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The New Central Sterile Supply Department of University Hospital Authority

St. Orsola- Malpighi Polyclinic

The new Central Sterile Supply Department (CSSD) of the University Hospital Authority St. Orsola-Malpighi Polyclinic was inaugurated in September 2010. The CSSD collects functions of diagnosis and treatment of high technological impact, such as emergency room, diagnostic imaging, operating blocks and intensive care. The intervention was executed by a service contract for the design, construction, management, operation and maintenance of the unique CSSD.

The creation of a unique CSSD to serve the entire polyclinic is a great benefit to the hospital, facilitating the adoption of uniform methods in the treatment of surgical instruments for all operating blocks. The complex activities performed within a CSSD, i.e. cleaning, disinfection (by hand, ultrasound, automatic washers), packaging (control and maintenance of the instruments, composition of the kits), loading of kits in autoclave, sterilisation and storage, require a careful functional design of the spaces for each stage of the process, from the arrival of surgical instruments at the CSSD until their return to the wards.

In the new CSSD, traceability systems for the surgical instruments have been installed ensuring the successful and proper execution of all phases of the sterilisation process. The CSSD spaces and technologies to be installed were dimensioned on the basis of the annual surgical activity provided by the entire polyclinic (about 30,000 surgical interventions/year), to which must be added activities of outpatient, Emergency Room and ward which require medical device sterilisation.

The CSSD has a gross surface of 1,100 square metres and provides distinct areas for contamination level as required by the Presidential Decree 14 January 1997, where it is stated that the sterilisation service must provide spaces divided into clearly separated areas, one area intended to the receiving, washing, packaging of materials, one to the sterilisation, one to the storage and distribution of the sterilised materials. The path must be progressive from the unclean to the clean area.

The minimum provision of environments for the sterilisation service must include areas for receiving, sorting, cleaning and preparing materials; a sterilisation area; an anteroom for the staff before they access the sterile area; a storage room for sterile materials; a storage room for soiled materials; staff toilets.

Material Flows

The material to be sterilised coming from the operating blocks of the surgery centre, the emergency room and other areas of the polyclinic arrives in the reception area via a dedicated elevator. The new CSSD has a layout that allows for a oneway flow for the instruments.

Unclean Area

Unclean reception area: This area, suitably dimensioned, allows the reception and temporary storage of the trolleys transporting the equipment to be sterilised which come from the operational areas of the surgery centre or from other pavilions of the polyclinic. The trolleys can reach this area by a dedicated elevator. Two computer stations provide access to the incoming goods information and verify the type of material to identify the specific treatment to be executed.

Unclean decontamination/pre-treatment area: After the acceptance phase the trolleys containing the goods are taken to the decontamination/pre-treatment area, where the first critical stage of the process in terms of "risk management" occurs.
In this area, pre-treatment for the removal of pollutants with automatic cycle is performed. It was designed to maintain this area at "negative pressure" compared with the surrounding environment to reduce the risk of contaminating the other areas of treatment. In fact, this is the area most at risk of contamination for the operators involved in the opening of containers and separation of the unclean material.

The position of this operational area is also strategic in terms of material flow due to the presence of two automatic pass-through washer-disinfectors where trolleys and containers, devoid of surgical instruments, can be directly treated. The exit from the washer- disinfectors is connected to both the packaging area through an anteroom and the distribution area. In fact, after the pretreatment, the containers should be made available in the packaging area to be reused for the reconstruction of the surgical kits which should be sterilised in autoclaves, while the clean trolleys will be stored in the distribution area in order to be filled with already sterile containers.

Washing Area

The surgical instruments decontaminated in the pre-treatment area are transferred by dedicated trolleys to the washing area. This area was provided with natural light in accordance with requirements for occupational health and safety. Natural light is provided not only in the washing area but also in the other operational areas such as the packaging, the sterile and distribution areas of the CSSD.

The washing area has wide operational zones equipped with tables for manual processing of surgical instruments and benches with washbasins, blowguns and ultrasonic cleaning units. In addition, a battery of six pass-through automatic washers is installed with a capacity of 10 DIN, which allows for excellent flexibility in terms of setting the cycles of treatment if compared with the washer-disinfectors.

The number of washers ensures an efficient back-up in the event of machine downtime. A pass box for transferring material from the packaging area to the washing area was installed in the wall equipped with the washers.

Nine computer stations were provided for activities that take place in this operating area. Also included is a deposit for stocking material needed for instrument treatment and a washing/cleaning room containing material used to sanitise this operating area and which is directly and functionally connected with the area to be treated.

It should also be noted the central position with respect to the operational areas of the head nurse room, which has glass walls to facilitate direct visual inspection of operations in the washing area and an easy visual communication with the packaging area.

Packaging Area

The packaging area is the one with the most climate control, it is maintained at higher pressure than the washing area, thus preventing air contamination from the adjacent dirtier areas.

Twelve large benches equipped with a computer station for the management and tracking of surgical instruments were provided for the staff involved in the packaging and control activities.

A storage area for new surgical instruments was also created. These new instruments will serve as a backup of any devices that might arrive damaged at the CSSD and that should be replaced without stopping or slowing down the process of preparing the surgical kits.

The connection of this storage area, through an appropriate filter, to the unloading area of the washer-disinfectors allows the movement of the treated containers directly to the packaging area, where they are ready to be used for the preparation of the kits.

The process of sterilisation is performed by means of six pass-through autoclaves of various capacities (12 - 8 and 6 U.S.), which transfers the sterilised material directly to the sterile area. Two additional single port gas plasma sterilisers permit the reconditioning of heat-sensitive devices, which are then transferred to the Sterile Area via pass-boxes.

Sterile Area

Cooling and packaging area: The operations subsequent to the sterilisation process are carried out in this area. During the cooling of containers, biological testing and electronic weighing of the containers are carried out to detect any residual humidity. Bundling machines for the application of a plastic shrink film were also provided to protect the primary packaging.
Three computer stations for the traceability system are installed in this area. The containers are then transferred in the distribution area by means of pass-through cabinets for preparing for the withdrawal phase.

Other Operational Areas

Distribution Area: The trolleys to transport the treated material are located in this area. The staff working here set up the trolleys with various devices (packages, containers) to be distributed to the operating theatres and to the other departments.

Importantly, the trolleys for transporting material will be sanitised every transport thanks to the architectural design of the CSSD that provides the entry into the two washer-disinfectors directly in the decontamination/pre-treatment, packaging and distribution areas and the output connected both at the packaging and the distribution areas.

Withdrawal Area:

This area is placed at the end of the path of the treated material. Here a computer station is provided for managing the delivery of materials and the transport documentation.

Areas of Support:

As well as the operational areas of the CSSD, additional rooms were planned for complementary functions to the production process. Particular attention has been paid to the comfort of staff, by dedicating relaxation areas for the workers both in the unclean and in the packaging and sterile

areas. In particular, the relaxation zone for the staff working in the unclean area has glass walls to maintain a visual communication with the head nurse room and with the working areas if needed.

Staff Pathways

Staff pathways in the different operational areas are particularly important to ensure safety of the instruments treated in the CSSD. There are two different changing areas, one for the staff in the unclean area, another for the staff in the packaging and sterile areas.

Changing Rooms for the Unclean Area:

Two pass-through changing rooms/anterooms for men and women were designed. Both changing rooms are equipped with toilets and showers and are dimensioned for about 20 people. From the two changing rooms operators can access a common area where they equip themselves with PPE and then enter the working area. This common area also has two large basins (surgeon sinks), which allow easy disinfection of the operators coming from the unclean area before entering the changing room. From the anteroom, operators can also access the relaxation area dedicated to workers in the unclean area.

Changing Rooms for Packaging and Sterile Area:

There are two large changing rooms for men and women, located in the area for withdrawing the treated material. These rooms, equipped with toilets and showers were designed so that staff that enter the distribution area from the withdrawal area have already changed their clothes. Before entering the sterile and packaging areas personnel must go through an additional anteroom to wear suitable clothing in order to protect the environment from exogenous contamination by operator.

Specific Materials Ensure Quality, Hygiene and Comfort

The choice of materials and finishes used to build the CSSD ensure high levels of quality, hygiene and comfort. The floors are easy to clean and can be treated with disinfectants, connected to vertical surfaces with coating leveled coving in order to ensure adequate and easy cleaning. Rubber floors were provided for the operational areas and support rooms.

In the changing rooms and anterooms the floors are made of granite-gres fine porcelain. The coatings were made with nonscratch, washable and treatable materials to ensure an adequate and easy cleaning.

Ventilation

The installation of the CSSD has an important role in relation to all aspects of air conditioning and ventilation systems that can have an effect on air bacterial contamination as well as on operator comfort; it must essentially be put at the service of production processes that play inside the CSSD. During the design and implementation, particular attention was paid to the integration of machinery and instruments necessary for sterilisation processes.

The ventilation system for the entire CSSD and related services such as changing rooms, relaxation areas and anterooms, is without air recirculation and integrates perfectly with the systems in the other areas of the surgery centre. The control of the airflow and temperature will be locally ensured by variable capacity single duct boxes and post-heating batteries that allow the temperature regulation room by room in full compliance with current standards on energy saving.

In order to achieve the correct pressure gradient in each operational area, a box was installed in the supply diffuser, which controls the inlet airflow and temperature, and a box in the exhaust grill, which regulates the airflow extracted from the environment.

All boxes are interfaced with the supervision system through which the parameters of the system can be displayed and recorded and the airflow and temperature set points can be controlled. Reading and controls are possible through a terminal located in a special room inside the CSSD.

By regulating airflows, pressure gradients among different areas can be created and maintained, subject to the minimum requirements. The monitoring of the relative pressures is provided by differential pressure sensors mounted on the partition walls between rooms. These sensors are constantly interfacing with the supervision system and will provide data for the assessment and feedback control of pressure by means of airflow modulation.

In addition to the systems traditionally used in Italy and exhibited so far, pressure stabilisers were introduced in some rooms. A pressure stabiliser behaves like a pressure relief damper installed on the wall that separates two environments with different pressures and, if the relative pressure between the two environments exceeds the set value, it allows air transit from the environment at higher pressure, cleaner, to the one at lower pressure, more dirt.

From the point of view of contamination control, the differential pressure is not important in itself but as an "engine" that drives the air and consequently the airborne contaminants from a higher pressure environment to an environment at lower pressure. Despite the fact that airflow into the room after an absolute filtration is free of bacteria, contaminants are introduced into the environment by operators or dirty equipment. In

order to protect those areas intended for sterile processes it is essential to ensure airflow from those areas to less clean environments.

The conditions of overpressure that can be created by balancing supply and resumption of airflows can be disrupted very easily from simple and common events such as opening a door that suddenly collapses to zero the relative pressure between the two environments. The pressure stabiliser, an entirely mechanical device, which can be easily adjustable to the desired differential pressure, opens automatically when the preset pressure is reached and, when opened, allows the air transit towards the less clean environment.

The ventilation system thus provides a different balance than a traditional system and must resume from a more dirty environment the air blown into a cleaner one; however this brings clear advantages during the transient phases and in particular during the opening of doors. While opening a door, the relative pressure between the two environments will fall down, the stabiliser will shut down instantly and the air that normally flows through the stabiliser will go through the door.
In particular, for the different ventilated rooms, the system allows to:

1. Ensure that contaminants are not released outside the decontamination area in which the packages containing the dirty instruments are opened (the dirtiest area of the entire CSSD);
2. Easily and safely maintain the head nurse room at positive pressure compared to the washing area, thus preventing that the typical smells of washing zone get inside the room itself;
3. Easily and safely maintain the washing zone at negative pressure compared to the packaging zone, with the certainty of not unbalancing the system during the opening of doors.
4.

Tracking

In addition to the architectural and engineering aspects, the adoption of appropriate management and tracking information system of surgical instruments is vital for the functioning of the CSSD. The application software installed in the new CSSD has been specifically developed for the following activities:

- Management control of the CSSD processes;
- Programming needs;
- Reporting consumption;
- Clinical traceability of the production and of devices use; administrative and statistical effective reporting; and
- Organisation and tracking of logistics, transportation, etc.
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Software allows the user to follow the life cycle of a set or a single instrument since its inclusion in the registry of the application, for all of the steps followed in the CSSD and at the end user, until disposal. Through the management system we are updated on the configuration of the surgical set by recording changes and replacement of worn or damaged instruments.

All phases of the materials process can be tracked and verified through two ways: Supervision through which we can follow the kit working phase inside the CSSD and see the record of maintenance; and tracking through which we can search a set of instruments through searching criteria (bar code, lot code, patient code, date of the surgical intervention, even partial description) and get a synthetic report of all data processing related to the wanted set.

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