functions

Sterile Processing Departments are typically divided into four major areas to accomplish the functions of decontamination, assembly and sterile processing, sterile storage, and distribution.

In the ***decontamination area***, 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 further processing (like sterilization).

After assembly or sterilization, items are transferred to the ***sterile storage area*** until its 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.



THE DECONTAMINATION PROCESS



Introduction

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. **Transport** - Used supplies and equipment should be collected and taken to the Decontamination Area in the Sterile Processing Department in a way that avoids contamination of personnel or any area of the hospital. Equipment should be covered and supplies should be moved in covered carts, closed totes or containers, or closed plastic bags.
2. **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.
3. **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.
4. **Soaking** - this is necessary only if you have [lumens](#) or other complex designs that are filled with debris or if the devices are very [bloody](#) and cannot be rinsed or wiped at the point of use.
5. **Washing**
 - detergent - should be compatible with the materials in the device and suited for the type of soil. Consult the recommendations from the device manufacturer.
 - equipment - many types of cleaning equipment are available, the most commonly used are:
 -  [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.
 -  [ultrasonic](#) - 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**.

-  [tunnel washers](#) - they resemble a mini car-wash. The chief advantage of these units is that most of them allow totally hands-off processing. Instruments in perforated or mesh-bottom trays can come directly from the operating room or other department and be placed into the tunnel washer without any further handling or arranging. Inside, the instruments are subjected to cycles of pre-rinse, washing, ultrasonic, rinse, and drying.
 -  [cart washers](#) - carts and other transportation vehicles and containers must be cleaned routinely to remove dust and spillage. Cartwashers have wash, rinse, steam and drying cycles. Carts are placed in the washer in a tilted position to enable water to drain out and prevent restriction of any moving parts within the washer. Items removed from this type of washer are very hot and must be allowed to cool before they are handled. Carts must be thoroughly dried before they have contact with clean or sterile supplies.
6. **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.



7. 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.



8. 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.

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THE ASSEMBLY & PACKAGING PROCESS

Introduction

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.



ASSEMBLY 1 ASSEMBLY 2

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 time between sterilization and use may range from a few minutes to several weeks to many months. The packaging material selected must also permit the device to be removed aseptically.

Types of Packaging

-  [textiles](#)
-  [nonwovens](#)
-  [pouch packaging](#)
-  [rigid container systems](#)

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THE STERILIZATION PROCESS

Introduction

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.

Steam

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.

Ethylene Oxide

Ethylene oxide is used to sterilize items that are heat or moisture sensitive. Ethylene oxide (EO) is a chemical agent that kills microorganisms, including spores, by interfering with the normal metabolism of protein and reproductive processes, (alkylation) resulting in death of cells. Used in the gaseous state, EO gas must have direct contact with microorganisms on or in items to be sterilized. Because EO is highly flammable and explosive in air, it must be used in an explosion-proof sterilizing chamber in a controlled environment. When handled properly, EO is a reliable and safe agent for sterilization, but toxic emissions and residues of EO present hazards to personnel and patients. Also, it takes longer than steam sterilization, typically, 16-18 hrs. for a complete cycle.

EO gas sterilization is dependent upon four parameters: EO gas concentration, temperature, humidity, and exposure time. Each parameter may be varied. Consequently, EO sterilization is a complex multi-parameter process. Each parameter affects the other dependent parameters.

Others

Dry heat - dry heat in the form of hot air is used primarily to sterilize anhydrous oils, petroleum products, and bulk powders that steam and ethylene oxide gas cannot penetrate. Death of microbial life by dry heat is a physical oxidation or slow burning process of coagulating the protein in cells. In the absence of moisture, higher temperatures are required than when moisture is present because microorganisms are destroyed through a very slow process of heat absorption by conduction.

Microwaves - the nonionizing radiation of microwaves produces hyperthermic conditions that disrupt life processes. This heating action affects water molecules and interferes with cell membranes. Microwave sterilization uses low-pressure steam with the nonionizing radiation to produce localized heat that kills microorganisms. The temperature is lower than conventional steam, and the cycle faster, as short as 30 seconds. Metal instruments can be sterilized if placed under a partial vacuum in a glass container. Small tabletop

units may be useful for flash sterilizing a single or small number of instruments, when technology is developed for widespread use.

Formaldehyde gas - formaldehyde kills microorganisms by coagulation of protein in cells. Used as a fumigant in gaseous form, formaldehyde sterilization is complex and less efficacious than other methods of sterilization. It should only be used if steam under pressure will damage the item to be sterilized and ethylene oxide and glutaraldehyde are not available. Its use for sterilization has been almost abandoned in the United States, Canada, and Australia. The method dates back to 1820, and it is still used in Europe and Asia.

Hydrogen peroxide plasma - 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.

Ozone gas - ozone, a form of oxygen, sterilizes by oxidation, a process that destroys organic and inorganic matter. It penetrates membrane of cells causing them to explode. Ozone is an unstable gas, but can be easily generated from oxygen. A generator converts oxygen, from a source within the hospital, to ozone. A 6 to 12 percent concentration of ozone continuously flows through the chamber. Penetration of ozone may be controlled by vacuum in the chamber, or enhanced by adding humidity. At completion of exposure time, oxygen is allowed to flow through chamber to purge the ozone. Cycle time may be up to 60 minutes depending on the size of the chamber or load.

Chemical solutions - liquid chemical agents registered by the EPA as sterilants provide an alternative method for sterilizing heat sensitive items if a gas or plasma sterilizer is not available, or the aeration period makes ethylene oxide sterilization impractical. To sterilize items, they must be immersed in a solution for the required time specified by the manufacturer to be sporicidal. All chemical solutions have advantages and disadvantages; each sterilant has specific assets and limitations. These chemicals are: peracetic acid, glutaraldehyde, and formaldehyde.

Ionizing radiation - some products commercially available are sterilized by irradiation. It is the most effective sterilization method but is limited for commercial use only. Ionizing radiation produces ions by knocking electrons out of atoms. These electrons are knocked out so violently that they strike an adjacent atom and either attach themselves to it, or dislodge an electron from the second atom. The ionic energy that results becomes converted to thermal and chemical energy. This energy causes the death of microorganisms by disruption of the DNA molecule, thus preventing cellular division and propagation of biologic life.

The principal sources of ionizing radiation are beta particles and gamma rays. Beta particles, free electrons, are transmitted through a high-voltage electron beam from a linear accelerator. These high-energy free electrons will penetrate into matter before being stopped by collisions with other atoms. Thus, their usefulness in sterilizing an object is limited by density and thickness of the object and by the energy of the electrons.

They produce their effect by ionizing the atoms they hit, producing secondary electrons that, in turn, produce lethal effects on microorganisms.

Cobalt 60 is a radioactive isotope capable of disintegrating to produce gamma rays. Gamma rays are electromagnetic waves. They have the capability of penetrating to a much greater distance than beta rays before losing their energy from collision. Because they travel with the speed of light, they must pass through a thickness measuring several feet before making sufficient collisions to lose all of their energy. Cobalt 60 is the most commonly used source for irradiation sterilization. The product is exposed to radiation for 10 to 20 hours, depending on the strength of the source.

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QUALITY ASSURANCE

To ensure that instruments and supplies are sterile when used, monitoring of the sterilization process is essential.

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.

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.

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.



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 filed as a permanent record for each sterilizer.

Central Supply Room

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from

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Manual Loaned by Becky Sawyer

Outline

- I. **Centralization of supplies**
- II. **Personnel**
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- IV. **Housekeeping and supplies**
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I. CENTRALIZATION OF SUPPLIES

Topic Preview

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7. **Rubber goods**

The centralization of supplies in hospitals is not a new idea. It has always been used, and with much success, but the centralization of surgical supplies and special equipment is the result of experiments which had their inception about 20 years ago.

Definition: Centralization, as the term is used here, means the concentration of all equipment in one place, under one head, where it may be cared for with the greatest efficiency and used to the best advantage.

The department in which this important work is carried out has been given several names, but the most common designation is Central Supply Room. It is then defined as a unit in the hospital which issues sterile supplies and most of the special equipment needed in the care of patients.

Location: This Central Supply Room should, if possible, be centrally located and must be directed by a competent supervisor. These two factors are of vital importance. With the former, time, labor, and money are saved in the service rendered, and without the latter, it would not be possible to carry out its extremely important function.

Scope: The size, scope and capacity of this unit will be determined, in large measure, by the individual requirements of the hospital. It will, therefore, vary

widely in hospitals of different sizes. It may be the place where surgical supplies are prepared and distributed, or if the plan of the hospital lends itself to a large department, it may control all surgical supplies from dressings to sterilization of obstetrical and surgical packs and all special equipment, including rubber goods. This takes in the preparation of sterile trays for certain treatments. In some hospitals, the collection and storage of blood has been added to the facilities offered by this room.

Solutions: Solutions for intravenous use may be made in this department. A room for the exclusive making of solutions must be used, as the air must be free from dust and lint. Special equipment is necessary and the person making solutions must be reliable and experienced. The water used must be especially distilled so that it will be free from impurities and minute particles of foreign material, sometimes found in ordinary distilled water. The other ingredients used must be the purest obtainable. The bottles and tubing are washed and rinsed with the greatest care and the tubing inspected regularly. These factors are as important as the making of the solution itself. Standard solutions for intravenous use may be secured in sealed flasks from commercial firms. The tubing requires the same care.

These factors will regulate the number of persons required to give exacting 24-hour service.

Purpose: The purpose of the Central Supply Room is to conserve time and material by reducing the duplication of supplies and effort. Such duplication has heretofore existed when dressings and sterile supplies were taken care of on the wards and floors, or in the dressing rooms in connection with each hospital department. The aim of the hospital in maintaining a Central Supply Room is to render to doctor and patient the best and most efficient service in the interest of each.

Before the inauguration of such service, it was the custom to issue all supplies from the main storerooms to the wards, and replacements were made as needed. Gauze and cotton were at one time included in these supplies, and dressings were secured from the operating room. This may still be the rule in some hospitals where dressing rooms off wards are considered necessary. Catheterization, douche, and bladder trays were set up as well as intravenous and hypodermoclysis trays. The solutions for the intravenous and hypodermoclysis trays came from the operating room.

With the advent of the Central Supply Room, this procedure has changed, and trays and solutions for all these treatments are now provided through this central

organization. The transfer from wards and floors to a single source where perfect technique is guaranteed is a definite forward step in the care of patients.

Services: The following services are given the various departments: Bladder irrigation, catheterization, coionic irrigation, douches, eye treatments, gastric analysis, gavage, hot and cold compresses, hand immersion containers, poultices, enteroclysis, myringotomy, and mortuary. Trays for such work are equipped, supplied, and supervised in the Central Supply Room in readiness for the nurse from the department in charge of the patient. Each hospital is obliged to work out its method of requisitioning equipment taken from this room. Everything must be signed "out" by the person taking it and reported "in" when it is returned. Trays are checked to make certain that everything has been returned in good condition. Each hospital, also, has its method of charging, and when this applies to the services rendered by this room, charge tickets are written when the equipment is given out.

Other trays used for dressings, aspiration, gastric decompression, intravenous therapy, hypodermoclysis, spinal puncture, cisternal puncture, and tracheotomy are taken care of by the nurse in the Central Supply Room, as is also the fracture cart.

The Central Supply nurse goes to the patient's bedside with specific equipment, assists with the treatment and makes certain that the nurse left in charge understands the subsequent procedure and further application of the recommended treatment.

Included in the list of equipment available through the Central Supply Room are bed elevators, respirator, resuscitator, oxygen tent or tank with special face or nose attachment, and an electric breast pump, if this item is not under the care of the obstetrical department. The glass parts for the enumerated apparatus are sterilized in the Central Supply Room. Other equipment which may be called for by the nurses in the several departments or delivered, as is routine in each hospital, includes the following articles: Atomizers, crib sides, hypodermic trays, luer syringes and accessory trays, electric heating pads, dressings, inhalators, stupe kettles, tongue depressors, restraints, drainage bottles, rubber goods, and equipment for isolating the individual patient in the ward, together with cans for disinfection of material from typhoid patients.

Rubber Goods: When rubber goods are considered a part of the supplies in the Central Supply Room all replacements are made from there. In this way, every department of the hospital has the advantage of first class equipment and material readily available and always in perfect condition. In the Central Supply Room, all supplies are carefully and regularly checked, needed repairs made, and materials

held ready for immediate call or stored for future use. Consequently, single pieces of equipment may be used where previously several were necessary and many important items which were earlier considered too expensive for routine handling may be serviced through this central department.

It is, therefore, easily apparent that the introduction of this so called "Room"-really a large department-constitutes actual progress in the standardization of hospital supplies.

II. THE PERSONNEL

The graduate nurse in charge of the Central Supply Room may have had a postgraduate course in operating technic or surgical nursing, or some postgraduate work in one or more Central Supply Rooms, or perhaps she is a nurse with particular aptitude for this work and interested in its every phase. In addition to her training, as a person she must be thoroughly conscientious, tactful, and adaptable in order to cope successfully with the constantly changing program involved in this work. Her students must give particularly intelligent and conscientious service, for here human lives are at stake in their hands, and the most scrupulous attention must be paid to all details.

While there is routine work which must be performed at the same time every day, all the emergency requirements are met with equipment from this department. It is obvious that cooperation must be an essential feature of this service. Upon the nurses in the Central Supply Room rests the responsibility for the efficient working of life-saving equipment.

Nurses from the Central Supply Room are frequently among the first to see patients after admission to the hospital. A special treatment may be necessary or the patient may have to be prepared for immediate operation, in which case the patient receives the attention of the Central Supply Room nurse. Thus her work can and does carry her into the hospital's "front line." This nurse must be able to meet people easily, create a good first impression, and exercise discretion at all times. Sick people are not ordinarily in a very happy frame of mind. They know an effort will be made to restore them to health, but they have entrusted themselves to strangers and look about them for some sign of personal sympathy.

The number of nurses needed to carry on the work of the Central Supply Work varies with the routine of the hospital. According to observation, a hospital of 250 beds with an active surgical service requires one supervisor, five students, and one night nurse. It is important to have just enough nurses. Often the department is

limited as to space and with too many nurses there is likely to be confusion. Naturally, an insufficient number makes the work difficult. A general staff nurse is vital to this room and the service it affords. She is in the unit when the supervisor is busy on the outside or is teaching or off duty.

A senior student nurse who is particularly interested in this type of work may be able to take charge of the room at night, but, where the service is very active, the responsibilities are frequently too great to be assumed by so young a nurse. A qualified general staff nurse who is conscientious and reliable, and who can handle the many angles of this important department when alone, is the one to assume this responsibility.

In some nursing schools, the entire training of students in the Central Supply Room and its technic is given at one time, with two weeks assigned to each branch of the work and eight weeks allotted for the complete service. In other schools, one month during the junior year and another in the senior year are designated for this work.

The night duty term in Central Supply Room is given after these other weeks have been completed. As the understanding of the intricate night duties grows, a Central Supply Room night nurse should be chosen with care in order that she may render to the patients the service for which the department was intended.

The use of a maid is optional, but there are many things which she can do well while the nurses are attending to more important tasks. The same is true of an orderly. If the department is large and all supplies are to be delivered by the department, an orderly is required. Otherwise, it will only be necessary to call an orderly from a department whenever heavy or awkward equipment is to be transferred.

III. DRESSING CARRIAGE

Topic Preview

1. **Technic of dressing**
2. **Procedure**
3. **Fracture carriage**

The dressing carriage is so complete in itself that it could be called an emergency room on wheels. It holds everything the doctor will need in doing a dressing or performing a slight operation.

The size of the hospital and the number of surgeons operating daily will determine the number of dressing carriages needed, and the number of dressings each attends will regulate the amount of equipment on each carriage.

In some large hospitals, dressings are done in a special room off the ward; in others, however, they are done in the wards and in the private rooms. With this complete carriage, the dressings can be done without moving the patient, and the slight operation which may be performed in the patient's room, with the sterile supplies on the carriage, is a saving in time to the surgeon and a saving in money to the patient, as it removes the necessity of taking the patient to the operating room.

Technic of Dressing: By the time the student is permitted to take the carriage out alone, she is thoroughly familiar with everything in it. This is one of the chief reasons why the doctors are so enthusiastic about the Central Supply Room. The nurse who goes out with the equipment from this department knows exactly what to do with it. Previously, it was not always a nurse thoroughly familiar with the carriage and dressings who was asked to assist the doctor.

Now, when the call comes for the carriage, the nurse takes it to the appointed place, and having learned to handle sterile supplies, is ready to assist intelligently. A modern dressing carriage has a place for everything which will be needed and everything in its own place.

The call which the nurse receives may be for one dressing, for six or eight dressings in various parts of the hospital, or for dressings on the ward. The nurse is ready in any case. When the doctor has several dressings to do, he usually plans to do the "clean" ones first.

Procedure: Although the procedure for a dressing is always the same, it may be well to mention it. The patient is screened, made as comfortable as possible, a good light obtained (some carriages have their own lights which may be plugged in any socket), the bed adjusted, gown and covers folded neatly, binder removed or bandage cut, newspaper or paper bag on the foot of the bed, top dressing removed and placed on the paper or in the bag, glove case opened and put in a convenient place for the doctor, then the dressings and instruments which the doctor will need are placed on this towel. When a Mayo stand is used, the towel is placed on it and the dressings and instruments arranged.

When a wound is to be irrigated, a mackintosh is placed under the patient's side, and a kidney basin held in place. Solution basin, asepto syringe, and solution are carefully but quickly procured. The doctor removes the rest of the dressings with

the forceps which have been placed on the towel. In taking sterile sponges from jars, the nurse must be careful not to strike the outside of the jar with the forceps; also, when holding forceps, she must remember to keep the point down, otherwise the solution will run up toward the handle, then down over the sterile end, and, be it ever such a small amount, the forceps are contaminated. It is safest to return the forceps to the container.

While the dressing progresses, the nurse must have everything ready as quickly as possible for whatever is to come next-the removal of sutures, cleansing of the wound, removal of drains, or irrigat- ing, etc. Dressings and adhesive are applied or tapes tied and bandage put on.

When the dressing is completed, soiled instruments are dropped in the container especially for them, and the gloves are put in their container. Soiled dressings are wrapped in the newspaper and tied with a string or, if a paper bag is used, the top of the bag is folded over and the package disposed of in the department. In this way it is possible to keep the carriage clean, and the soiled instruments and gloves are easily handled upon the return of the carriage to the Central Supply Room.

The Central Supply Room nurse will not always be able to replace the binder; therefore, the nurse on the ward follows to do this. It is to be hoped that the nurse assigned to each patient can be present for the dressing; otherwise, any nurse on the department may accompany the doctor and nurse with the carriage and record the changes in the dressing from day to day. If a ward nurse does not go with the carriage, the Central Supply Room nurse must make a note of the changes and give this note to the supervisor of the department.

Important points to be rememered by the nurse in order to assist with dressings are:

1. Be quick to learn the various dressings in order to have things ready for the doctor.
2. Be systematic in the arrangement of the covers, towels, dressings and instruments, and the articles on the carriage.
3. Be conscientious in the help given, never using anything when in doubt as to its sterility.
4. Be alert in seeing that extra dressings are provided as needed; that nothing comes in contact with the sterile dressings or forceps; that instruments used in the dressing are not reinserted into ointment jars, sponge and packing jars.
5. Be gentle with the patient in this important treatment.

Fracture Carriage: A cart or carriage set up to carry ropes, pulleys, screws, adhesive, ace adherent, bandages, splints, and all other equipment necessary to put on a splint or Buck's extension is a very helpful service from this department. It may be adjusted as time and space permit so that much of the fracture work on any department may be done from this carriage. Painting Balkan frames different colors helps to keep them together and easy to assemble.

IV. HOUSEKEEPING AND SUPPLIES

Topic Preview

1. **Routine**
2. **Supplies:**
 - a. **Gauze**
 - b. **Linen**
 - c. **Glass**
 - d. **Instruments**
 - e. **Suture needles**
 - f. **Suture material**
 - g. **Stainless steel and enamel ware**
 - h. **Drugs**

Hospital housekeeping is an important subject, and all its details should be kept in mind while working in the Central Supply Room. A clean unit, ample supplies, equipment well cared for and in working order will produce the results expected of this group.

Routine: The housekeeping itself should be perfect; the ceiling and walls of the department kept clean as well as the floor. Cupboards, cabinets, and drawers should be cleaned at least once a week; shelves may require daily dusting as supplies are rearranged on them. It is important to remember that if the doors of these cupboards are closed as soon as articles have been removed or replaced, less dust and lint will accumulate on the shelves. Store and splint rooms require going over at least once a week, with a regular time established for taking account of stock. Extra paper and boxes should be disposed of at once. Sterilizers and other metal equipment need weekly polishing-the autoclave a daily scrubbing with soap and water.

Glass syringes, intravenous trays and other much used supplies may require a daily checkup. With so much of the equipment in constant use, and the checking of material out and in, it is possible to know almost daily what is in the department. However, stock taking is important.

All equipment must be ready and in perfect working order at any hour of the day or night. It should always be kept in the same place.

Supplies: The good housekeeper will have plenty of supplies. In this department these will include: Gauze, linen, muslin covers, instruments, glassware, stainless steel and enamel utensils, sutures, suture material, and a certain number of drugs. Here are factors to consider:

Gauze: When ready-made dressings are used in the hospital, there is less handling of material, therefore, less lint so that dressings may be wrapped in the main workroom. When bolts of gauze are cut and folded into dressings, it is well to have a separate gauze room, be it ever so small. Sponges are prepared for use in several ways; small packages wrapped in paper, while larger ones may be wrapped in muslin. Where large quantities of sponges are in use, either on the carriage or in the departments, they are placed in cans and sterilized. In this case, the sterile sponges are removed with sterile forceps. Sponges wrapped with paper may be sealed with Scotch tape; those wrapped with muslin are pinned.

Linen: Large pieces of linen are not needed in this department, but the small pieces used must be in perfect condition before they are wrapped. These include: Gowns, towels, drapes, laparotomy and peritoneal sheets, and muslin covers. They all must be inspected for tears, worn places, and lost strings. The covers for intravenous and hypodermoclysis sets, catheter and douche trays, glass syringes, etc., are made of double muslin, and will wear well if fastened with pins. The corners of the covers should be inspected carefully, and if strings are used, they must be in good condition. All muslin-wrapped packages must have in one corner, plainly visible, the initials of the person wrapping the package, and the date it was wrapped.

Glass: Rinsing after a thorough washing is important in the care of glass. The ease with which it may be broken must be borne in mind. Atomizers used for tannic acid spray are washed with soap and water, especial attention being given the top, as the hole may be clogged. A stylet will open it easily.

Instruments: These utensils are expensive. The initial cost is great, and so is the upkeep; but, with proper handling, these instruments will render the wear they were made to give. Instruments used in the Central Supply Room may be classified as "clean" and "dirty." Those used on known "clean" cases may be soaked in cold water for a few minutes, then scrubbed with a cleansing powder and lukewarm water. "Dirty" instruments should be soaked for 15 minutes in a five percent lysol solution before scrubbing. Teeth and crevices should receive particular attention;

clamped instruments should be opened and separated, then cleaned, dried, and immediately reclamped. A light application of mineral oil may be applied when the instruments are dry. Care must be exercised in the cleaning of scalpels, particularly those used on "dirty" cases. The cutting edge of all sharp instruments should be protected before being put away.

Suture Needles: These needles may not be requested every day, but they must be ready when they are needed. They may be washed as instruments are, but never with them. All points should be inspected before the needles are put away. When prepared for suture kits or hemorrhage trays, they are stuck in a piece of gauze bandage. When wrapped alone, a piece of cardboard is placed under this gauze to protect the needle and to prevent the point from coming through the cover.

Suture Material: Sutures of all varieties should always be ready for use. They include catgut in all sizes, silk, linen, silkworm, horsehair, and clips.

Stainless Steel and Enamelware: Many important utensils are made of these materials. They are expensive and must be handled carefully. If they are returned from departments in bad condition, the cause should be investigated.

Drugs: The drugs used here are not as numerous as those in the wards or on private floors, but an ample supply of the ones required must be on hand. Ointments are sterilized for various uses. Boric acid, zinc oxide, and vaseline, for example, are sterilized in small jars, which are filled about three-fourths full. While boric acid and zinc oxide are cooling, they should be stirred with a sterile tongue blade.

V. TRAYS AVAILABLE IN THE CENTRAL SUPPLY ROOM

Intravenous Tray

- 1 intravenous set (muslin wrapped)
- 1 flask solution
- 1 flaskholder
- 1 splint (padded)
- 1 mackintosh covered with towel
- 1 accessory tray containing:
 - 1 bottle alcohol, 70 per cent
 - 1 bottle isotonic iodine
 - 1 jar sponges or cotton balls
 - 1 tourniquet

- 1 file
- 1 2-cc. syringe and needle
- 1 No. 19 needle, 1 1/2 in. or 2 in.
- 1 1-cc. amp. 2 per cent novocaine
- 1 2-in. bandage
- 1 roll 1/2-in. adhesive

Gloves optional

Standard may be sent out with tray.

Intraperitoneal Tray

- 1 50-cc. syringe with adapter
- 1 20-cc. syringe
- 1 No. 20 short bevel needle
- 1 No. 22 short bevel needle
- 2 applicators
- 1 small piece of best cotton

Solution at proper temperature

When tray goes out, send accessory tray with sterile gown and gloves; Tr. metaphen and collodion.

Hypodermoclysis Tray

- 1 hypodermoclysis set (muslin wrapped)
 - 1 flask solution
 - 1 flaskholder
 - 1 accessory tray
- Gloves optional
- Standard, if required.

Accessory Tray

- Alcohol, 70 per cent, sprinkler top bottle
- Isotonic iodine, 3-oz. bottle
- Jar for sponges or cotton balls
- Tourniquet.
- File

Wangensteen Tray

- 1 duodenal drainage tube - Levine, Rehfuss or Wangensteen
- Glycerine
- Sod. bicarb.
- 1 16-oz. graduate

- 1 large kidney basin
- 1 medicine glass
- 1 teaspoon
- 1 large basin (for ice)
- 1 rubber apron
- 1 mackintosh covered with towel
- 1 2-oz. Luer syringe (with tubing and connector)
- Drainage apparatus (Wangensteen)

Lumbar Puncture Tray

- 1 2-cc. syringe
- 1 No. 24 and 1 No. 22 needle
- 3 spinal needles: No. 20 32 in., No. 20-3 in., No. 18--3 1/2 in.
- 1 spinal manometer with adapter
- 2 specimen tubes marked I and 2
- 1 laparotomy sheet '
- 4 applicators
- 1 small piece best cotton

When tray goes out send: Accessory tray, collodion, 1 amp. novocaine 2 per cent, adhesive 1/2 in., sterile gown, and gloves.

Tonsil Hemorrhage Tray

- 6 curved Kelly hemostats
- 2 straight Kelly hemostats
- 2 Allis forceps
- 1 plain forceps
- 1 toothed forceps
- 1 straight scissors
- 1 pillar retractor
- 1 needle holder
- 2 curved needles
- 8 tonsil sponges
- 12 3x3 gauze sponges
- 1 2-in. bandage
- 1 sol. cup

Metal tongue blade, sutures and sterile water added when tray goes out, also head lamp or mirror and can of tonsil sponges.

Venous Section Tray

- 1 scalpel. No. 10 blade

4 mosquito hemostats
1 probe
1 grooved director
1 toothed forceps
1 plain forceps
1 scissora
2 cannulae-1 glass
1 aneurysm needle
2 straight skin needles
1 lap sheet
5 applicators
1 2-cc. syringe and needle
12 3x3 gauze sponges
1 2-in. bandage

Add sterile water to sol. cup and suture material to tray. Also send accessory tray,
1 amp. novocaine 2 per cent, sterile gown, and gloves.

Scrub Tray

4 solution cups
12 cotton balls
4 dressing towels
2 111's
1 2-in. bandage

Gloves

Solution added to tray when ordered.

Shave Tray

1 sprinkler top alcohol, 70 per cent
1 tube shaving cream
1 towel
1 safety razor with extra blade
1 straight razor with extra blade
1 solution basin
12 cotton balls
4 applicators
8 3x3 gauze sponges
1 small rubber sheeting

Solutions added to tray before it leaves room. No bichloride used on bone cases.

Suture Tray

1 lap. sheet
4 applicators
1 scalpel No. 10 blade
3 mosquito hemostats
4 straight hemostats
1 curved Kelly hemostat
1 straight scissors
1 needle holder
1 toothed forceps
1 solution cup
2 Allis forceps
2-cc. syringe
1 No. 24 and 1 No. 22 needle
6 curved cutting edge needles
2 straight skin needles
12 3x3 gauze sponges
1 111
1 2-in. bandage

Add water to sol. cup, take accessory tray, 1 amp. novocaine 2 per cent, adhesive, gown, and gloves.

Blood Culture Tray

Alcohol, 70 per cent
Tr. iodine
Jar of cotton balls
Tourniquet
Alcohol lamp and matches
10-cc. syringe
1 No. 22 and 1 No. 4 needle

Also scrub tray

Removing 2 towels, I'll's and 1 sol. cup

Adding 3 sterile applicators and the solutions.

Male Catheterization Tray

2 solution cups
1 large kidney basin
1 16-oz. graduate
1 catheter introducer

1 catheter container with Nos. 16-18-20 catheters

1 towel

4 3x3 gauze sponges

1 111

1 gauze sponge for K.Y.

Solutions and K.Y. added when tray is ordered, also gloves.

Male Bladder Irrigation Tray

To regular catheterization tray add asepto syringe. Use graduate on tray for solution, which is added when tray is ordered, also K.Y. and gloves. Check temperature of solution.

Female Catheterization Tray

2 sol. cups with 4 cotton balls in each

2 large and 2 small cotton balls on tray

1 large cotton ball between them

1 perineal sheet

1 8-oz. graduate

1 med. sized kidney basin

1 catheter container with 2 No. 12-14 catheters

Nos. 8-10 catheters on child's tray

K.Y. on cotton ball and sol. in cups when tray is ordered. Add gloves.

Sterile bottle when sterile specimen is to be obtained.

Female Irrigation Tray

Large white enamel tray-2 quart irrigation can

Y connector

2 sol. cups, 4 large cotton balls in each

3 large and 2 small cotton balls

1 large kidney basin

1 hemostat

2 No. 16 catheters

1 medicine glass

Solution added when tray is ordered, also gloves. Asepto syringe or funnel may be used instead of can.

Coionic Irrigation Tray

I gal. irrigating can

I gal. pitcher

1 kidney basin

2 clamps

5 rectal tubes: No. 22-No. 32

Y connector

Vaseline

Bucket

Douche Tray

2-qt. irrigating can with rubber nozzle

1 sol. cup with 4 cotton balls

4 cotton balls

1 small kidney basin

Perineal repair:

Nos. 16-18 catheters

6 3x3 gauze squares

1 V.P.

2 small cotton balls

Solution proper temperature is added when tray is ordered. Gloves.

Eye Tray

1 sterile eye flush jar with solution

Jar with cotton balls

1 kidney basin

Mackintosh covered with towel

Enteroclysis Tray

2-qt. irrigating can with tubing

1 Murphy drip

1 clamp

1 glass connector

1 catheter No. 18

Ear Tray

1 ear syringe

1 medicine glass

1 medicine dropper

Gastric Analysis Tray

1 mackintosh covered with towel

1 med. sized kidney basin

1 med. sized basin

1 Rehfuß tube

1 medicine glass

1 bottle glycerine
1 2-oz. syringe
1 specimen rack
1 small roll adhesive
1 safety pin, 1 clamp

Venous Pressure Tray

1 manometer with adapter
1 10-cc. syringe, Nos. 19-20-21 needle
2 applicators
Lap. sheet
Accessory tray, gown, gloves
1 amp. novocaine, 2 per cent

Vaginal Examination Tray

1 sol. cup with 4 cotton balls
1 perineal sheet
2 applicators
3 cotton balls on tray
1 med. sized kidney basin
2 glass slides in container
1 uterine forceps
Solution, K.Y., and gloves are added. Speculum if necessary.

Flaxseed Poultice Tray

Flaxseed
Olive oil
Sod. bicarb.
Double boiler .
Spatula and wooden spoon
1 enamel graduate, 16 oz.
Sol. cup with 4 large cotton balls
Muslin
Wax paper
Small tray with dressing towel

Mustard Plaster Tray

Mustard, flour, olive oil in proper containers
Measuring spoons
Spatula
Wooden spoon

Basin (small)
1 sol. cup with 6 cotton balls
Muslin
Wax paper
Board
Hot water bottle
Small enamel tray with dressing towel

Nasal Packing Tray

2 nasal specula
1 metal applicator
1 nasal forceps
1 No. 12 catheter and 1 piece black silk
1 scissors
1 medicine glass
6 3x3 gauze sponges
1 piece good cotton
1 hemostat
1 medicine dropper
1 1in. bandage

When going out, add bottle Adrenalin chloride and 1 bottle 1/2-in. packing

Sterilization. Past and Future

by Tim Galekop

A lot of things have changed over the years in the sterilization area. The sterilization department has increasingly become much more important. The changes occurred, among others, in the area of organisation, packaging, and legislation. In the past CSSD staff members were considered the dishwashers of the operating room, or the CSSD was treated, as the "social workshop" of the hospital where employees were parked which were not fit for anything else. Today this department has become a highly technical unit with sophisticated requirement. In several European countries there are Sterilization Associations and special courses for sterilization managers and personnel. Thus, the CSSD has become the heart of the hospital, i.e. if it does not work, the OR can-not operate.

Back in the nineteenfifties or in the beginning of the sixties it was probable the UK who introduced the first CSSD (Central Sterilisation Supply Department) in Europe which was copied from the USA. The day to day practice at that time, however, was that every operating room did their own cleaning, disinfecting, packaging, sterilizing and storing.

It was also in the UK where in 1966 the first meetings took place between the Ministry of Health and the Medical Packaging Industry. This led in 1967 to the first published TSS standards for Sterilization paper plain, Crêpe paper, and paper sterilization bags.

In March 1981 the Netherlands officially published the law for Medical Devices for hospitals. This was the first comprehensive law for hospitals. In 1980 the Netherlands started with the Dutch norms for sterilization (RIVM), the first standards were officially published in 1984. (Steriliseren Steriliteit). The Netherlands became a leading country in Sterilization certainly in Europe, but probable even on a global scale. On 14th June 1993 European Council Directive 93/42/EEC was published concerning medical devices and the CEN standards to minimise the risks and optimise security for use and patient.

Nosocomial infections - implications for packaging

The first surgical operation took place in Babylon about 4000 years ago. In the 19th century, approximately 60% of the patients died of hospital fever. Today we are still talking about infection control and the amount of postoperative infections, which do occur. Several figures have been published and it is shocking to see how much this all costs. Some time ago a damning report on infections caught in English hospitals says they are killing 5,000 patients a year and are implicated in the deaths of another 15,000 people. The report criticises hospital managers and reveals wide differences in the amount trusts spend on infection control. Similar reports have now been published in other European countries. In Belgium, 70,000 infections occurred and 2,800 patients died. In Germany, 640,000 hospital related infections were reported, with a death rate of 1 - 2 %. In the Netherlands, \pm 5% of the patients who are hospitalised, meaning 80,000 people, get infected. About 2,600 people die. Huge costs are involved. Not only the huge cost is important but also, of course, the human grief. The Dutch National Health Council stated, "A patient is taken into hospital to recover and not to get another illness". Another problem is the resistance of bacteria against antibiotics and penicillin not yet taking about the new viruses or illnesses like Creutzfeldt-Jacob's Disease, hepatitis, MRSA (Multi Resistant Staphylococcus aureus), AIDS, and SARS.

It was around 1881 that Robert Koch started the steam sterilisation followed in 1890 by the introduction of the Schimmelbush drum. This round steel drum was probably the first packaging system and had holes in the sides to allow steam to enter. A sliding steel band was closed directly after sterilising to cover the holes. Regrettably, in certain countries this drum is still used. In \pm 1930 textile was introduced as a sterilisation packaging material. At that time still in white. During the 2nd world war the colour changed to green. The reason for this was most likely that the textile industry had to produce textile for the army, so there was no white textile available. About 5 years later the first developments on sterilisation paper started, which led to the so-called Bripac sterilisation boxes. It was around 1940 that Germany developed and introduced the aluminium containers followed in 1950 by the paper sterilisation bags. 10 years later the first heat-sealable peel pack pouches came onto the market. The advantage of this packaging system was that one could see what was packed and that an aseptic opening was possible. In 1970 it was an American company called C.H.Dexter (now part of the Finish group Ahlstrom) who introduced the first nonwoven sheets of sterile barrier systems under the name Dextex.

Sterile barrier systems on their own will not prevent nosocomial infections from happening. However, the sterile barrier system, which is the minimum packaging configuration that maintains sterility of the package contents until aseptic presentation at the point of use, is one of the most important parts of sterilisation, after cleaning and disinfection. The advantage of single-use packaging materials is prevention of migration of microorganisms. It should by now be well known that conventional textile cannot be considered a bacterial barrier and is therefore not appropriate to be used as a sterilisation packaging material. Single-use packaging systems offer maximum safety, sterility and efficiency. After sterilisation a barrier is needed to protect the packed medical devices and to maintain sterility until the point at which they will be used. Therefore every medical device which needs to be sterilised has to be packed. The choice of packaging material depends on several important criteria:

- The medical device which has to be packed.
- The sterilant has to pass through (porosity).
- The material should not release any harmful substances nor go through considerable change (chemically or physically) during sterilisation.
- The material has to pack easily, so it has to be soft, yet strong during packaging, sterilisation, transport, and storage.
- It must show damages and not create false safety (pinholes).
- The packaging material must prevent recontamination.
- Aseptic opening must be possible.
- The material is possibly being used as a sterile field, meaning it has to be repellent towards low-tension liquids. We counted in a university hospital 13 different kinds of low-tension liquids used in the OR.
- The material must be lintfree. Lint is a potential hazard for the patient.

The loss of sterile package integrity is usually regarded as an event related, rather than time related. Shelf life is a complex matter and depends on a lot of different factors, which have to be taken into consideration, like e.g.:

- How stable is the medical device that has been packed.
- How stable are the raw materials of which the packaging material is manufactured.
- The change of penetration of microorganisms during transport / storage.
- How and by whom has it been packed.
- The method of sterilisation.
- The way of transport.
- Storage conditions.
- How easy is it to open the packaging aseptically and how has it been opened in the theatre?

The advice is to use always two layers of sterilisation wrap and to wrap the medical device subsequently. There are several reasons for this advice:

- Two sheets used in a single action are in practice only one sheet. To create a tortuous path to prevent migration of organisms from reaching the sterile contents different folds are necessary, which can be created by subsequently packing two sheets.
- To use different qualities, dimensions and interleaved colours to be able to differentiate between sterile and non-sterile, and to facilitate detection of damage to the packaging in the theatre. With interleaved colours damages like holes or tears are more easily detected.
- Using interleaved coloured wrap you always know that you have subsequently wrapped. Due to the colours you do not forget a layer.
- If the outside of the inner pack is expected to be sterile, double wrapping is necessary and makes it easier to distinguish sterile and non-sterile.
- To facilitate aseptic opening.

The industry is working to all kinds of quality systems and are trying very hard to supply you with the best quality products.

So you can supply the best quality to your customers like the theatre and the patient. Why is quality so important?

- Better control over the process
- Increasing and improve productivity and quality
- Lower cost
- Satisfied customers/patients
- Manufactures can provide you with the best quality of packaging materials but what if it is wrongly packed or opened?

Sterile barrier systems materials are a vital part of the medical device for the hospital and industry. Budgeting on packaging materials is the wrong thing to do. After all, we are talking about the safety of the patient.

Packaging - legal and normative requirements

CEN TC 102 WG 4 was established on May 3rd 1988, to deal with European Standards concerning single use and reusable packaging. The aim was to harmonise all existing European Sterilization Packaging Standards, like DIN (German), AFNOR (French), BSI (British), Steriliseren Steriliteit (Dutch) and others. A working group is restricted to individual members appointed by the parent body or by CEN, to serve as an expert. Members to WG 4 are i.e.:

- Hospitals
- SBA - Sterile Barrier Association (formerly ESPA - European Sterilisation Packaging Association)
- EDANA - European Disposable and Nonwovens Association.
- EUCOMED - European Confederation of Medical Devices Associations.
- Departments of Health and others.

Document EN 868-1 has been ratified and was published in the official European Journal in February 1997. This document is in line with the Medical Device Directive and all packaging materials will have to fulfil Part EN 868-1 "Packaging Materials and Systems for Medical Devices Which Are to Be Sterilised - Part 1 General Requirements and test methods". Documents EN 868 - 2 and subsequent parts are dealing with the requirements and test methods and can be used to show compliance with these particular requirements. (A tool to prove compliance to part 1). Products in compliance with these requirements are in compliance with part 1. Non-compliance to these parts of the standard, however, does not mean or infer non-compliance to part 1. Parts 2 to 8 have been ratified and were published in June 1999. Standards are tools to prove the conformity with the Medical Device Directive. European standards published by CEN have to be transcribed without any modification into national standards, and as a result all pre-existing national standards dealing with the same contents and contracting the European standard will be cancelled. On a global scale, we have the International Standardization Organization (ISO). Within the ISO there is the Technical Committee 198 Working Group 7; this WG has published document ISO/FDIS 11607 "Packaging for Terminally Sterilized Medical Devices". The big difference between these and the EN 868 documents is that the ISO document is dealing with forming and sealing and does not conform to the Medical Device Directive. ISO/TC 198 has agreed in Kyoto that a joint combined revision of ISO 11607, EN 868-1 will be developed under the Vienna agreement, with an ISO lead, to create one global packaging standard. It is very important that the future new packaging standard has to show compliance with the essential requirements or other provisions of the European Directives.

The new harmonised standard will consist of two parts:

- *Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging.*
- *Packaging for Terminally Sterilized Medical Devices - Part 2: Validation and Requirements for Forming, Sealing and Assembly Processes.*

This International Standard is applicable to industry, health care facilities, and wherever medical devices are packaged and sterilised. CSSD in hospitals will be considered as "industry" as well - as far as I am concerned this the right decision. For where is the difference between hospitals and manufacturers? Let us not forget that we are talking about the safety of the patient.