

Sterilization and the Importance of Sterilizer Monitoring

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The regulatory colleges for healthcare practitioners in Ontario are responsible to ensure that the clients of their registrants/members receive safe, effective care, including ensuring that appropriate and acceptable infection control protocols are followed.

The College of Dental Hygienists of Ontario Standards of Practice state that “Dental hygienists have an obligation to their clients to establish and maintain practice environments that have organizational structures, policies and resources in place that are consistent with legal, professional and ethical responsibilities that promote safety, respect and support for all persons within the practice setting.” One of the most critical ways that dental hygienists meet this practice standard is through ensuring that their infection control protocols and practices are performed, based on current scientifically accepted infection control guidelines.

In a survey commissioned by the CDHO and conducted by Ipsos Reid, the public was surveyed to assess their awareness of, and attitudes towards dental hygienists. One component of the survey included the assessment of public perception related to sterilization and sterilizer monitoring. The survey results are considered accurate to within +/- 3.5 points 19 times out of 20. The key findings of the survey related to sterilization and sterilizer monitoring included the following:

- There is unanimous support for the idea that it is important to sterilize dental instruments and a nearly unanimous belief that the instruments used in the dental practices they frequent are being sterilized correctly.
- When an explanation was provided about the purpose of spore testing, Ontarians placed a high degree of importance on spore testing and on it being performed correctly and at the required frequency.

- Ontarians are very confident that the dental office they frequent is using spore testing to validate the proper sterilization of dental equipment.
- Given the choice, Ontarians are much less likely to frequent a dental office that does not conduct spore testing.
- Ontarians believe that the dentist is responsible for ensuring that spore testing is being done correctly but agree that if the dentist is not carrying out this responsibility, then it is the responsibility of the dental hygienist to do so.

Through the Quality Assurance Program, dental hygienists are required to record the infection control practices and procedures used in their daily practice as part of the Typical Day in their quality assurance records. The quality assurance assessors use criteria based on current infection control guidelines in their assessment of the professional portfolios. Failure to provide evidence that these guidelines are followed is a contributing factor leading to an on-site audit of a dental hygienist’s practice environment.

From 2012–2016 in the Quality Assurance Program, 64 on-site visits have occurred. Of these, 60 dental hygienists have successfully demonstrated to the assessor that they were using acceptable infection control techniques, including providing evidence of spore testing with acceptable results and at the required frequency. Of the 4 remaining dental hygienists, 3 demonstrated compliance with accepted infection control protocols at or before their second visit, and 1 registrant has a follow-up visit scheduled. These statistics provide overwhelming evidence that demonstrates that dental hygienists in the province are dedicated to meeting the expectations of their clients in regards to infection control procedures and sterilization/sterilizer monitoring.

How Are Sterilizers Properly Monitored in Practice?

The effectiveness and proper performance of a sterilizer must be confirmed through a combination of three types of monitoring: physical or mechanical, chemical and biological. Use of one type of indicator does NOT replace the need to use the other two types.

1. Physical or mechanical indicators

Physical indicators include all devices used to assess cycle time, temperature and pressure. These include examining the sterilizers printout, if available, and by observation of the gauges or displays on the sterilizer. Although correct readings do not provide proof of sterilization, they can be used as an indication that a sterilizer may be malfunctioning. Each cycle should be observed to ensure that numbers in the manufacturer-recommended target ranges are being achieved.

2. Chemical indicators

Chemical indicators are those that use chemicals sensitive to heat to assess changes that have occurred during the sterilization cycle. These respond to changes in variables such as temperature, presence of steam or processing time. Examples of chemical monitors include autoclave tapes and sterilizer bags with indicators that change colour when a parameter is reached. Chemical strips are designed to be placed inside sterilization bags and may also be used for verification of sterilizing conditions. These indicators also serve a second purpose in allowing operators to verify if a package has been exposed to the sterilization process. Like physical or mechanical monitoring, these indicators do not indicate that a package is sterile but rather only that the measured parameter has been reached. A failed chemical test may be an early indication that a problem may exist.

3. Biological indicators (BI or spore testing)

Biological indicators use highly resistant and living microorganisms (spores) impregnated on strips or contained in vials to monitor the sterilization process and, according to all current evidence-based infection control guidelines, their use is the most accepted method of ensuring sterilization has occurred.

For quality control purposes, these systems work by using two identical strips or vials from the same lot. The “test” strip or vial is processed within a normal sterilization load. The second strip or vial is used as a “control” and is not subjected to the sterilization process. When the two are incubated and cultured to determine if the spores have survived, those from the “test” strip or vial should be completely inactivated and not grow (negative result) while those from the “control” should survive and grow (positive result). Ontario’s Provincial Infectious Diseases

Advisory Committee (PIDAC) infection prevention and control guidelines require that **spore testing be conducted on a daily basis**. Procedures should be developed to follow if any “test” strips or vials show a positive result, as this is an indication that sterilization has failed. Where mechanical monitoring has indicated proper sterilizer function, a second spore test should be performed to rule out operator error. The sterilizer should be temporarily taken out of service until the results of the second test are obtained. If the physical and chemical monitors indicate that the sterilizer is functioning properly and the repeat test is negative, the sterilizer can be put back into service. A second positive result indicates the need for service and the sterilizer should not be used until it has been inspected and repaired. Prior to putting it back into service, three spore tests should be performed to confirm sterilization is occurring.

There are currently many different in-office and commercial mail-out biological monitoring systems available for use. In-office monitoring may be more cost-effective with no delay between testing and the receipt of results but are technique-sensitive and require careful handling to achieve accuracy. Commercial mail services are convenient, require no equipment commitment and the companies confirm the results but they can be more costly and there is a delay in receiving results due to mail delivery schedules. Each office should assess their needs to determine which system will work best for them taking into consideration the need for daily monitoring.

With all types of monitoring, it is crucial that manufacturers’ instructions be followed for proper use and storage. Indicators that are beyond the expiry date must be replaced and only used for the sterilizer type for which they are recommended.

The CDHO record keeping regulation requires that equipment servicing records must be kept for all instruments or equipment used for examining, treating or rendering services to clients including that used to sterilize equipment or instruments. Results of the monitoring, repair and preventive maintenance measures related to sterilizers must be maintained including a log of the biological monitoring results.

Given the choice, Ontarians are much less likely to frequent a dental office that does not conduct spore testing.

Interested in reading more about sterilization monitoring? Go to the Public Health Ontario website at publichealthontario.ca and search for PIDAC. **CDHO**