For: *Infection Control, GI Endoscopy, Operating Room, Instrument Reprocessing, Risk Managers, et al.*

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What's News

In mid-October (2011) several newspaper articles reported that a clinic in Ottawa, Ontario, had been improperly reprocessing upper and lower gastrointestinal (GI) endoscopes for almost a decade, requiring the notification of 6800 patients. *Visit*: www.MyEndoSite.com for a listing of these newspaper articles, for more details of this incident, and to subscribe to this newsletter.

Founder, Editor

This newsletter/journal's articles are written by its founder, **Lawrence F. Muscarella, Ph.D.** *Subscribe:* www.MyEndoSite.com

What is 'Q-Net'?

Q-Net is a technology assessment, infection control-based **net**work of **q**uestions, answers, and perspectives. Its newsletter, or journal, is *The* **Q-Net™** *Monthly*.

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and operating room communities to improve patient care not only by asking good questions but also by demanding well referenced, evidence-based answers.

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

Federal Register: Reprocessing Reusable Medical Instruments

Five important instrument-reprocessing topics are discussed, in reply to a recent request by the FDA for public comments.

This newsletter's issue:

- discusses a letter written by Lawrence F. Muscarella, Ph.D.—the founder of this newsletter—to the FDA in reply to the Agency's solicitation in the *Federal Register* for public comments to improve the quality of reprocessing reusable medical instruments;
- requests clarification of five potentially confusing reprocessing topics that may pose an increased risk of healthcare-associated infections (HAIs);
- provides a number of suggestions to prevent HAIs; and
- also provides comments in reply to the FDA's "*Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*," which is a *draft* guidance document that the Agency issued in May, 2011.

INTRODUCTION: Healthcare-associated infections (HAIs) are responsible for as many as 99,000 patient deaths each year in the U.S. and an estimated $20 billion in healthcare costs.[1] Whether in an intensive care unit (ICU) or other patient-care setting, HAIs have many different causes—including the improper reprocessing of reusable medical instruments.[2]

Blood pressure cuffs, gastrointestinal (GI) endoscopes, and laparoscopes are examples of reusable *non-critical, semi-critical*, and *critical* medical devices, respectively, whose inadequate cleaning and disinfection, or sterilization, pose an increased risk of HAIs.[3]

Flexible endoscopes—several types of which are complex in physical design and challenging to reprocess—are associated with more HAIs than any other type of reusable instrument.[4] A thorough understanding of the designs, uses, and reprocessing requirements of these and other reusable medical instruments is crucial to their safe and effective use.[3,4]

(Continued on page 16)

- Two box articles about liquid chemical sterilization are featured on p. 18.
- An article about the public reporting of infections is featured on p. 20.

(Continued from page 15)

FDA, CDC: During the past two decades the *Food and Drug Administration* (FDA) and *Centers for Disease Control and Prevention* (CDC) have published a number of alerts, advisories, and notices discussing the improper reprocessing of reusable medical equipment.[4-7] Among other important aspects of reprocessing, these publications have focused on the impact of design changes on the safety of automated reprocessing devices;[5] the importance of quality assurance to prevent HAIs associated with the improper reprocessing of flexible endoscopes;[6] and the responsibilities of manufacturers to ensure the proper reprocessing of reusable instruments.[7]

FEDERAL REGISTER: The FDA recently established a docket, or an electronic folder, that features transcripts and other information about the reprocessing of reusable medical devices. Included in this docket is a notice that the FDA published in the July 28, 2011, issue of the *Federal Register*.[2] (This docket and notice are identified by the codes, respectively, of *FDA-2011-N-0294* and *FDA-2011-N-0294-0004*).[2]

Briefly, this notice provided the public with the opportunity to comment on another important aspect of instrument reprocessing: factors affecting reprocessing's quality and effectiveness. These factors are several and include the physical designs of reusable medical equipment, which may not necessarily facilitate reprocessing, and the practices employed by healthcare facilities to reprocess this equipment.

LETTER: In reply to the FDA's notice in the *Federal Register*, Lawrence F. Muscarella, Ph.D. (who is this newsletter's founder) wrote a letter to the Agency, dated August 5, 2011, requesting the clarification of five specific instrument-reprocessing topics. Each of these topics is listed in Table 1, and Dr. Muscarella's letter to the FDA—which is the focus of this newsletter issue—is identified in the FDA's docket by the code of *FDA-2011-N-0294-0006*.[8]

PURPOSE: The purpose of Dr. Muscarella's letter requesting clarification of these specific five topics (listed in Table 1; also *see*: Box A) is: (1) to mitigate confusion that may surround each topic; (2) both to improve the quality of instrument reprocessing and to prevent HAIs; and (3) to provide healthcare professionals with a template to prepare and submit their own responses to the FDA, in reply to the FDA's notice in the *Federal Register* and to future requests by the Agency soliciting comments to improve public health.

DRAFT GUIDANCE: While Dr. Muscarella's submitted letter was written in reply to the FDA's specific solicitation for public comment in the July 28, 2011, issue of the *Federal Register*,[2] his letter also responds to content in the FDA's *draft* guidance document entitled *"Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,"*[9] which was posted on-line on May, 2, 2011, and has not been finalized or officially adopted.

Table 1. *Five Reprocessing Topics*. Phrased as questions, the following is a list of five topics addressed in Dr. Muscarella's letter to the FDA, in reply to the Agency's solicitation in the *Federal Register* for public comments to improve the quality of instrument reprocessing.

1. Sheathed "ENT" endoscopes: *Does covering with a sheath an ear-nose-throat ("ENT") endoscope (i.e., a flexible nasopharyngoscope) or any flexible endoscope "lower" the device's classification from semi-critical to non-critical for which intermediate-level disinfection would be suitable?*

- *See: References #3, #9—12, #17.*

2. Laryngoscope handles: *Like the blade to which it attaches, is not the rigid laryngoscope's handle a semi-critical device that requires at least high-level disinfection?*

- *See: References #13, #15—18.*

3. Skin electrodes: *Are skin electrodes (e.g., those used on the scalp during "EEG") non-critical devices, even though they may contact abraded skin during routine use?*

- *See: Reference #9.*

4. Liquid chemical sterilization: *Are instruments processed by automated "liquid chemical sterilization" systems "sterile" for use, despite the processed instruments being terminally rinsed with water that is not sterile?*

- *See: Box A, Box B and References* #21—33.

5. The FDA's definition of "sterile, sterility": *Is an instrument that is heavily soiled with non-viable debris capable of causing patient harms of non-infectious origins (examples include pyrogenic responses and toxic anterior segment syndrome, or TASS) still defined as "sterile"?*

- *See: References* #9, #19, #20.

Topic #1: ENT endoscopes

Background: A number of years ago Dr. Muscarella wrote the FDA requesting the Agency review for clarity and consistency its published guidance document for manufacturers seeking to market disposable sheaths used as protective barriers to cover ear, nose, and throat ("ENT") endoscopes.[10] Entitled *"Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers,"*[11] this guidance document (which has not

(Continued on page 17)

(Continued from page 16)

been updated or revised) was issued on March 12, 2000.

In this correspondence with the FDA,[10] Dr. Muscarella focused on the following statements in this guidance document about sheaths used to cover ENT endoscopes:[11]

- ENT endoscopes are "*semi-critical* devices as they come in contact with mucous membranes, which may or may not be intact"; and

- "the Center for Disease Control (CDC) and Association of Practitioners in Infection Control (APIC) recommend *high-level disinfection* as the minimum acceptable level of reprocessing for *semi-critical* medical devices such as endoscopes."

Suggesting that the use of an effective protective sheath, however, would "lower" the ENT endoscope's infection-control device classification from *semi-critical* to *non-critical*, this same FDA guidance document also states that:[11]

- "Reprocessing of the endoscope after removal of the used sheath and before application of a new sheath must be recommended and described in the user's information manual (e.g., labeling). If the applicant (i.e., the manufacturer) sufficiently demonstrates protective barrier properties of the finished device, a cleaning procedure followed by an *intermediate disinfection* step will be required"; and

- "In addition to cleaning, an *intermediate disinfection* step such as wiping with a 70% isopropyl alcohol soaked gauze pad should be recommended.* This step is added to reduce the likelihood that any viable organisms remain on the endoscope prior to application of a new sheath."

Discussion: These statements in this FDA guidance document raise a number of questions, in part because they are seemingly inconsistent with: (*i*) the FDA's current advice, which is provided in the Agency's aforementioned *draft* guidance document on the reprocessing of medical devices (issued May, 2, 2011);[9] (*ii*) the FDA's stated goal to improve the quality of instrument reprocessing and prevent HAIs; and (*iii*) the CDC's published guideline for the disinfection and sterilization of instruments in healthcare facilities.[3]

As previously noted, the FDA acknowledges that ENT endoscopes are *semi-critical* devices.[11] But, whereas its guidance document discussing the clearance of protective sheaths (finalized on March 12, 2000) recommends intermediate-level disinfection of the endoscope after removal of the used sheath,[11] the FDA asserts in its *draft* guidance document on the reprocessing of medical devices[9] (which has not been finalized) that a reusable instrument's reprocessing instructions "should assume (that) the device is used *uncovered*" (i.e., as if no sheath had been used during the procedure), "because of the potential for loss of cover integrity during use"[9]—which is an instruction that requires the reusable *semi-critical* instrument be at least high-level (*not* intermediate-level) disinfected after the sheath's removal.

The CDC would agree, having similarly stated in its guideline on disinfection and sterilization that the use of a protective sheath to cover a reusable instrument neither lowers the instrument's infection-control classification (e.g., from *semi-critical* to *non-critical*) nor reduces its required level of disinfection (e.g., from *high-level* to either *intermediate*– or *low-level disinfection*).[3] Whether confusion about the minimum reprocessing requirement of an endoscope sheathed during the procedure has been linked to HAIs is unclear.

The use of a protective sheath does not reduce a reusable semi-critical *instrument's minimum level of disinfection from high-level to intermediate-level.*[9]

Action: The FDA is respectfully requested to consider updating its published "*Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers*" (and all other relevant documents) to prevent user confusion; improve the quality of instrument reprocessing; minimize the risk of disease transmission; and to be consistent both with the FDA's *draft* guidance document discussing the reprocessing of medical devices[9] and with CDC guidelines.[3]

(Continued on page 19)

Article at a Glance: Improving the quality and effectiveness of instrument reprocessing

◆ **BACKGROUND**: The FDA recently provided the public with an opportunity to provide suggestions for improving the quality of reprocessing flexible endoscopes and other types of reusable medical devices.

◆ **FOCUS**: A letter that this newsletter's founder (Dr. Muscarella) submitted to the FDA respectfully requesting that the Agency clarify five potentially confusing instrument-reprocessing topics is discussed.

◆ **CONCLUSION**: Clarification of these five topics, which are listed in Table 1, is recommended to improve the quality of instrument reprocessing and prevent HAIs. ●

* The suggestion to "wipe" an instrument's surfaces with a gauze pad soaked with 70% isopropyl alcohol to achieve *intermediate-level* disinfection is questioned. Whereas this practice might achieve *low-level* disinfection, wiping does not ordinarily provide a sufficient exposure time to achieve *intermediate-level* disinfection, defined to destroy most types of microorganisms, including fungi, viruses, and mycobacteria, but not bacterial endospores.

Box A: ***Topic #5: Liquid chemical sterilization.*** Using the same format as this newsletter's main article, this box article features the fifth topic discussed in a letter Dr. Muscarella wrote to the FDA. *(Please refer to the main article.)*

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Background: The FDA astutely concludes in its notice in the *Federal Register* that "the adequate reprocessing of reusable medical devices is a critically important factor in protecting patient safety."[2] To achieve this outcome, however, several criteria must be met, including that the reusable device's instructions—often referred to as the device's "IFUs," or *instructions for use*—be clear, succinct and consistent, no matter the device type. Otherwise, users may become confused, posing an increased risk of improperly reprocessing the device and of transmitting diseases.

Discussion: For more than two decades, confusion and ambiguity have surrounded the claim of *liquid chemical sterilization*.[21-33] Indeed, published reports, including those by the FDA, suggest that the outcome of processes labeled with this claim may be more akin to disinfection.

For instance, the FDA's *draft* guidance document on the reprocessing of medical devices (*see*: the main article) ostensibly equates *liquid chemical sterilization* with *high-level disinfection*, as if the two processes are comparable and interchangable.[9] Discussing in the same context these two processes—which both require the instrument be immersed in a liquid chemical sterilant/high level disinfectant, followed by water rinsing—this FDA *draft* guidance document states that:[9] "active device drying is another post-processing procedure which may reduce or eliminate re-contamination of unwrapped devices after high level disinfection/liquid chemical sterilization reprocessing of devices because they will be wet at the end of reprocessing." *

Further, the FDA states that: (a) biological indicators (BIs) "are *not* appropriate (or required) for monitoring liquid chemical sterilization process(es)";[21] (b) the terminal water rinse produced by liquid chemical sterilization processes is not sterile;[21,22] and (c) liquid chemical sterilization is not associated with a sterility assurance level† (SAL)[21-33]—each limitation of which is similarly shared by processes labeled to achieve high-level disinfection.[31] Consistent with these three limitations, the FDA has also published that instruments exposed to *liquid chemical sterilization*, like those exposed to high-level disinfection, "are not sterile."[22]

More discussion: Yet, these limitations notwithstanding, the FDA's *draft* guidance document[9] on the reprocessing of medical devices also confusingly discusses *liquid chemical sterilization* in its description of steam, ethylene oxide gas, gas/plasma, dry heat, and chemical vapor sterilizers, almost as if *liquid chemical sterilization* achieves an outcome distinct from high-level disinfection and, possibly, more similar to that of these other listed sterilizers.

The FDA defines liquid chemical sterilization[21] *less by what this claim actually achieves than by its shortcomings and what it does not achieve.*

More confusion: The claim of *liquid chemical sterilization* remains as confusing to some today as in 1988 (*see*: Box B), when it was first introduced.[5,7,21,22,32,33] Similarly confusing are the nuanced IFUs of a *liquid chemical sterilant processing* system that the FDA cleared in 2010.[22] The FDA cleared this device for liquid chemical sterilization while acknowledging, if oxymoronically, that this system's processed instruments, like its filtered rinse water, "are not sterile."[21,22] Whether confusion about *liquid chemical sterilization*—namely, what systems labeled with this claim actually do and do not achieve—has caused HAIs is unclear, although systems with this claim have been federally rebuked and their use linked to HAIs.[5-7,25,26,28,32]

Action: The FDA is respectfully requested to consider mitigating this confusion and clarifying for manufacturers and healthcare practitioners its definition of *liquid chemical sterilization* (like, too, its definition of *sterile*; *see*: main article). No doubt, a device's clear and consistent labeling, IFUs, reprocessing instructions, FDA clearance, and intended uses, like its operating instructions, are crucial to prevent user confusion, improve the quality of instrument reprocessing, minimize the risk of disease transmission and HAIs, and ensure the device's safe and effective use. ●

Box B. ***"Liquid chemical sterilization," as defined by the FDA:*** This newsletter has published for years several articles expressing concerns about the safety and effectiveness of *liquid chemical sterilization* (*see*: Box A). Dr. Muscarella's reservations about this claim were expressed on the front pages of *The Wall Street Journal* and *Investors Business Daily*.[32,33]

In short, the claim of *liquid chemical sterilization* can convey a false sense of security by implying a sterility assurance level (SAL) with which it is not associated.[21-33] The processed instruments, like the terminal rinse water, are *not* sterile,[21,22] which would seemingly belie the claim's validity and appropriateness for use in operating-room settings. That the FDA defines *liquid chemical sterilization* less in terms of its effectiveness and by what it actually achieves than by its limitations and what it does *not* achieve only adds to the confusion.[21,22] ●

* Whether the FDA recommends drying the processed, wet instruments after completion of a process labeled to achieve *liquid chemical sterilization* both between patient procedures and before storage is unclear, although it is an important issue to resolve (*see*: p. 19 of the FDA's *draft* document[9]).

† Almost not warranting mention, a process labeled to achieve sterilization is associated with a sterility assurance level (SAL), can be monitored on-site using biological indicators (BIs), and, of course, renders the processed instrument *sterile*.

(Continued from page 17)

Namely, the revised guidance document would no longer recommend intermediate-level disinfection of ENT endoscopes after removal of the used sheath. Instead, it would presumably reiterate that ENT endoscopes are *semi-critical* devices that require *high-level disinfection* (or sterilization), no matter whether covered with a protective sheath.[9,12]

Topic #2: Laryngoscope handles

Background: Published guidelines classify the blades of rigid laryngoscopes (used for intubation) as *semi-critical* devices that require cleaning followed by high-level disinfection (or sterilization) after each use.[3,13-15] Based primarily on a step-by-step set of instructions that Dr. Muscarella published in this newsletter (in 2004) for reprocessing rigid laryngoscopes,[15] California issued a notice requiring that the rigid laryngoscope's blade *and* handle be cleaned and high-level disinfected (or sterilized) after each use.[13]

Proper reprocessing of the rigid laryngoscope's handle, like that of its blade (to which the handle attaches), is important to prevent HAIs.[13]

Discussion: Whereas some other guidelines similarly classify the rigid laryngoscope's handle to which the blade attaches as a *semi-critical* device,[16] a few discordantly classify the handle as *non-critical*[14] requiring cleaning and low-level (or intermediate-level) disinfection after each use.[9] Whether such inconsistencies among guidelines for reprocessing these handles has been a contributing factor to documented instances[13,17,18] of inadequate reprocessing of rigid laryngoscopes is unclear. Similarly, whether a lack of clarity about the FDA's and CDC's recommendations for reprocessing the laryngoscope's handle is another potential contributing factor to inconsistent reprocessing of rigid laryngoscopes is also unclear.

Both the FDA's aforementioned *draft* guidance document on the reprocessing of medical devices[9] and the CDC's guideline for disinfection and sterilization (published in 2008)[3] classify the rigid laryngoscope's blade as *semi-critical*. Introducing the potential for user confusion and for inconsistent reprocessing, however, neither of these two documents discusses the laryngoscope's handle and whether it is a *semi-critical* or *non-critical* device. No matter whether due to inconsistent guidelines for reprocessing these handles, a lack of clarity about the handle's device classification and/or minimum reprocessing requirements, or another factor, the improper reprocessing of rigid laryngoscopes has been linked to HAIs, with associated morbidity and mortality.[13,18]

Action: The FDA (and CDC) is respectfully requested to consider clarifying for manufacturers and for healthcare practitioners whether it classifies the handle of rigid laryngoscopes (which attaches to the laryngoscope's blade and may become contaminated during direct or indirect contact with mucous membranes, or during the blade's folding) as a *semi-critical* device requiring, like the blade, high-level disinfection (at a minimum) after each use. Standardization of the reprocessing requirements of the rigid laryngoscope's blade *and* handle is important to prevent user confusion, for the completeness and consistency of published guidelines, to improve the quality of instrument reprocessing, and minimize the risk of HAIs.

Topic #3: Skin electrodes

Background: The FDA's *draft* guidance document on the reprocessing of medical devices identifies skin electrodes as *non-critical* devices.[9]

Discussion: During their routine use, however, skin electrodes may contact non-intact or abraded skin, with exposed blood, which is to suggest that these instruments would be classified as *semi-critical*. An example of skin electrodes includes scalp electrodes used during "EEG." Whether confusion about the minimum reprocessing requirements of skin electrodes (i.e., high-level, intermediate-level, or low-level disinfection) has been directly or indirectly linked to HAIs is unclear.

Action: The FDA is respectfully requested to consider clarifying for manufacturers and healthcare practitioners whether skin electrodes are *semi-critical* devices requiring high-level disinfection (or sterilization). Standardization of the reprocessing requirements of skin electrodes is important to prevent user confusion, improve the quality of instrument reprocessing, and minimize the risk of HAIs. (*Note*: As with many other types of *semi-critical* devices, disposable, single-use skin electrodes are offered as an alternative, to eliminate reprocessing and the risk of disease transmission.)

Topic #4: "Sterile, Sterility"

Background: The FDA defines "sterile" in its *draft* guidance document on the reprocessing of medical devices as a "state of being free from viable microorganisms."[9] This definition would seem incomplete, however, because, according to it, an instrument heavily soiled with non-infectious debris—for example, with non-infectious residues, endotoxins, or toxic chemicals capable of causing patient injury (*see*: Table 1)—is still defined as "sterile." This definition would also seem to be

(Continued on page 20)

(Continued from page 19)

potentially misleading, because the "sterility" of an instrument implies that the device is clean and incapable of transmitting potentially harmful soils or other contaminants.

The FDA's definition of "sterile" does not account for the contamination of instruments with non-infectious soils and materials capable of causing patient harm.

Discussion: The claim that a surgical instrument is sterile connotes, not just the absence of *infectious* agents, but also both its cleanliness *and* inability to transmit *non-infectious* debris capable of causing patient harm. More than a decade ago, reports documented an outbreak of corneal endothelial decompensation following ophthalmic surgery.[19] Acute and non-infectious, corneal endothelial decompensation—like toxic anterior segment syndrome (TASS), which is a non-infectious inflammation of the eye's anterior segment—may be caused by contaminants on surgical instruments.[20]

An investigation linked these cases of corneal endothelial decompensation to the use of ophthalmic instruments whose surfaces became contaminated with residues of zinc and copper toxic to corneal endothelial cells.[19] Through oxidation, these residues formed during the exposure of the brass components of the ophthalmic instruments to a peracetic acid-based low-temperature sterilization process. The FDA removed this process from the market in 1998.[19]

Indeed, although not contaminated with infectious debris, these ophthalmic instruments nevertheless caused serious eye injuries, reportedly through the introduction of toxic residues into the eye during surgery. Yet, according to the FDA's definition, these instruments were "sterile," which is seemingly inconsistent not only the intent of the true definition of "sterility," but also "sterility's" inextricable association with cleanliness. (Whether confusion about the definition of "sterile" has been linked to HAIs is unclear.)

➡ *Box A on p. 18 features an important discussion: "Topic #5: Liquid chemical sterilization."*

Action: The FDA is respectfully requested to consider mitigating this confusion and revising its definition of "sterile" to be a "state clean and free of both viable, infectious microorganisms *and* of non-infectious contaminants capable of causing patient harm." A clear definition of "sterile" is important to prevent user confusion, improve the quality of instrument reprocessing, and minimize the risk of patient harm. ■ *The End* [Main and box articles by: *Lawrence F. Muscarella, Ph.D.*]

The Public Reporting of HAIs: "Fraught with Problems"?

This newsletter has featured a number of articles discussing published rates of central line-associated bloodstream infections, or CLABSIs, which are routinely used, whether soundly or not, to compare and rank the safety of hospitals.[34] Published in this newsletter's May-June-July, 2011, issue, one of these articles critiqued a recent report by the *Centers for Disease Control and Prevention* (CDC) in *MMWR* that used published CLABSI rates to evaluate changes in the quality of health care in the U.S. since 2001.[35]

This CDC report concluded that the number of CLABSIs has decreased dramatically since 2001, likely due to state and federal efforts coordinated by the CDC.[36] This newsletter's review of this CDC report found, however, that the majority of the CLABSI data used by the CDC to calculate this dramatic reduction had not been validated, which suggests that this CDC report's conclusions might be more conjectural and speculative than scientific and sound.

Corroborating this suggestion, Passaretti et al. (2011) wrote this past August in an infection-control journal that: (a) "public reporting of HAIs is fraught with problems"; (b) "the politics of measuring HAIs may have outpaced the science"; and (c) in many instances of the public reporting of HAIs, "the role of politics far exceeds that of science."[37]

Both this newsletter's and Passaretti et al.'s (2011) findings suggest that the public reporting of HAIs and CLABSIs is, at times, a flawed process requiring improvement. That reports by the CDC (and others) discussing HAIs might be less scientific than political is concerning. ●

➡ **REFERENCES** to this newsletter are available at:
www.myendosite.com/htmlsite/2011/refs081011.pdf

Thank you for your interest in this newsletter, which I founded. *I have addressed each topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
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