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Steps in Performing a Risk Assessment

This information is presented to demonstrate a potential sequence of events that may occur during a Risk Assessment following a sterilization failure in instrument reprocessing, or during an investigation of an alleged IPAC lapse.

Background

It is important to have an understanding of what may occur during investigations of sterilization failures resulting from:

- Cycle errors
- Human errors
- IPAC lapses

As clinicians, we are responsible for whatever occurs in our practices.

We must understand that there is a range of potential problems, from simple to complex, and we must be able to assess the risk to patients, to determine if/how they will be affected, resulting from these problems.

There is a lack of information available to dentists in the subject of risk assessment.

Disclaimer

The author makes no claim to be an expert in the field of IPAC, but merely wanted to share this important information with colleagues.

Reference

There is an absence of information in this subject. After a reasonable search, the following reference was found and used in this presentation:

Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. Am J Inf Cont 2013; 41(5): 76-71.

Links

PIDAC Checklist related to steam sterilization failures and recall:

https://www.publichealthontario.ca/en/eRepository/CDS_Recalls_Steam_Sterilization.pdf

RCDSO list of possible reasons for a positive BI (also a good reference for reasons for steam sterilization failure):

https://az184419.vo.msecnd.net/rcdso/pdf/ipac/RCDSO_4884_Potential%20causes%20of%20a%20positive%20BI%20V.2.pdf

According to Weber and Rutala, there are 15 steps in performing a risk assessment in a sterilization failure.
Some are geared for larger institutions, like hospitals or care homes.
Some of the details may not fit or make sense for private dental practices.
There is decidedly a void of information available, but this does provide a sensible framework for assessment.

Step 1 - Confirm the failure.

Step 2 - Do not use the suspected instruments.

Step 3 - Remove the suspected sterilizer from service.

Step 4 - Inform key stakeholders.

Step 5 - Quickly perform a complete and thorough evaluation of the failure.

Step 6 - Prepare a list of potentially exposed patients.

Step 7 - Assess whether the failure increases the risk of infection.

Step 8 - Inform expanded list of stakeholders.

Step 9 - Develop a hypothesis for the failure and initiate corrective action.

Step 10 - Initiate a more detailed study of possibel adverse outcomes in patients.

Step 11 - Notify the appropriate authorities.

Step 12 - Consider notification of patients.

Step 13 - Advise testing.

Step 14 - Devise a long-term follow-up plan.

Step 15 - Report.

Here are the details of each step.

Step 1 - Confirm the failure
·Review the BI, MI's, CI's and try to determine if it is human error or mechanical error.
·Determine if there has been a deviation from the normal or recommended sequence of events in reprocessing.
·This demonstrates why it's so important to follow your specific steps in instrument reprocessing.
·If, for example, you have determined that the failure is due to a corrupted BI vial, then run another BI and if it checks out, there is no risk and you can exit this inviestigation at this point.

Step 2 - Do not use the suspected instruments
·This is different from an instrument recall.
·At this point, you're investigating a cycle error and you're dealing with one load of instruments.
·Set them aside and do not use them.
·It's different if you have a failed BI. Public health says run another vial and check the results.
·This is where having a short incubation spore and a minimized quarantine helps.
·Properly quarantine the instruments and do not release them form quarantine until you have verified the results.

Step 3 - Remove the suspected sterilizer from service
·Do not use it until you've determined what went wrong.

Step 4 - Inform key stakeholders
·If you're an assistant, tell your supervisor.
·If you're the supervisor, start documenting. Start a report and log as a cycle error in your cycle logs.

Step 5 - Quickly perform a complete and thorough evaluation of the failure
·This is not exactly like step 1, which confirmed THAT a failure has occurred.
·This step is to determine WHY the failure has occurred.
·If you're reprocessing as you should, you're only investingating a cycle error: eg, low water in your sterilizer, or a poor door seal, etc.
·If so, the investigation could end here and you can safely assume that there's no risk to anyone.
·Add the determined reason to your cycle log and exit this investigation.

Step 6 - Prepare a list of potentially exposed patients
·Up to now, this has focused on a cycle error.
·If you're following proper IPAC practices, you'll need to perform this step if things have gone wrong.
·If you're being investigated for an IPAC lapse, the list will become everyone you've treated since the earliest time that PHO has determined you've NOT been following IPAC practices, which may be dependent on your recall policy (make sure you have one!).

Step 7 - Assess whether the failure increases the risk of infection
·From your patient list, identify which procedures involved critical areas and critical instruments.
·Then consider the types of instruments used in the procedures, eg. a single-piece uncomplicated instrument carries a far lower risk than a multi-piece instrument that cannot be disassembled, making it harder to clean and sterilize.
·Of that group of patients, use your medical histories to determine if there are any high risk patients.
·Evaluate if all of the links of the chain of infection are present. If not, then your risk assessment actually ends here.
·Remember: steam sterilization has an enormous safety margin; they say a small deviation sform standar practice may not represent a patient hazard.

Step 8 - Inform expanded list of stakeholders
·This means call public health, plus call your lawyer.

Step 9 - Develop a hypothesis for the failure and initiate corrective action
·Reviewing the reasons for the failure, but now, develop ways to avoid it in the future. It's sensible.
·Better suited for larger facilities, such as hospitals.

Step 10 - Initiate a more detailed study of possibel adverse outcomes in patients
·Again, this step seems suited to larger facilities.

Step 11 - Notify the appropriate authorities
·Again, this step seems directed for use in larger facilities, not private dental offices.
·Lawyer up.

Step 12 - Consider notification of patients
·PHO may mail your patient list and fax blast every health care provider in your jurisdiction, and may alsp advise the media just to make sure that nobody on the mail list misses it.

Step 13 - Advise testing
·PHO has taken care of this step for you as well. They usually advise testing together with counseling.
·Your lawyer may suggest that it is prudent for them to share their algorithm and calculations of risk assessment with you.
·There are protocols to be followed for postexposure management of patients exposed to Hep B, Hep C and HIV.

Step 14 - Devise a long-term follow-up plan
-Once corrective action has been taken, it is crucial to see whether these actions have elimiated the problem.

Step 15 - Report
·Document everything. At this point, your lawyers are probably doing this for you.
·This information can be used to prevent other such events elsewhere.
·It shows you've been cognizant of the problems and have tried to rectify the problems, to prevent recurrence.

Things to remember

Ensure that you're following recommended IPAC procedures and do not deviate from them.

Ensure your ultrasonic cleaner or instrument washer is receiving recommended scheduled manitenance and documentation.

Ensure your sterilizers are receiving recommended scheduled maintenance and documentation.

Steam sterilizers have a robust margin of error.

All of the links in the chain of infection must be present.

The viruses they're most worried about are fragile and are very easy to kill.

An infection is not automatic if an exposure occurs.

Ask to be shown any algorithm and calculations of risk assessment as well as how they were generated and applied.
-You are entitled to make a request through the **Freedom of Information Act through the Provincial Privacy Commissioner**.