

# Performance improvement project in the Sterile Processing Department at a university hospital in Egypt: redesign to centralize the process

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## Abstract

Reprocessing of medical instruments is a complex process requiring several steps. In the last few years, many reports were delivered to our infection control unit about defects in the sterilization service. This study aims to describe improvements in the performance of the Sterile Processing Department (SPD), thus improving safety for patients and healthcare professionals. The FOCUS-PDCA strategy and root cause analysis were used to define the problem, investigate the underlying causes and develop a quality improvement plan. Defects in the service provided were detected, including inadequate procedures and training, breaches in reprocessing, and suboptimal workplace ergonomics and design. We developed an institutional policy and standard operating procedures for the SPD, implemented a training program for SPD staff, and improved the workplace layout to improve separation of clean and soiled equipment.

**Keywords:** Sterilization; Disinfection; Infection control; Drug resistance, microbial

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## Introduction

Reprocessing of medical instruments is a complex process requiring several steps. Skipping or incorrectly performing a crucial step can result in the distribution of a potentially unsafe instrument<sup>1</sup> with subsequent transmission of infection.<sup>2</sup> Documented outbreaks of infections associated with contaminated reusable instruments have been published.<sup>3-6</sup> It is the duty of the Sterile Processing Department (SPD) to reprocess and deliver the correct sterile surgical instruments to the Operating Room (OR) or other clinical units, in the right condition and at the right time. In this perspective, SPD plays a major role in patient safety and infection control.<sup>7</sup> Centralizing the process of instrument reprocessing helps ensure uniform standards of practice, improves workflow (soiled, to clean, to sterile) and facilitates the training and education of skilled technicians. It is an economic option, as pooled resources require less personnel and equipment.<sup>8</sup>

In our hospital, several incident reports outlining inadequate reprocessing of reusable instruments were delivered to the infection control unit, necessitating a prompt solution. This project was conducted to improve the performance in SPD of the selected facility.

## Methods

This study was conducted from January 2012-January 2013 in Zagazig University Hospital (ZUH) in Sharkia, Egypt, the only university hospital to serve a population of over five million. ZUH includes nine specialized hospitals. We selected the SPD at the New Surgery Hospital which serves six surgical departments: Gynecology and Obstetrics, Urosurgery, Ear Nose and Throat, Neurosurgery, Orthopedic Surgery, and General Surgery. In addition, it serves a diagnostic radiology department, an intensive care unit, a central laboratory, a blood bank and 24 operating rooms. This department was originally designed based on international standards and it worked for years in an efficient way.

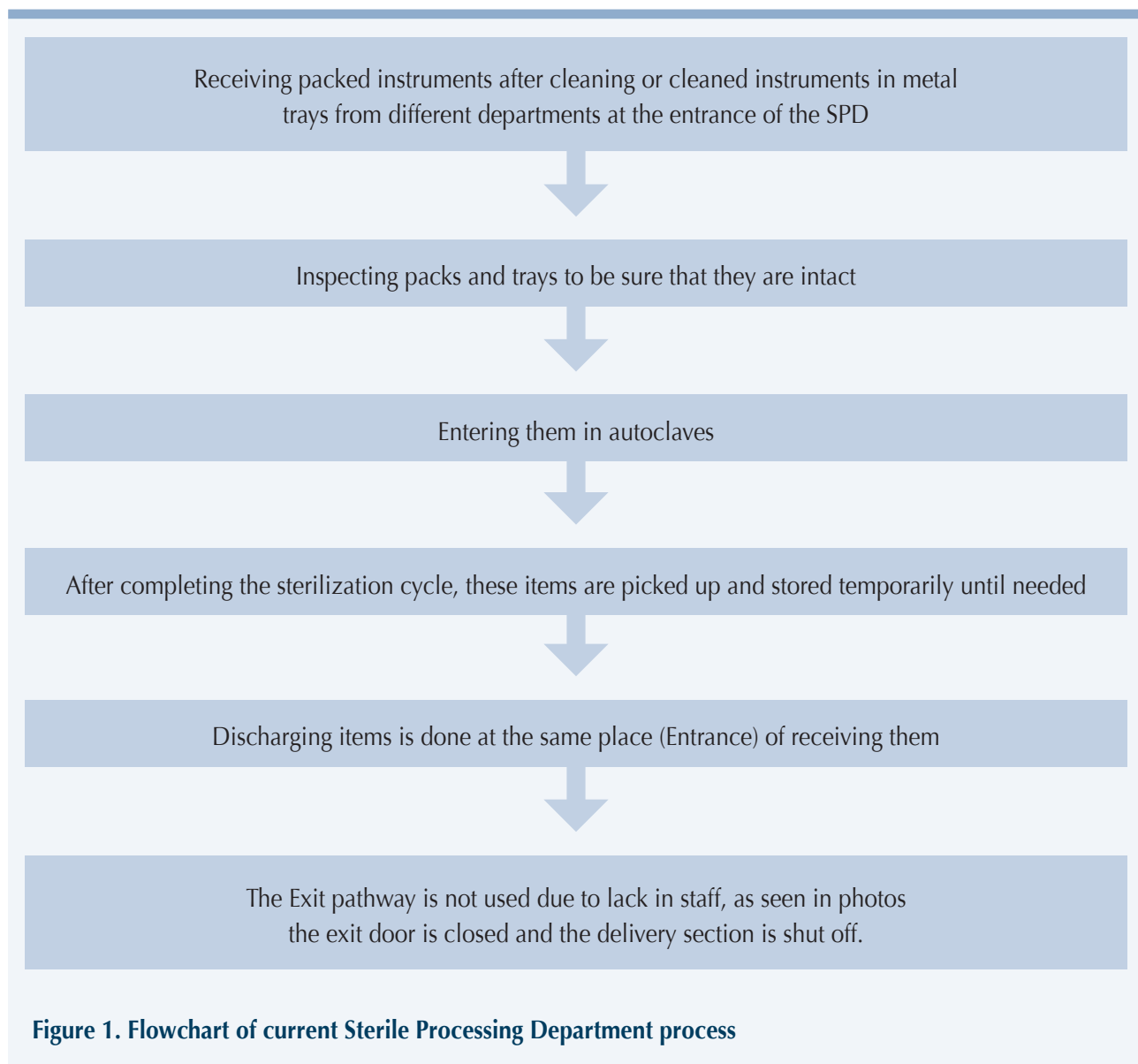
We used the FOCUS-PDCA approach<sup>9</sup> to identify the problems within this SPD and implement changes. The FOCUS approach involves several steps: **F**ind the problem to improve, **O**rganize a team to work on

improvement, **C**larify the current process, **U**nderstand variation in the process, and **S**elect a strategy for ongoing improvement. The tools used to gain a better understanding of sterilization processes and improvement opportunities included brainstorming, process mapping, surveys, interviews and visits to the workplace, practice audits, and benchmarking (to compare existing processes/outcomes with comparable standardized services). Input from stakeholders was sought, regarding the problems and potential solutions as well as potential barriers to change. We used PDCA (Plan-Do-Check-Act) cycles as the method for monitoring our progress.

## Results

We identified that the main problem was sub-optimal quality in our sterilization service. This was determined based on non-conformity reports identified through infection control team audits which revealed breaches in instrument reprocessing and shortages in manpower, stakeholder complaints of low quality reprocessed instruments (e.g., wet packs, absence of quality controls such as chemical indicators), and complaints by SPD staff members about inadequate ergonomics within the workplace, which interfered with good work practice (e.g. absence of separation between soiled and clean areas and poor ventilation). A multidisciplinary team consisting of three infection control physicians, technicians, one SPD nurse, the hospital manager and one surgeon was formed to lead our quality improvement process. Stakeholders included patients, nurses, physicians, other workers and employees, all hospital departments, the infection control team, hospital managers, and equipment suppliers.

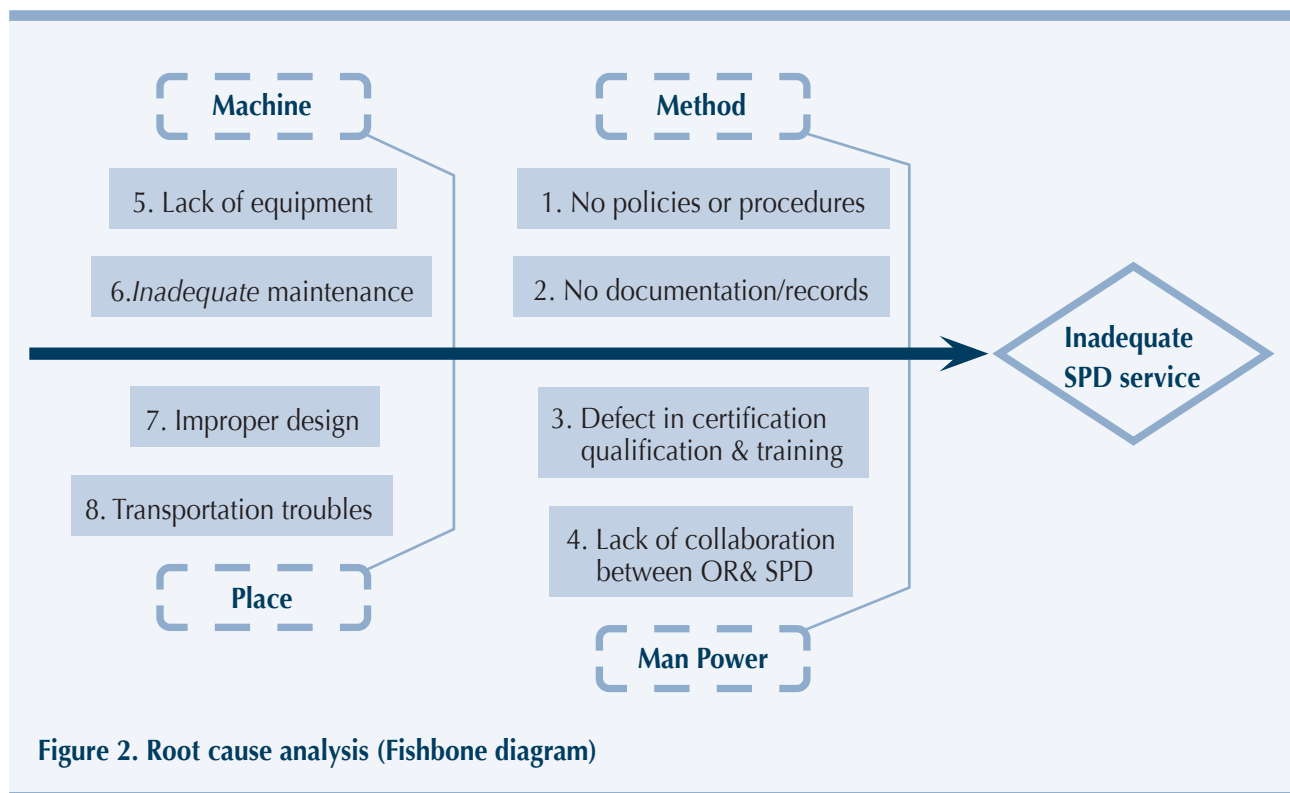
The flowchart outlining the existing reprocessing process is shown in Figure 1. Our analysis indicated that the initial reprocessing of soiled instruments was carried out by nurses in the hospital departments where these instruments had been used. The process was fragmented between SPD and the instrument users throughout the hospital. In addition, root cause analysis (Figure 2) identified that no reprocessing policies or procedures were available for staff members to follow; documentation related to the sterilization process were inadequate; SPD staff received no specialized training; and there was absence of collaboration between the SPD and ORs.



Sufficient space was available within the SPD, which was designed to accommodate a decontamination area, a clean area for preparation and packaging separated by a door, and a pass-through window. Review of the physical facilities revealed that sinks were not available for manual instrument cleaning within the SPD. A washer/disinfector was available but was not used. There was a water treatment unit for the autoclave water supply. Four double door autoclaves were available, but for each only one door was used for both loading soiled equipment and unloading sterile equipment. Staff used one sterilization cycle for all instruments. No other sterilization methods for heat sensitive items such as a gas plasma sterilizer were available. A sterile storage area was separated from the clean area by the four autoclaves but was not being used (Figure 3).

Temperature and humidity were not controlled within the unit, with marked elevation in temperature in the sterilization area.

Maintenance of all equipment was done on regularly recorded visits, but no verification testing was documented in maintenance reports. There was a lack of back up instruments, poor instrument maintenance and inappropriate use of immediate-use (flash) steam sterilization. High-level disinfection with glutaraldehyde was sometimes used as an alternative to steam sterilization procedures for surgical instruments. Transportation of equipment was done using trolleys that were used for all purposes and were not adequately cleaned. There were no dedicated pathways or elevators for soiled and clean items.



Based on our findings, we prepared a proposal to improve SPD performance titled “SPD: Redesign to centralize the process”. The proposal contained all required details for implementation. Tasks were specified, time frames were set and required resources were determined. The proposal was revised in keeping with national and international standards. An action plan for implementation of the proposed items was developed, documented, and communicated to top management. The proposal included several initiatives, including development of policies and a standard operating procedure (SOP) manual; improved record keeping; SPD staff training and certification; procurement of additional reprocessing equipment for the SPD; and improved unit design and transportation procedures.

We developed hospital policies for SPD that followed government regulations, national and international guidelines and hospital management systems. The policies would be reviewed and submitted through our organizational chain of command for final adoption and approval. Our SOP manual included all processes performed by the department. We recommended that documentation must be carried out by all SPD employees for all devices, equipment and sterilization

cycles, and include the following information: load number, general contents of the load, exposure time and temperature, name or initials of the operator, results of the biological test when applicable, and any reports of inconclusive or non-responsive chemical indicators found later in the load. Records should be maintained for three years.

We prepared a training program for staff in SPD which included: 1) orientation sessions that cover SPD policies and procedures, with information about infection control, safety, attire, personal hygiene, and compliance with governmental regulations, and national and international guidelines; 2) a continuous educational program in the form of sessions at regular intervals, to review and update staff knowledge and skills and to maintain their competency and certification; and 3) training sessions for new devices and equipment. Education and training programs would include information on workplace hazards, US Occupational Safety and Health Administration (OSHA) recommendations on occupational exposure to blood-borne pathogens,<sup>10</sup> the importance of vaccinations, standard/transmission-based precautions, the use of personal protective equipment, and emergency procedures.

Figure 3. SPD design: current situation

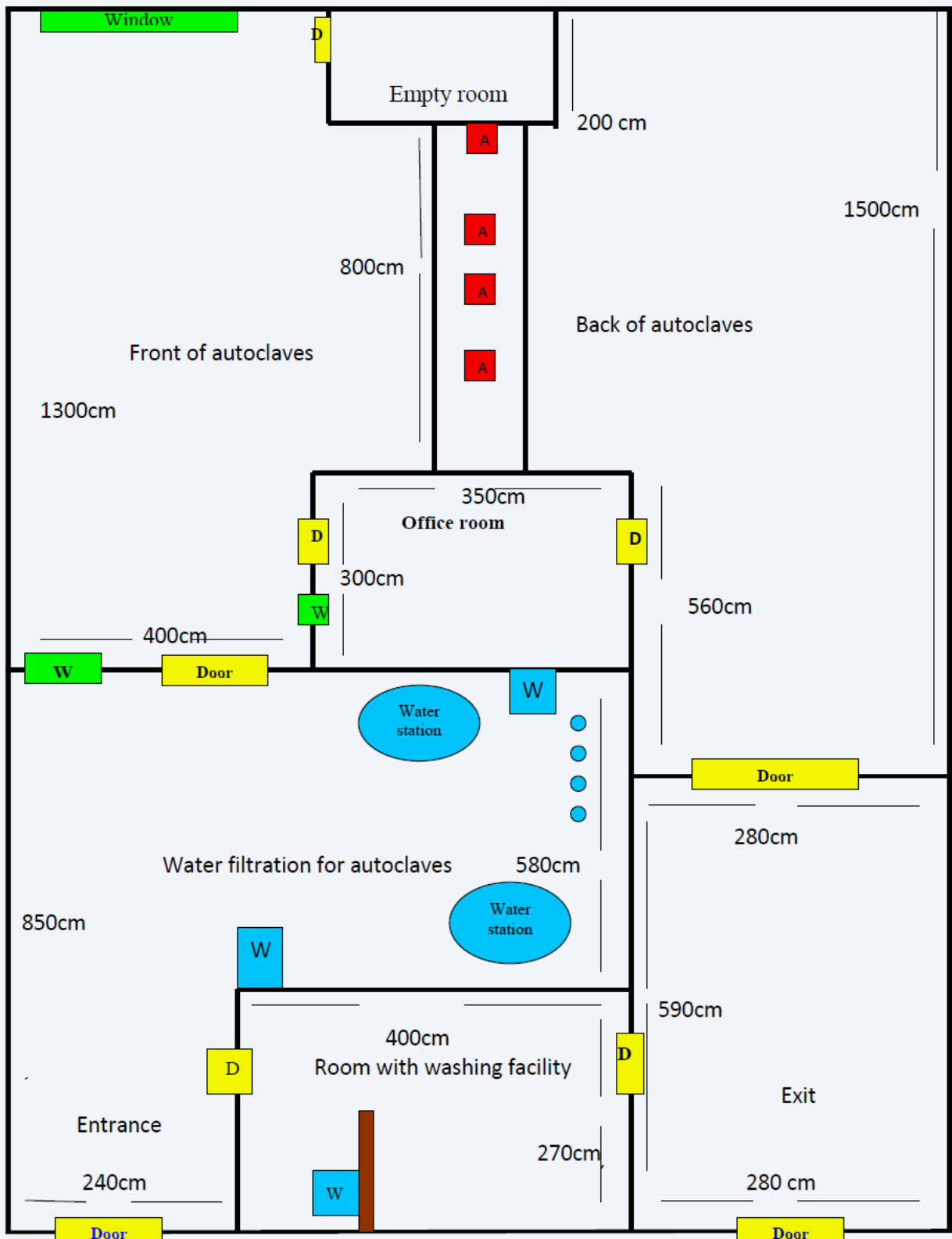
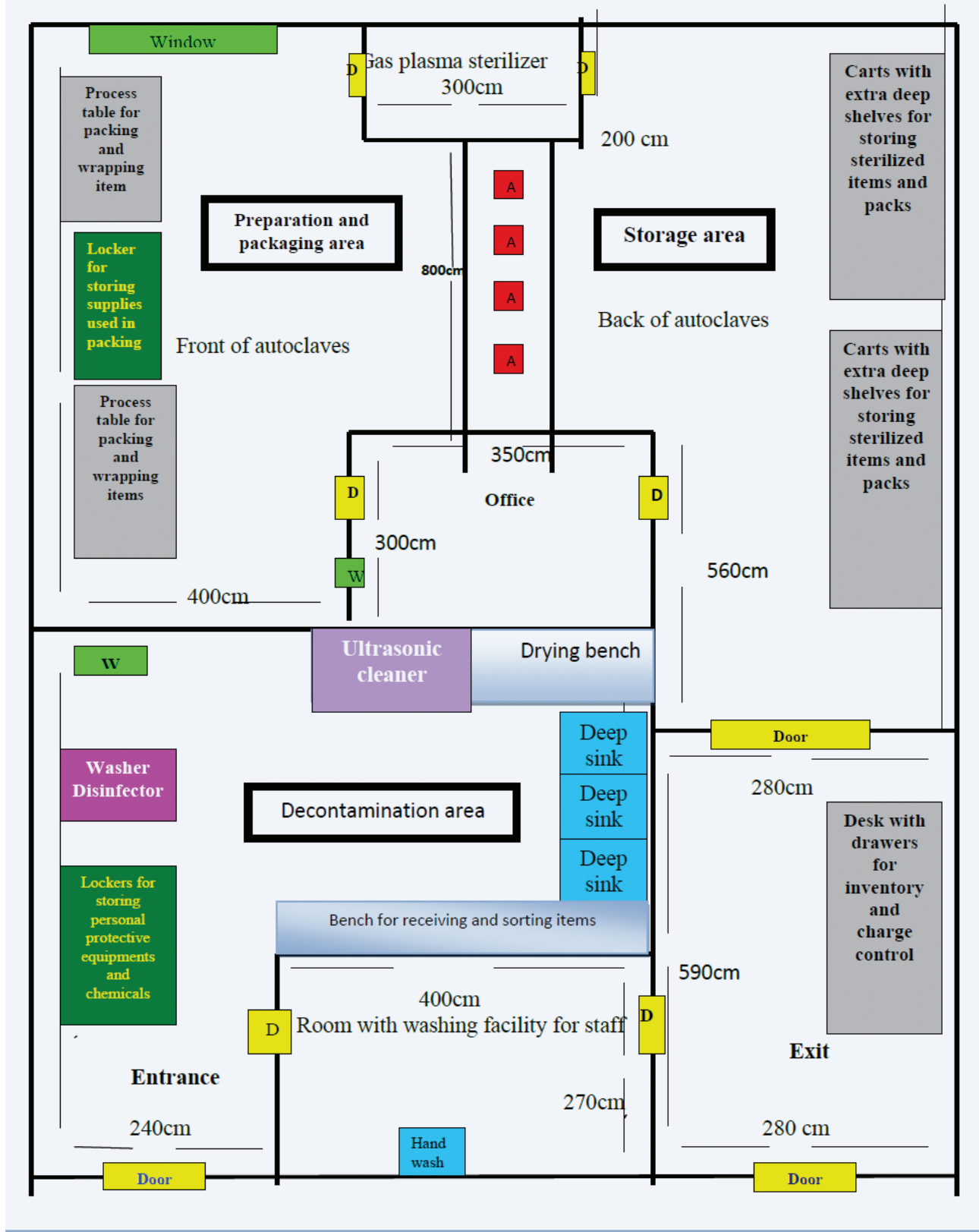


Figure 4. SPD design: recommended modifications



We also developed communication systems and clearly defined responsibilities for pre-cleaning, soaking and transport procedures. Closed carts for transportation of soiled and sterilized items are needed, as well as dedicated elevators for each of the clean and dirty equipment. There should be specific dedicated workers for transportation.

We proposed the following for improving equipment status: purchasing new sterilization equipment such as a gas plasma sterilizer, regular maintenance of available autoclaves, purchasing an ultrasonic cleaner, regular validation of autoclave performance by chemical and biological indicators, and recommended a detailed list of needed instruments, so we had instrument back up.

Finally, we recommended physical separation of work areas. The pass-through window should only be used to deliver clean items to the preparation and packaging area, which contains large tables and lockers. After sterilization in autoclaves, the sterile loads would be delivered at the distribution area near the exit, thus assuring complete separation of sterilized items from contaminated ones (Figure 4).

## Discussion

The first step in creating a quality system is to standardize the process. Since each hospital provides different services based upon its customer base and its mechanical and physical layout, it is important to develop policies and procedures that are specific to the individual process.

Policies are broad based documents that provide direction to personnel in all aspects of a process. For SPD this includes but is not limited to: receiving; decontamination; preparation; sterilization, storage and distribution. Staff involvement is critical to developing procedures for each step of the process.<sup>11</sup> An SOP is a controlled document that outlines detailed steps on how to perform a specific task, and helps produce predictable results by providing staff with a document for reference as they work through a process. It ensures that every employee performs the procedure in the same way, every time. As all staff follow the same SOP, performance differences between staff members are minimized. It also provides direction, eliminates guesswork, and reduces procedural breakdown.<sup>12</sup>

Documentation “ensures that the sterilization process is monitored as it is occurring, ensures that cycle parameters have been met, and establishes accountability. In addition, documentation helps personnel determine whether a recall is necessary, should evidence subsequent to lot release, such as a positive BI or nonresponsive CI, suggest sterility problems. Knowing the contents of the lot or load enables personnel to identify the medical devices to be recalled. In addition, this documentation provides evidence of the department’s quality control program”.<sup>13</sup>

In order to improve patient safety, OR and SPD must work together. Surgeons and OR staff may have little knowledge of sterile processing problems. Consideration of OR staff needs is also a major component of the quality system process. The SPD’s ability to consistently satisfy its customers’ needs is the first step towards being considered “reliable” and “professional”.<sup>8</sup>

Nowadays surgical interventions are witnessing a great revolution. Minimally invasive surgeries, and endoscopic and robotic procedures are the way of the future. Sterile processing departments no longer deal with simple surgical instruments, and often have multiple sterilization modalities and medical devices requiring many different methods of sterilization and cycle parameters,<sup>1</sup> so using a sole method of sterilization will not keep pace with future needs. It is vital that staff education and training, work processes and physical design of the department be standardized and optimized in order to maintain efficiency and meet required standards.

**Ethical approval:** Approval for this project was obtained from the hospital manager and authorized personnel in our facility.

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