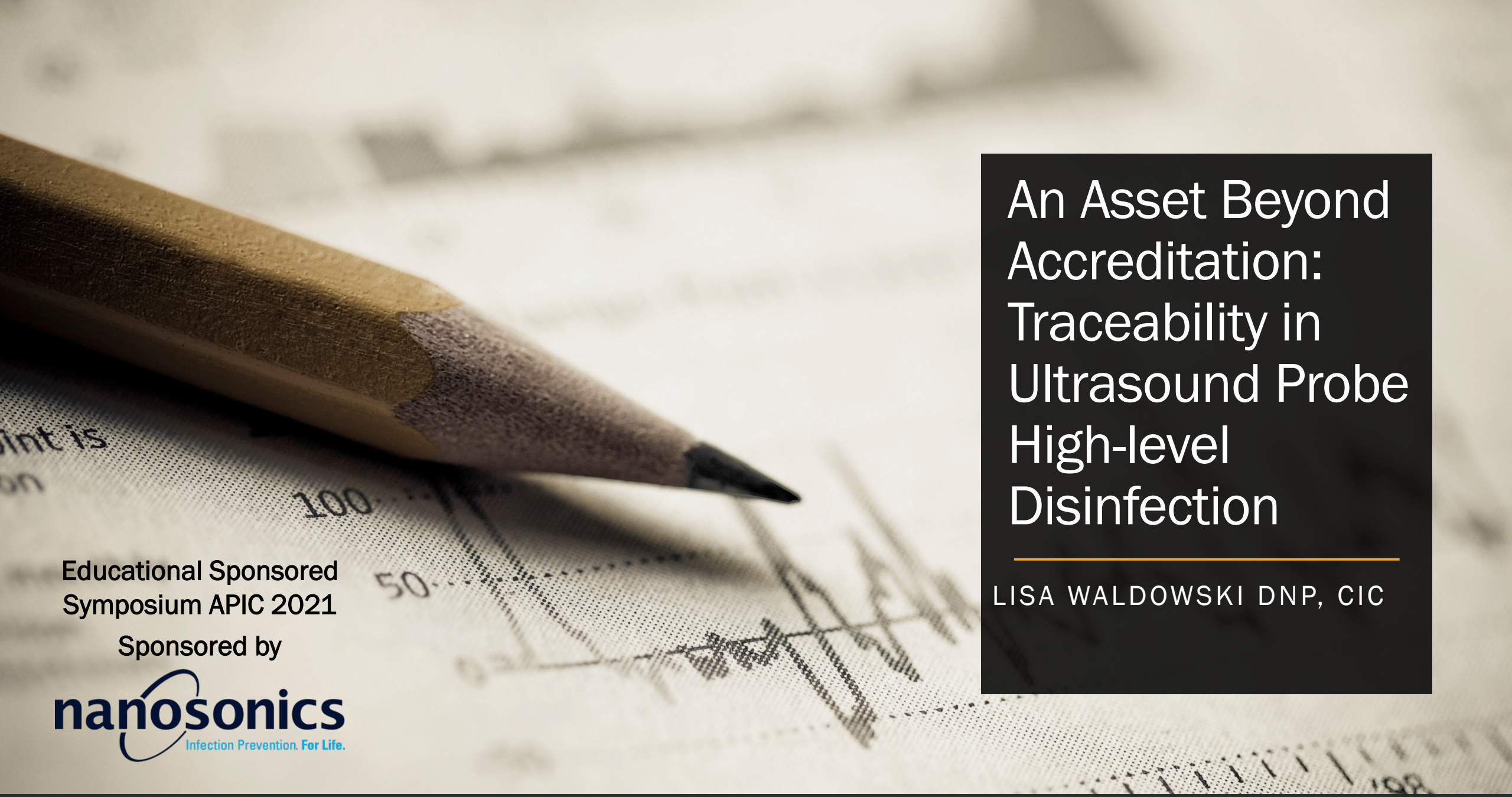

An Asset Beyond Accreditation: Traceability in Ultrasound Probe High-level Disinfection

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LISA WALDOWSKI DNP, CIC

Learning Objectives

Define	Define traceability & its importance to Infection Prevention and Control and Patient Safety.
Describe	Describe the benefits a traceability system can bring to a department or facility.
Identify	Identify common challenges facilities make when implementing traceability systems for ultrasound probe reprocessing.
Discuss	Discuss current strategies for implementing standardized traceability processes for ultrasound probe high level disinfection across a facility.

Definitions

Spaulding Classification

- Three levels of germicidal activity (sterilization, high-level disinfection (HLD), and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and noncritical).

High-level Disinfection

- Destruction of all microorganisms except for low-level bacteria spores.

Traceability

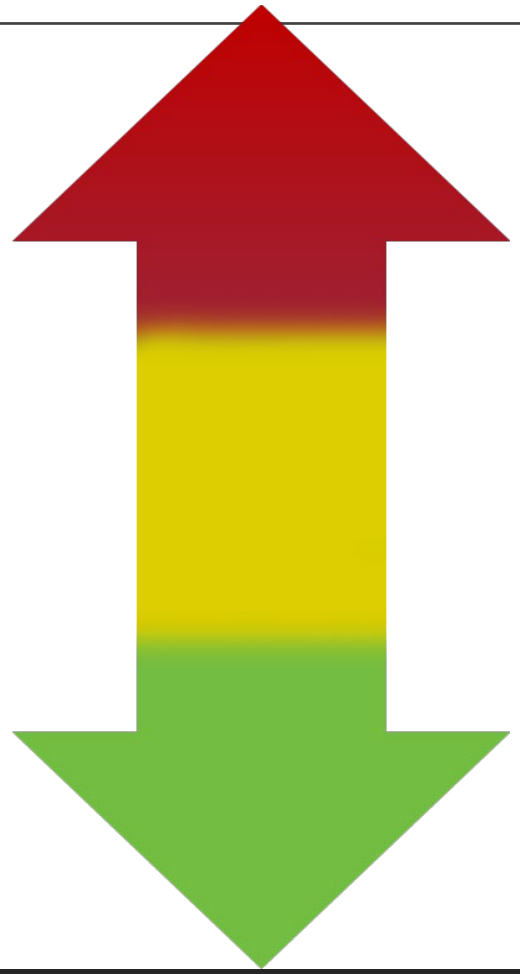
- A record of the HLD cycle to link the probe and the HLD cycle, date, and time with the patient and the procedure.

Spaulding Classification

Critical:
Sterile areas, blood

Semi-critical:
Mucous membranes & non-intact skin

Non-critical:
Intact Skin



Sterile

High-Level Disinfection

Low/Intermediate Level Disinfection

Approach to Ultrasound Probe Reprocessing

- Law & Regulation
- Manufacturer's Instructions for Use
- Evidence-based Guidelines

Law & Regulation

FDA

Document: Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. Guidance for Industry and Food and Drug Administration Staff. Document issued on: June 27, 2019.

Excerpt from Appendix E Cleaning, Disinfection, and Sterilization -

*The probe used in a **semi-critical application** should be **cleaned and undergo sterilization or at least receive high level disinfection after use even if a sheath was used**. Sheaths can fail during use and the level of resulting contamination may not be easily visible.*

Manufacturer's Instructions for Use (IFUs)

Excerpt from: Philips Care and Cleaning of Ultrasound Systems and Transducers-

To choose an appropriate care method for your transducer, you first must determine the classification of the transducer, based on its use. The care method for your transducer determines the appropriate disinfectant for your transducer.

Retrieved from: https://www.philips.co.uk/healthcare/resources/feature-detail/ultrasound-care-and-cleaning#:~:text=Philips%20Ultrasound%20systems%20and%20transducers%20require%20proper%20care%2C,and%20sterilise%20your%20Philips%20Ultrasound%20system%20and%20transducers.

Manufacturer's Instructions for Use (IFUs)

Excerpt from GE Transducer Cleaning and Disinfection Guidelines -

When choosing a disinfectant, determine the required level of disinfection based on device classification. If the possibility of cross-contamination or exposure to unhealthy or non-intact skin exists, then high-level disinfection should be performed.

Retrieved from:

http://www3.gehealthcare.com/static/ge-transducers/GEHC-Guidelines-Transducer_Cleaning_Disinfection_Guidelines.pdf

Evidence-based Guidelines

- AAMI ST58:2013 (R2018) : Chemical sterilization and high-level disinfection in health care facilities.
- AORN Guidelines for Perioperative Practice 2021: High-level Disinfection Guidelines (2019).
- CDC: 2008 (Update May 2019): Guideline for Disinfection and Sterilization in Healthcare Facilities.

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 Update: May 2019

3. Indications for Sterilization, High-Level Disinfection, and Low-Level Disinfection

- b. **Provide, at a minimum, high-level disinfection for semicritical patient-care equipment** (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that **touches either mucous membranes or nonintact skin**.

10. Disinfection Strategies for Other Semicritical Devices

- a. **Even if probe covers have been used, clean and high-level disinfect other semicritical devices** such as rectal probes, vaginal probes, and cryosurgical probes with a product that is not toxic to staff, patients, probes, and retrieved germ cells (if applicable). Use a high-level disinfectant at the FDA-cleared exposure time.

Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail.

Evidence-based Guidelines

AORN Guidelines for Perioperative Practice 2021. Guideline for Manual Chemical High-Level Disinfection.

9.2 Maintaining records of manual chemical high-level disinfection helps ensure that parameters for correct high-level disinfection have been met. Enables retrieval of HLD solutions in the event of a recall and establishes traceability and accountability.

"identity of the patient on whom the device was used"

CMS CoP & The Joint Commission Standard/EP

CMS: §482.51 TAG: A-0940 (Surgical Services)

The Joint Commission: IC.02.02.01 (2019 Top Non-Compliant Scored Standard)

- IC.02.02.01 The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.
  - EP2 Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

Traceability

- FDA: If a failure or non-conformance is identified at any stage throughout the entire supply and manufacturing process or within patient use, then the manufacturer needs to be able to identify the potential impact on other devices.

Selected evidence-based guidelines

Link the ultrasound probe to the patient

Procedures for high-level disinfection (HLD) based on a quality process

Documentation Elements (AAMI ST 58: 2013 (R2018))

Assigned AER, soaking container, cycle number
Specific contents of the load
Patient's name and MRN, if available
Procedure, physician, identifier of the device
Exposure time and temperature
Shelf-life date, date opened, date poured into secondary container, expiration date
Operator initials
Results of the chemical indicator (CI) or test strip results
Minimal effective concentration (MEC) results
Any failures to include corrective action

Manual Documentation Log Example

Date Test Strip Bottle First Opened _____ Mfg. exp. _____ Do Not Use After _____ Bottle Lot #:_____

QC Test Results _____ (Date) QC Test Date_____ Tested By (initials) _____

Date	Time	Quality Test Pass Solution			Quality Test Fail Solution			Indicator Test Result 90 Sec	Solution Temp. 68°F / 20°C	Item Description (Model # / Serial # if Applicable)	Patient Name Medical Record Number Physician	Employee Name
		1	2	3	1	2	3					

Automated Sonicated H_2O_2 High Level Disinfection Log

Month: _____ Department: _____ Serial # _____

- CARTRIDGE REPLACEMENT: When using a new HLD CARTRIDGE, document: DATE LOADED, LOT BATCH # & EXP. DATE.
- NEW CHEMICAL INDICATOR BOX: When opening a new box of CHEMICAL INDICATORS, document: LOT BATCH #, & EXP. DATE. Transfer information to next log sheet as needed
- Transfer information to next log sheet as needed

Use a new Log Sheet when a Cartridge is replaced, a new box of Chemical Indicators is opened, or a new month has started

CARTRIDGE REPLACEMENT			CHEMICAL INDICATOR	
Date Loaded	Lot Batch #	Expiration Date	Lot Batch #	Expiration Date

PATIENT LABEL	HLD DEVICE LABEL	PATIENT LABEL	HLD DEVICE LABEL
1. Place patient label here Patient Name: _____ Date of Birth: _____ Medical Record # _____	1. Place HLD device label here Date & Time: _____ Disinfection (P/F): _____ Indicator (P/F): _____ Operator ID: _____ Probe SN: _____	2. Place patient label here Patient Name: _____ Date of Birth: _____ Medical Record # _____	2. Place HLD device label here Date & Time: _____ Disinfection (P/F): _____ Indicator (P/F): _____ Operator ID: _____ Probe SN: _____

Why Audit Traceability Documentation

Patient Safety

Risk Management

Accreditation/Survey Readiness

Documentation Pitfalls

- HLD cartridge load date, lot number and expiration date were omitted (left blank)
- Chemical indicator (CI) lot number and expiration date were omitted (left blank)
- Leaving blanks, gaps, omissions on the manual log

Example Survey Documentation Finding

Standard/EP	CoP	Finding
IC.02.02.01 EP 2 The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.	§482.51 TAG: A-0940	Documentation logs did not reflect complete information to link the probe to the patient.

Documentation Wins

MANUAL

- Ensures parameters have been met
- Traceability
- Accountability

AUTOMATED

- Ensures that parameters have been met
- Traceability
- Accountability
- Legibility
- Accuracy
- Data Integrity

Recommendations

- ✓Follow manufacturer's IFUs
- ✓Standardize products, supplies, and processes (to include documentation)
- ✓Be knowledgeable of oversight, audits, and validation
- ✓Standardize selected evidence-based guidelines and P&Ps

Recommended Resources

Law and Regulation

Manufacturer Instructions for Use

Evidence-based Guidelines

Vendor Partners

References

- ANSI/AAMI ST58:2013 (R2018). Chemical Sterilization And High-Level Disinfection In Health Care Facilities.
- AORN Guidelines for Perioperative Practice 2021. Guideline for Manual Chemical High-Level Disinfection (2018).
- Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 Update: May 2019.

https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf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Q & A