Sterilization Center Design

Efficient instrument flow enhances office safety

A state-of-the-art central sterilization area improves clinical efficiency and enhances safety for both patients and dental team members. Whether building a new clinic or renovating an existing facility, paying attention to this critical element of dental office design can improve efficiency and provide peace of mind. While available space and resources may not allow every practice to create an ideal central sterilization area, the principles of thoughtful room design can be applied to improve any instrument processing program.

Sterilization center design is based on the five steps of instrument processing: decontamination, rinsing, drying and packaging, sterilization, and sterile storage. Workstations designated for each of the five steps walk instruments from “dirty” to “sterile” for maximum efficiency and sterility assurance.

Streamlined instrument flow requires sufficient instrument inventory, appropriate packaging materials, consistent cleaning and sterilization procedures, adequate space, thorough staff training, and teamwork. The entire dental team should participate in the selection of instruments, cassettes, and equipment as well as facility design. Effective hands-on training also helps develop team “ownership” of and enhance compliance with office policies and standard operating procedures. Efficient sterilization design, combined with effective training, can reduce the risk of sharps injuries, prevent instrument damage, and reduce stress, all while saving the practice time and money.

Central Sterilization

Operatories and instrument processing workstations should flow efficiently, eliminating bottlenecks, workspace crowding, and instrument backlogs. The central instrument processing area should start with a separate and distinct “dirty” area at one end of the room and proceed to a “clean” area at the other end, with few obstacles and turns in between. Create a “sterile pass-through” area from the instrument processing center to the operatories to facilitate access and prevent the spread of contamination to patient-care rooms.

Workspace Requirements

The central sterilization area should be located close to the operatories to reduce the number of steps required when transporting instruments. Use smooth, nonporous materials that are water- and chemical-resistant for counters, cabinets, and counters.

Learning Objectives

➤ Understand the rationale for creating a central sterilization area
➤ Describe the design and flow of a central sterilization area
➤ Detail the components and purpose of each of the five sterilization stations
➤ Be able to calculate instrument throughput to estimate equipment needs

continued on page 2
Sterilization Center Design

continued from front cover

and floors. Each of the five workstations requires at least 24 inches of counter-space. To determine the amount of counterspace necessary, consider the average number of patients seen and instruments used daily, the number of sterilizers needed, and the number of team members using the area.

Estimating Throughput

In most clinical settings, instrument recirculation creates a potential for bottlenecks that can affect the number of patients a dental office can see each day. Processing time and capacity dictate the recirculation rate, or “throughput.” Throughput is the number of instruments that can be processed per cycle. The slowest or lowest-capacity step in the process — usually either instrument cleaning or sterilization — determines throughput.

A number of variables influence the rate of recirculation:
- the number of patients to treat and the estimated number of instruments or instrument sets to use during each patient visit;
- the time required to clean, sterilize, dry and return instruments to the clinical team;
- the per-cycle capacity of cleaning and sterilization equipment and;
- staffing to process instruments.

Changing any of these variables can alter the dynamic of instrument recirculation and affect the number of patients that can be seen during a clinic day. If any variable is fixed (for example, autoclave cycle time, which cannot be adjusted), another variable must be modified to accomplish treatment goals.

To calculate throughput, determine the amount of time that it takes to process instrument kits, the capacity of the slowest or lowest-capacity step in the process, and the number of instrument kits needed to meet scheduling requirements. This information determines how many sets can be recirculated during an hour or a clinic day and identifies the maximum number of patients that can be accommodated during that time period.

When making throughput calculations, consider both the time and capacity of a process. For example, an ultrasonic cleaning cycle may take only 15 minutes; an instrument washer can take up to 45 minutes per cycle. Although the ultrasonic cleaner’s cycle is shorter, when the increased capacity of the instrument washer and the labor savings afforded by the more automated process are factored in, the instrument washer may be the more efficient cleaning method.

Staff Considerations

Whether designing new space or remodeling an existing one, schedule a team planning session to get staff input, discuss options, and evaluate processes. Be sure that staff members are familiar with basic infection control principles, including the chain of infection, standard precautions, and Centers for Disease Control and Prevention instrument classifications (that is, critical, semicritical, and noncritical); these concepts affect sterilization workflow. Discuss the different types of sterilization and decontamination equipment available, and select items to optimize safety and efficiency. Flowcharting instrument processing procedures as a group activity provides an excellent way to get all staff members involved in the process and at the same time ensures that proper protocols are being followed. Afterward, post the flowcharts as reminders to enhance compliance.

When procedures are in place and running smoothly, consider photographing or videotaping the instrument processing sequence to make a customized orientation program for new employees or as a refresher for experienced staff.
Dental Health-Care Settings, 2003

necessary for sterilization were present spores; verifies that all the parameters nec-
darized population of resistant bacterial
the sterilization process by using a stan-
sterilization failures from incorrect packaging,
 sterilization process by changing color
in the central sterilization room

CDC “[Dental healthcare personnel] should process all instruments in a design-
nated central processing area to more eas-
ily control quality and ensure safety. The cen-
tral processing area should be divided into sections for 1) receiving, cleaning, and decontamination; 2) preparation and packing; 3) sterilization; and 4) storage. Ideally, walls or partitions should separate the sections to control traffic flow and contain contaminants generated during processing…. Space should be adequate for the volume of work anticipated and the items to be stored.” — Centers for Disease Control and Prevention, Guidelines for Infection Control in Dental Health-Care Settings, 2003

FDA “Section 510(k) of the Food, Drug
and Cosmetic Act requires those device
manufacturers who must register [includ-
ing makers of dental instrument process-
ing equipment] to notify FDA [of] their intent to market a medical device. This is
known as Premarket Notification (PMN) or 510(k). Under 510(k), before a manu-
facturer can market a medical device in the United States, they must demonstrate to FDA’s satisfaction that it is substantially equivalent (as safe and effective) to a de-
vice already on the market. If FDA rules the device already is ‘substantially equivalent,’
the manufacturer can market the device. If [a] device ... has been in commercial dis-
bution before 1976 or is substantially equiva-
 lent to a device already on the market, [it will be listed in] FDA’s 510(k) releasable database [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm].” — Food and Drug Administration, Learn if a Medical Device Has Been Cleared by FDA for Marketing

**Glossary**

**Biological indicator** device that monitors the sterilization process by using a stan-
ardized population of resistant bacterial spores; verifies that all the parameters nec-
ecessary for sterilization were present

**Chemical indicator** device that monitors the sterilization process by changing color or form with exposure to one or more ster-
ilizing conditions; intended to detect ster-
ilization failures from incorrect packaging, sterilization loading, or equipment failure

**Contaminated** the presence of microorgan-
isms, blood, or other potentially infectious materials on living or nonliving surfaces

**Critical instruments** instruments that pen-
 erate soft tissue or contact bone, the blood-
 stream, or other normally sterile tissue (for example, surgical instruments, scalers, scalpels, blades, surgical dental burs)

**CSR wrap** material for packaging cassettes in the central sterilization room

**Detergent** compound with cleaning ac-
tion but no antimicrobial activity

**Disinfectant** chemical agent used on in-
imate (nonliving) objects to destroy virtually all recognized pathogens, but not nec-
essarily bacterial endospores

**Holding solution** solution that keeps the instruments wet so debris does not harden while waiting to be cleaned; also may be supplied as a foaming spray

**Instrument washer/thermal disinfect-
or** automatic device that uses a high-temper-
atu re cycle to clean and thermally disinfect instruments

**Noncritical instruments** instruments/ items that contact intact skin (for example, radiograph head/cone, blood pressure cuff, facebow, pulse oximeter)

**Semicritical instruments** instruments/ items that contact mucous membranes or nonintact skin but do not penetrate soft tissue or bone or enter the bloodstream or other normally sterile tissue (for example, amalgam condenser, impression tray)

**Sterilization** the use of a physical (such as heat) or chemical procedure to destroy all microorganisms, including highly resistant bacterial endospores

**Surgical milk** anticrorsive bath/lubricant for hinged instruments and carbide in-
struments

**Throughput** the number of instruments that can be processed per cycle

**Infection Control In Practice** is a re-
source prepared for clinicians by the Organization for Safety & Asepsis Procedures with the assistance and ex-
pertise of its member-contributors. OSAP is a nonprofit, independent organization providing information and education on infection control and occup-
ational health and safety to dental care settings worldwide.

Information in this issue has been brought to you with the help of the following individuals:

**Contributors**

Jackie Dorst, RDH, BS, is a microbiologist, practic-
ing dental hygienist, and owner of Safe Practice, a sterilization consultancy

Shannon Mills, DDS, is a past OSAP Chairman, co-
editor of The OSAP Report, and Editor-in-Chief of Infec-
tion Control in Practice

**Editorial Staff**

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Editor-in-Chief

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Putting It All Together

Designing or Updating the Sterilization Center

Once you have made the decision to centralize your instrument reprocessing program, a systematic approach to planning is critical. Change can be hard. Engage staff members early in the planning process. Team members get to take some ownership of the process, and team leaders benefit from valuable input from the staff members most involved in instrument processing procedures.

Remember: Designing the most efficient central sterilization area involves establishing five distinct workstations. See OSAP Charts and Checklists on “The Sterilization Stations” (next page) for details.

1. Review your existing floorplan and identify a readily accessible location physically separated from patient treatment areas.

2. Measure the available space and note the number and location of existing plumbing connections. This helps determine the usable space available for central processing.

3. Sketch your planned design using the five-workstation concept (described on page 5).

4. Estimate the average and maximum number of cassettes, trays, or packs used each day. Calculate instrument throughput needs by determining the capacity and speed requirements for cleaning and sterilization equipment.

5. Inventory existing equipment and compare the “as is” equipment condition against the desired state. Decide whether to retain or replace existing devices.

6. Consider equipment options. Ultrasonic cleaner or instrument washer? Gravity or vacuum autoclave? Look for products that meet your speed, capacity, and budgetary requirements.

7. Decide on cabinetry.
   - Install or renovate fixed cabinetry and countertops
   - or —
   - Install a modular off-the-shelf sterilization center.

8. Build a requirements list for equipment that considers:
   - speed,
   - capacity,
   - electrical needs,
   - plumbing requirements,
   - labor costs,
   - costs for consumable supplies, and
   - waste disposal requirements.

10. Check with both instrument and equipment manufacturers to verify compatibility between your handpieces and instruments and cleaning and sterilization methods.

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Ask OSAP

**Q**: Why is it important to package instruments for sterilization and storage? — A.F.O., Carson City, Nev.

**A**: Packaging cleaned instruments prior to placing them in the sterilizer is a standard of care that protects instruments and maintains their sterility until they are ready for use on a patient. Unprotected instruments may be re-contaminated with dust and spatter or by coming into contact with any number of non-sterile surfaces during transport, storage, tray set-up, and operatory set-up. — OSAP

**Q**: Can we store our sterile dental instruments under the sink? — B.L., Indianapolis, Ind.

**A**: Sterile items should not be stored on the floor, under the sinks, on windowsills, or adjacent to air vents. Conditions in these areas can compromise the sterility of the packages and in turn, instruments they contain. — OSAP

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For Academic and Institutional Settings...

Designing and building a central processing area for an academic or institutional dental setting? You may need to meet requirements from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). The Association for the Advancement of Medical Instrumentation (AAMI) has published an updated American National Standard (AAMI ST-35, 2003). Titled “Safe Handling and Biological Decontamination of Reusable Medical Devices in Health-Care Facilities and Non-Clinical Settings,” it outlines design criteria for decontamination areas and describes transport and decontamination processes. Visit www.aami.org for details.
The Sterilization Stations

Instrument processing in a fast-paced private practice setting is one of the most critical — and most time-consuming — sets of procedures in day-to-day dentistry. A well-designed sterilization center, up-to-date equipment, and regular team-member training ensures that sterile instrument inventory is replenished safely and efficiently.

From receiving through sterile-instrument storage, make sure your instrument processing workstations are stocked with everything needed for safe, efficient procedures.

1. Receiving, Decontamination, and Cleaning Station
   - Adequate counterspace for trays/cassettes
   - Waste containers
   - Trash containers located under counters with countertop access
   - Biohazard containers for medical waste
   - Sharps containers, wall-mounted or under-the-counter sharps containers (to save space)
   - Instrument cleaner
   - An automatic instrument washer/washer-disinfector
   - Large, recessed ultrasonic cleaning units (which reduce noise and improve visibility and access)

2. Rinse Station
   - A large sink with a flat bottom
   - A high-arch, swinging faucet with a single lever or foot control for rinsing instruments after they have been ultrasonically cleaned
   - Spray nozzle with a long hose to simplify rinsing

3. Packaging Station
   - At least 24 inches of counterspace for draining, sorting, and wrapping instruments
   - A “surgical milk” anticorrosive/lubricating rinse for hinged and/or carbide instruments (if desired)
   - Handpiece cleaner/lubricator and the compressed-air outlet it requires
   - A shallow drawer for CSR wrap, pouches, autoclave tape, and chemical indicators
   - Cabinets and racks for pouches and clean patient-care items

4. Sterilization Station
   - Table-top autoclave, chemical vapor sterilizer, or dry heat sterilizer
   - To accommodate cassettes, a sterilizer with at least a 10-inch diameter chamber
   - Large, recessed ultrasonic cleaning units (which reduce noise and improve visibility and access)

   **TIP:** Two sterilizers permits alternate cycling and provides a backup in case of equipment malfunction.

   **TIP:** Newer pre- and post-vacuum steam autoclaves (also known as Class-B sterilizers) have faster cycle times and eliminate the need for prolonged “open-door” drying after the heat cycle.

5. Storage Station
   - Enclosed sterile-storage cabinets or drawers, or a closed pass-through area at least 4 inches off the floor and separate from areas where nonsterile items are stored
   - Never store sterilized items where they may become wet. Wet packs are not considered sterile. Avoid storing such items above autoclaves, next to or under sinks, or adjacent to ultrasonic cleaners.

OSAP
To help practices stay on track, OSAP provides this calendar listing typical schedules for periodic maintenance, recordkeeping, and infection control activities. This schedule is intended only to serve as a guide. Proper practices, procedures, and maintenance schedules can vary according to the kinds of products used, the practice type, and patient volume. Always follow the device or equipment manufacturer’s instructions for maintenance and infection control.

For a monthly dental office calendar you can customize to best meet the needs and schedules in your practice, visit osap.org/calendars/index.htm. (Adobe Acrobat Reader required.)

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1. The flow of instruments in the dental instrument processing area should go from:
   a. the sink to the holding area
   b. the rigid leakproof container directly into the instrument washer
   c. “dirty” to “sterile”
   d. left to right

2. The five steps of instrument reprocessing do not include:
   a. decontamination
   b. rinsing, drying, and packaging
   c. sterilization
   d. disposal of hazardous chemical waste

3. What is necessary for smooth instrument flow?
   a. inventory, consistent procedures, adequate space
   b. a conveyor belt
   c. extra staff
   d. an instrument washer

4. Efficient sterilization flow reduces stress, costs, instrument damage, and:
   a. tarnish
   b. sharps injuries
   c. number of sterilizers needed
   d. broken appointments

5. Which federal agency regulates the marketing of sterilizers, instrument washers, and other dental instrument processing equipment in the United States?
   a. OSHA
   b. EPA
   c. CDC
   d. FDA

6. The minimum amount of counterspace needed in the sterilization area depends on:
   a. the number of patients seen and instruments used daily
   b. whether gravity or pre-vacuum sterilizers are used
   c. the size of cassettes and trays used
   d. the current market price of laminate

7. The receiving and decontamination station is for:
   a. receiving sterile items
   b. disposing of medical waste
   c. storing supplies
   d. storing sterile instruments

8. Surgical milk rinse, CSR wrap, autoclave tape, chemical indicators, and the handpiece cleaner/lubricator are located in:
   a. the rinse station
   b. the receiving and decontamination station
   c. the packaging station
   d. the sterilization station

9. The sterilization station must include:
   a. a table-top autoclave, chemical vapor sterilizer, or dry heat sterilizer
   b. an extra, “high-speed” sterilizer for handpieces
   c. a dishwasher
   d. a sink

10. The storage station:
    a. must have drawers and cabinets at least 14 inches off the floor
    b. should be as close as possible to the decontamination area
    c. should maximize space use by using areas under sinks
    d. should be separate from areas storing nonsterile items

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Compliance with laws and mandates issued by the government agencies that regulate healthcare delivery remains a challenge for practicing dentists today. San Diego-area consultant Joy Howard, RN, BSN, has some tips for encouraging worker compliance and in turn, easing employer stress.

First and foremost, she recommends, provide staff with a clear explanation of the regulations for your area. “Informed workers are compliant workers,” she says. “If your staff understands the reason for the regulations, they’re more likely to comply.” Consider sending them to courses offered by the American Dental Association or OSAP; for compliance courses on local regulations, look to your local dental society.

Second, assign an on-site “compliance officer” to help make sure that regulations from the state dental board, local health department, and state or federal Occupational Safety and Health Administration (OSHA) are followed. Your office manager or a long-term employee who is familiar with such regulations and how they are applied in practice makes a good choice, ensuring continuity and facilitating employee training on office procedures. Include all clinical staff members in the compliance process, Ms. Howard recommends. For example, assign one person to label chemicals, another to compile and maintain the office’s Material Safety Data Sheets (MSDSs). “By taking on responsibilities, staff are more likely to buy in to the compliance process and follow through with office policies,” she explains.

Third, she states, “Remember that patients watch you perform many of your duties.” They can draw quick conclusions from observing infection control and safety procedures. “The dentist must lead the way by example,” she explains. “If the dentist doesn’t support the process, staff is unlikely to take compliance seriously.”

OSHA regulations are in place to ensure a safe environment for both staff and patients. A safer dental office starts with a positive attitude and an understanding of the principles behind the rules.

An OSAP member since 2001, Joy Howard, RN, BSN, owns Dental Ed, Inc. A continuing-education provider for the California Board of Dental Examiners, she offers courses in OSHA compliance, infection control, and other topics to more than 450 dental offices in San Diego County. She can be reached at 760-519-5790.

Do you have a practice tip you’d like to share with other OSAP members and subscribers? Send your suggestions for enhancing dental infection control and safety in practice to editor@osap.org. Be sure to include contact information, a photo, and a brief bio. Thanks!