# The Q-Net™ Monthly

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## What's News

Two articles are presented in this issue. The first addresses the legal implications of using 2% glutaraldehyde in a manner not necessarily indicated on its label. The second article advises against soaking instruments for less than 20 minutes. Refer to this newsletter's November 1995 and February-March 1996 issues.

## GI: 'General Interest'

We have received many requests for our book, "Q-Net 96: Questions and Answers in Infection Control and Endoscopy, Part 1," which is a collection of all of Q-Net's 1996 newsletters. We thank you for your orders. To obtain a copy, please send us your request: the cost is $9.95. Tthis monthly newsletter is free!

## 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.

# 20 v. 45 minutes

### *A risk management discussion*

This article discusses the use of 2% glutaraldehyde to achieve high-level disinfection in 20 minutes at room temperature (20ºC) (also known as the '20/20' claim), despite its label's 45 minute at an elevated temperature (25ºC) claim.

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Virtually all endoscopy and infection control organizations recommend high-level disinfection for flexible endoscopes (reference 1, below). (High-level disinfection is all that should be expected when processing an endoscope in a liquid chemical sterilant.)

Moreover, each of these organizations, which includes AGA, ASGE, and SGNA, recommends immersion in 2% glutaraldehyde for 20 minutes at room temperature (reference 1), provided: (a) the solution is above its minimum effective concentration, and (b) the instrument is meticulously pre-cleaned.

The Association for Professionals in Infection Control and Epidemiology (APIC) (reference 2) and AORN (reference 3) also endorse the '20/20' use of 2% glutaraldehyde to achieve high-level disinfection as long as the facility employs a standardized cleaning protocol (reference 4).

*... assertions that using 2% glutaraldehyde for 20 minutes (at room temperature) may pose a legal risk are without foundation.*

Addressing the use of a device in a manner not necessarily indicated on its label, AORN published that 2% glutaraldehyde's instructions for use are based on the assumption that, contrary to standard practice, the instrument may not be thoroughly cleaned prior to chemical immersion.

AORN stated that, " ... the glutaraldehyde label (is) applicable only to those items that are not pre-cleaned before being subjected to the disinfection solution" (reference 3).

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## *What about a 10 minute soak?*

**A nurse's question:** *We always thoroughly pre-clean our instruments. If we heat our 2% glutaraldehyde solution above 25ºC, can we reduce our soaking time to 10 minutes?*

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AORN, APIC, SGNA, and ASGE (see adjacent article) each recommends soaking the entire endoscope in 2% (alkaline) glutaraldehyde for 20 minutes at room temperature (20ºC) to achieve high-level disinfection (references 1-4, below).

And while common sense suggests that heating glutaraldehyde may accelerate its sporicidal properties, which could permit it to achieve high-level disinfection in as few as 5 to 10 minutes, none of the current glutaraldehyde labels supports this claim.

➡ *Reducing the soaking time below 20 minutes may place the patient at risk.*

A worst-case scenario in which the

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AORN further noted that, "In some instances, perioperative nurses must consult not only product labels but also seek from manufacturers and independent laboratories additional information that may not be evident in product labels" (reference 3).

The '20/20' recommendation of these organizations is a good example of the occasional need to supplement a product's label with published data and guidelines that speak to a more clinically relevant setting (e.g., the adequacy of a shorter immersion time to achieve high-level disinfection if the instrument is meticulously pre-cleaned).

Addressing issues of liability, the Laboratory Section of the American Public Health Association (APHA) formed a committee to discuss the legal risks associated with using 2% glutaraldehyde to achieve high-level disinfection in a shorter soaking time than indicated on its label (reference 5). The consensus of this committee, which included representatives from the FDA, EPA, and CDC, was to recommend adherence with APIC's '20/20' guideline. This committee also concluded that there is "no justification for penalties by a federal or accreditation agency" if a hospital were to follow APIC's '20/20' guideline, instead of to adhere to glutaraldehyde's 45 minute label claim at 25°C (reference 5).

There are no published studies demonstrating a clinical difference in the infection rate between thoroughly pre-cleaned instruments soaked in 2% glutaraldehyde for 20 minutes at room temperature (20°C) and those soaked for 45 minutes at 25°C.

➡ And, therefore, it is reasonable to conclude that assertions that using 2% glutaraldehyde for 20 minutes (at room temperature) may pose a legal risk are without foundation.

Thank you for reading this newsletter. *I have responded to these issues to the best of my ability. Respectfully, the Publisher:* ***Lawrence F. Muscarella, PhD.*** Please direct all correspondence to:

Lawrence F. Muscarella, PhD, Publisher
*Director, Research & Development*
*Chief, Infection Control*

**Custom Ultrasonics, Inc.**
144 Railroad Drive, Ivyland, PA 18974
*Tele:* 215.364.1477; *Fax:* 215.364.7674



*(Continued from p. 9: What about a 10 minute soak?)*

glutaraldehyde solution: (1) is frequently used, (3) is at the end of its indicated use-life (e.g., 14 days), (2) is diluted with rinse water, and (3) contains organic soil and other patient debris, must be considered. A 20 minute soak provides a suitable margin of safety that protects the patient were the concentration of the glutaraldehyde solution to drop to 1.5%, its minimum effective concentration (MEC).

✓ *Is the patient infection rate likely to increase if pre-cleaned endoscopes are soaked in 2% glutaraldehyde for only 10 minutes at an elevated temperature above 25° C ?*

Unlikely;* however, until presented with validated and peer-reviewed data that support a soaking time for 2% glutaraldehyde shorter than 20 minutes at a specific elevated temperature, this practice is not recommended.

Because of its higher concentration, 3.4% glutaraldehyde may be more likely to achieve high-level disinfection during a 10 minute soak than 2% glutaraldehyde, with all other variables the same (reference 6). This 28-day formulation contains surfactants, however, and may therefore be difficult to remove during rinsing.

Moreover, vapors released from a 3.4% glutaraldehyde solution may be more detectable than a 2% concentration. Particularly when increasing glutaraldehyde's temperature, ensuring an adequate number of room exchanges is essential to reduce the airborne glutaraldehyde level to a sufficiently low level. *THE END*

* Some guidelines indicate that as few as 4 minutes may be sufficient to destroy all vegetative bacteria and viruses, including HBV and HIV (reference 7). But because the endoscope may be contaminated with resistant mycobacteria, a longer soaking time is clearly necessary. Also, a study found a 5 minute soak in 2% glutaraldehyde after thorough cleaning to be clinically indistinguishable from a 10 to 20 minute soak (reference 8). To be sure, the germicide's concentration and temperature are likely to be as essential to a shorter immersion time as thorough instrument cleaning.

## References

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