

The Q-Net™ Monthly

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What's News

This is the twelfth and final issue of 1999, making this a time to reflect and reassess what we can do to improve the status quo. For while current infection control practices may be adequate, there is always room for improvement. Indeed, all of your efforts to improve patient safety are appreciated. *Wishing you all a very happy and healthy New Year!*



Happy Holidays!

'Q-Net 99'



'Q-Net-99,' a bound collection of all of 1999's newsletters, will be published in January 2000.

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

Chemical indicators for LCGs

Question and Answer

"Last week we had a JCAHO survey. The nurse surveyor asked how often we check the strength of the glutaraldehyde solution we use to disinfect endoscopes. I provided the surveyor with ASGE's white paper, which provides guidelines on reprocessing endoscopes. The surveyor then called the manufacturer of our glutaraldehyde solution who (probably trying to minimize its liability) said the concentration should be checked before each scope is reprocessed. My question is this: How often does the glutaraldehyde solution's concentration require checking?"

Background: Most liquid chemical germicides (LCGs) used to reprocess endoscopes and other semi-critical devices are reused several times. Whereas the labels of some LCGs indicate that they may be reused for a maximum of 30 days, others may require the LCG be discarded within 7 days. (Some LCGs may be labeled for only one use.)

There are several advantages to reusing LCGs (and other products), one of which usually is a reduction in costs. One disadvantage with reusing a LCG, however, is the requirement to monitor periodically the concentration of its active ingredients. Several factors, including the number of instruments reprocessed in the LCG and the dilution of the LCG with rinse water remaining in

the instrument after cleaning, contribute to reducing the LCG's concentration and shortening its reuse life.

In order to satisfy its label claims, the LCG must remain at or above its *minimum effective concentration* (MEC). Whenever the LCG drops below its MEC (which can occur in fewer than the maximum number of days indicated on its label), the LCG must be discarded and replaced with a fresh solution.

Most 2% (alkaline) glutaraldehyde formulations, for example, can be reused for as many as 14 days. Some busy endoscopy units, however, may find that the glutaraldehyde solution's MEC of 1.5% is reached in as few as 7 to 10 days, requiring it be discarded and no longer reused. Using the LCG at a concentration below its MEC can result in inadequate disinfection.

How does the health care facility know when the LCG has reached its MEC? Like biological indicators (BIs) used to evaluate the effectiveness of sterilization processes, chemical indicators (CIs) are routinely used to monitor rapidly the LCG's effectiveness. One type of commonly used CI is a test strip that changes color depending on the concentration of the LCG's active ingredients. Comparing this color change with a color chart provided with the CI's labeling aids in evaluating whether the LCG can continue to be reused, a practice that is essential to the prevention of patient infection. (Note: At least one LCG

(Continued on page 24)

cleared by the FDA contains two active ingredients. Its label therefore requires that two different types of CIs be used to monitor independently the concentration of the LCG's two active ingredients.)

As with any medical device, CIs are not foolproof and have their limitations. In general, CIs yield qualitative results, such as *pass* or *fail*, not more informative quantitative results, like the LCG's actual concentration. Moreover, the CI's results are often equivocal and difficult to interpret, especially if the LCG's concentration is at or near its MEC. As the labeling of some CIs recommends, using several test strips to sample the LCG's concentration two or three times may yield more reliable and accurate results.

And no CI confirms that high level disinfection was achieved (nor can a BI confirm sterilization). Rather, most CIs indicate, when used in accordance with their labeling, whether the LCG's active ingredients are present and above, near or below their respective MECs. (CIs, though of a different type, are often used to show whether a packaged item has been exposed to a sterilization cycle.)

And how often is the LCG to be monitored? In 1995 the American Society of Gastrointestinal Endoscopy (ASGE) published a position paper entitled, "Reprocessing of flexible gastrointestinal endoscopes" (*Gastrointest Endosc* 1996 May;43(5):540-5). This position paper, which was jointly prepared by ASGE and the Society for Gastrointestinal Nurses and Associates (SGNA), presents specific recommendations for the appropriate reprocessing of flexible gastrointestinal endoscopes. In addition to stressing the importance of cleaning followed by high level disinfection to prevent patient infection, this position paper recommends testing the concentration of reused LCGs, such as glutaraldehyde and hydrogen peroxide, "at least once each day ... or more frequently as dictated by high numbers of endoscopes being reprocessed or as directed by the manufacturer of the germicide."

In truth, the labels of some LCGs indicate that their concentration be tested prior to reprocessing *each* endoscope. While this practice is ideal, some health care facilities may find it more practical to implement a quality control policy that predicates the frequency of testing the LCG's concentration on how often the LCG is reused, as provided in ASGE's recommendation (refer to: APIC guidelines for infection control practice. *AJIC Am J Infect Control* 1996;24:313-42).

Facilities using a 14-day, 2% glutaraldehyde solution, for example, may find that monitoring the LCG's concentration only once-a-day for the first few days of its reuse, when the concentration of the glutaraldehyde is well above its MEC, does not jeopardize patient safety. But as the number of days of its reuse increases, and the glutaraldehyde concentration decreases and approaches its MEC of 1.5%, using a CI to

monitor its concentration more frequently than once-a-day may be necessary, particularly in a busy endoscopy unit.

Recommendations: Monitor the LCG's concentration as frequently as indicated by its labeling. Only use CIs cleared by the FDA for use with the specific LCG, and ensure the CIs are used in accordance with their labeling.

For those health care facilities using a LCG whose label requires that its concentration be monitored prior to reprocessing each endoscope, but who consider this requirement impractical, if superfluous, and instead monitor the LCG only once-a-day, performing the following test may be useful:

- (1) Monitor the LCG's concentration once-a-day, per the facility's current quality control policies, for at least two weeks. Use the appropriate CI and record the results (which the facility is probably already doing). Remember that as the number of reprocessed endoscopes increases, the need to monitor the reused LCG more frequently will likely also increase.
- (2) Next, alter this monitoring pattern and test the LCG's concentration at least twice-a-day (if not prior to reprocessing each endoscope). Again use the appropriate CI and perform this test for at least two weeks. Record the results.
- (3) Finally, analyze and compare the results of these two different monitoring patterns.

If this test's data show that monitoring the LCG's concentration once-a-day was sufficient to prevent the use of the LCG below its MEC, then this practice is probably adequate. But if this test's data show that monitoring the LCG's concentration at least twice-a-day was crucial to detecting when the LCG dropped below its MEC, then the facility would have performed an important test that demonstrated the inadequacy of monitoring the LCG's concentration only once-a-day. (If for any reason the number of times the LCG is reused changes significantly, this test should be repeated and the results reevaluated. Of course, individual results may vary.)

Happy Holidays!

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

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