Importance of Infection Control in Ultrasound

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Disclosures:
I am an employee of Nanosonics Ltd, a company which manufactures and sells a device for ultrasound probe disinfection.

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Common Ultrasound Procedures and Probe Types

Endocavitary procedures
- Transvaginal procedures
- Transrectal procedures
- Transesophageal procedures

Surface probe procedures
- Ultrasound use on healthy skin (abdominal scan)
- Intra-operative ultrasound procedures
- Ultrasound guided interventional procedures (biopsies, venous access)
- Ultrasound use on broken skin (wound scans)

Wide range of ultrasound procedures, settings with different end-users/reprocessors
Probe contacts sterile tissue or vascular system. Used during:
- surgery
- intraoperative procedures
- drainages
- biopsies
- needle guidance
- transvaginal oocyte retrieval
- venous catheter placement
- vascular ablation

CRITICAL

STERILIZATION

HIGH LEVEL DISINFECTION & use with a sterile sheath/gel

Probe contacts mucous membranes & non-intact skin. Used during:
- transvaginal scans
- transrectal scans
- transesophageal scans
- wound scanning
- burn graft evaluation
- surface ultrasound (broken skin)

SEMI-CRITICAL

HIGH LEVEL DISINFECTION & use with a sheath

Probe only contacts healthy, intact skin. Used during:
- transabdominal scan
- surface ultrasound
(e.g. carotids, breast, bladder, thyroid, testicles, musculoskeletal, and peripheral vascular imaging)

NON-CRITICAL

LOW LEVEL DISINFECTION

Chart based on CDC Guidelines
ASUM/ACIPC Ultrasound Reprocessing Guidelines

Australian Guidelines 2017

- World first collaborative guidelines between national infection prevention and ultrasound society
- Draws attention to expansion of ultrasound to departments
- HLD (minimally) of all semi-critical and critical ultrasound probes even if sheath is used
- Includes recommendations on gel use, workflows, staff responsibilities and equipment cleaning
Australian Guidelines Address Proliferation of Ultrasound Procedures in Departments

Table 1: Reference Guide to cleaning ultrasound transducers in the Emergency Medicine Department

<table>
<thead>
<tr>
<th>Transducer</th>
<th>Procedure</th>
<th>Use of transducer cover</th>
<th>Recommended cleaning method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal intact skin</td>
<td>No</td>
<td>LLD</td>
<td></td>
</tr>
<tr>
<td>Open wound eg ulcers</td>
<td>Yes</td>
<td>HLD</td>
<td></td>
</tr>
<tr>
<td>Intact infected skin</td>
<td>Yes</td>
<td>HLD^</td>
<td></td>
</tr>
<tr>
<td>US guided interventional procedure</td>
<td>Yes</td>
<td>HLD^</td>
<td></td>
</tr>
<tr>
<td>Eg Joint aspiration</td>
<td>No</td>
<td>HLD</td>
<td></td>
</tr>
<tr>
<td>Foreign body removal</td>
<td>No</td>
<td>HLD</td>
<td></td>
</tr>
<tr>
<td>Suprapubic bladder tap</td>
<td>No</td>
<td>HLD</td>
<td></td>
</tr>
<tr>
<td>Peripheral IV Line Insertion</td>
<td>Yes</td>
<td>HLD^</td>
<td></td>
</tr>
<tr>
<td>CVC / PCC insertion</td>
<td>Yes</td>
<td>HLD</td>
<td></td>
</tr>
</tbody>
</table>

Table addressed in Other depts.:
- Radiology Department
- O&G Department
- Vascular Department
- Cardiac Department

Semi-critical and critical ultrasound probes (intracavity & surface probes across all hospital departments) should undergo HLD even if used with a probe cover.
What types of issues can occur?
Infections from ultrasound procedures

Patient death from hepatitis B infection after a procedure with an improperly reprocessed endocavitary ultrasound probe in 2012.¹
Infections from ultrasound procedures

In 2017, 10 patients were infected with *Burkholderia cenocepacia* after undergoing ultrasound guided central line placements and drainages using contaminated gels in Australia. A similar outbreak occurred in Saudi Arabia resulting in 2 patient deaths.\(^2\)\(^-\)\(^4\)

Patient death from hepatitis B infection after a procedure with an improperly reprocessed endocavitary ultrasound probe in 2012.\(^1\)
Infections from ultrasound procedures

In 2017, 10 patients developed septicaemia with *Burkholderia cenocepacia* after undergoing ultrasound guided central line placements and drainages using contaminated gels in Australia. A similar outbreak occurred in Saudi Arabia resulting in 2 patient deaths.²⁴

Alerts on infectious outbreaks from contaminated gels used in ultrasound procedures have been issued by other regulatory bodies across the globe like FDA and Health Canada in the past.⁴⁵

Several other infectious outbreaks from ultrasound procedures using contaminated gels have been published in literature.⁷–¹⁰

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Infection risk at the population level

- First epidemiological study to assess infection risk with endocavitary procedures at population level
- Published by Health Protection Scotland and NHS Scotland based on a retrospective analysis of healthcare data
- At the end of the study period (2010-2016), only 9.5% of sites were performing high level disinfection of endocavitary probes. Scotland introduced guidance recommending HLD in 2016.

- 30 days after a TV scan \( (p<0.001) \):
  - Patient 41% more likely to have positive bacterial cultures
  - Patient 26% more likely to be prescribed antibiotics

- 30 days after a TR scan \( (p<0.001) \):
  - Patient 3.4x more likely to have positive bacterial cultures
  - Patient 75% more likely to be prescribed antibiotics

Example: Kidney Biopsy, Worst Case Scenario

- No probe cover
- Non-sterile gel
- Puncture site is contaminated prior to biopsy
- Biopsy needle passes through gel
- Traumatically implants contaminants into organ

- Organisms that have been recovered from gel:
  - ESBL *Klebsiella pneumoniae*¹
  - *Pseudomonas aeruginosa*²,³
  - *Staphylococcus aureus*³,⁴

Example: Kidney Biopsy, Worst Case Scenario

Correct interpretation of guidelines is vital for biopsies.
There is international consensus on most aspects of probe reprocessing. Guidance exists today that must be followed to ensure patient safety.

**Guidelines Specificity**

1. ACIPC/ASUM 2017¹ Ultrasound probes.
2. WFUMB 2017² Ultrasound probes.
3. ECMUS 2017³ Ultrasound probes.
4. Irish 2017⁴ Ultrasound probes.
5. Scottish 2016⁵ Ultrasound probes.
6. AIUM 2014⁶ Ultrasound probes.
7. CDC 2008⁷ Partly addresses ultrasound probes.

**Standards, Regulation Specificity**

1. FDA 2000⁸ Semi-critical & critical medical devices.
2. AAMI 2008⁹ Semi-critical & critical medical devices.
3. TJC 2016¹⁰ Semi-critical & critical medical devices.

**Semi-critical ultrasound probes (intracavity or surface) must undergo HLD even if used with a probe cover.**

**Semi-critical reusable medical devices must minimally undergo HLD.**
Guidelines are consistent, but are they being followed?
Infection Control Breaches in Ultrasound – TJC Alert (USA)

The TJC cites instrument disinfection & sterilization non-compliance (2017)¹

- 74% of all immediate threat to life declarations were related to improperly sterilized or HLDed equipment.

- Non-compliance has worsened in TJC accredited hospitals, critical access hospitals, ambulatory and office-based surgery facilities.

Infection Control Breaches in Ultrasound – ESR Survey (Europe)

2.7% claimed to be aware of infection transmission cases through US procedures

Non-compliance to reprocessing requirements in endocavitary and interventional procedures

Disinfection for Endocavitary Procedures

- Wiping off gel and disinfection with foam/wipe after each patient: 69%
- HLD wipes: 11%
- Dedicated washer: 9%
- Wiping probe at the end of the day: 9%

Disinfection for Surface Interventional Procedures

- 76%
- 10%
- 7%
- 6%

*Some respondents did not answer this question thus total is <946
Infection Control Breaches in Ultrasound – ESR Survey (Europe)

Incorrect gel types used in endocavitary and interventional procedures

USA Expert Group and Survey

- A roundtable of 9 infection control experts were convened in Oct 2016 to discuss issues in probe reprocessing.

- Conducted a pilot survey of APIC members in 2016 finding extensive non-compliance with guidelines

- Expert group decided to undertake a further survey of ICPs in USA in a study led by Ruth Carrico.

- First large scale USA survey of IPs on ultrasound probe reprocessing practice

- Expert group members:

  **Sue Barnes**  
  RN CIC, FAPIC Infection Prevention Consultant - recently retired National Infection Control Leader  
  Kaiser Permanente

  **Ruth Carrico**  
  PhD FNP-C, FSHEA CIC, Associate Professor, Division of Infectious Disease, University of Louisville, School of Medicine, Louisville, KY

  **Roy Boukidjian**  
  MSN, PHN, CIC, System Director, Infection Prevention, Dignity Health, San Francisco, CA

  **Sylvia Garcia-Houchins**  
  RN, MBA, CIC Director, Infection Control Program, University of Chicago and JCR Consultant, Chicago, IL

  **Amy Nichols**  
  RN, MBA, CIC, Director, Infection Control, UCSF Medical Center

  **Mary Lou Manning**  
  PhD, CRNP, CIC, FNAP, FAAN, Associate Professor, Thomas Jefferson College of Nursing, Philadelphia, PA

  **Robert Garcia**  
  BS, MMT, CIC Director of Healthcare Epidemiology, Stoneybrook University Medical Center, Stoneybrook, NY

  **Russ Olmsted**  
  MPH, CIC Director, Infection Prevention and Control, Catholic Health-East/Trinity Health

* Nanosonics funded group meeting and survey research project
Infection Control Breaches in Ultrasound – USA survey

Data is adapted from interim analysis (N=268) presented at the SDMS Annual Conference in October 2017 by Assoc Prof Carrico.

**Endocavitary ultrasound**

- 90% (241 respondents) indicated procedure done
- Best compliance rates (most well known to HLD)
- 97% used a sheath, 72% used single use gel

**Scan across non-intact skin (eg skin breakdown, burn)**

- 31% (83 respondents) indicated procedure done
- Lower compliance with guidelines
- 18% didn’t use a sheath, 24% used multi-use gel

Infection control measures are better for endocavitary procedures but not for semi-critical and critical surface probe procedures.
Vascular access – CVC

- 78% (209 respondents) indicated procedure done
- Of those performing the procedure, 63% believed they were compliant

Infection Control Breaches in Ultrasound – USA survey

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**Level of disinfection/sterilization?**

<table>
<thead>
<tr>
<th></th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLD/ILD</td>
<td>66%</td>
</tr>
<tr>
<td>HLD</td>
<td>33%</td>
</tr>
<tr>
<td>Sterilization</td>
<td>1%</td>
</tr>
</tbody>
</table>

**Is a probe cover always used?**

<table>
<thead>
<tr>
<th>Cover Type</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, sterile cover</td>
<td>80%</td>
</tr>
<tr>
<td>Yes, clean cover</td>
<td>10%</td>
</tr>
<tr>
<td>No</td>
<td>10%</td>
</tr>
</tbody>
</table>

**What type of gel is used?**

<table>
<thead>
<tr>
<th>Gel Type</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-use sterile gel</td>
<td>71%</td>
</tr>
<tr>
<td>Single-use clean gel</td>
<td>10%</td>
</tr>
<tr>
<td>Multi-use gel bottle</td>
<td>19%</td>
</tr>
</tbody>
</table>

Only OK if probe sterile
Infection Control Breaches in Ultrasound – USA survey
Data is adapted from interim analysis (N=268) presented at the SDMS Annual Conference in October 2017 by Assoc Prof Carrico.

Vascular access – Peripheral line

• 60% (162 respondents) indicated procedure done
• Of these, 58% believed they were compliant
• Non compliance greater when line is peripheral

Probe risks contacting sterile tissue/blood
Probe is critical

Level of disinfection/sterilization?

- LLD/ILD: 77%
- HLD: 22%
- Sterilization: 1%

Is a probe cover always used?

- Yes, sterile cover: 54%
- Yes, clean cover: 20%
- No: 27%

What type of gel is used?

- Single-use sterile gel: 51%
- Single-use clean gel: 16%
- Multi-use gel bottle: 33%

Only OK if probe sterile
Australian example - ED/ICU surface probes are heavily contaminated

- Study tested patient-ready ultrasound equipment across 5 EDs and 5 ICUs.
- 57% → probes contaminated with blood (51% of these visibly)
- 46% → probes contaminated with bacteria
- None of the EDs and ICUs had any probe disinfection policy

**Table 2. Positive tests by equipment type**

<table>
<thead>
<tr>
<th>Sample site</th>
<th>Sample type</th>
<th>No. positive/ tested</th>
<th>Percentage positive (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gel</td>
<td>Blood</td>
<td>10/24</td>
<td>42% (22%–61%)</td>
</tr>
<tr>
<td></td>
<td>Microbial</td>
<td>16/46</td>
<td>35% (21%–49%)</td>
</tr>
<tr>
<td>Keyboard</td>
<td>Blood</td>
<td>10/16</td>
<td>62% (39%–86%)</td>
</tr>
<tr>
<td></td>
<td>Microbial</td>
<td>8/16</td>
<td>50% (26%–74%)</td>
</tr>
<tr>
<td>Transducer leads</td>
<td>Blood</td>
<td>14/16</td>
<td>88% (71%–100%)</td>
</tr>
<tr>
<td></td>
<td>Microbial</td>
<td>10/16</td>
<td>62% (39%–86%)</td>
</tr>
<tr>
<td>Transducer</td>
<td>Blood</td>
<td>21/37</td>
<td>57% (41%–73%)</td>
</tr>
<tr>
<td></td>
<td>Microbial</td>
<td>17/37</td>
<td>46% (30%–62%)</td>
</tr>
<tr>
<td>Work surface</td>
<td>Blood</td>
<td>12/16</td>
<td>75% (54%–96%)</td>
</tr>
<tr>
<td></td>
<td>Microbial</td>
<td>12/16</td>
<td>75% (54%–96%)</td>
</tr>
</tbody>
</table>

• Breast biopsy
• Liver biopsy
• Lymph biopsy
• Lung biopsy
• Kidney biopsy
• Abdominal/chest biopsy
• Bone/tissue biopsy
• Prostate biopsy
• Tumour biopsy
• Urinary catheterization/ nephrostomy
  • Central venous access
  • Peripheral venous access
  • Tracheostomy
  • Perineural catheterization
  • In vitro fertilization
• Pericardiocentesis
• Arthrocentesis
• Paracentesis
• Thoracentesis
• Tumour ablations
• Tumour resections
• Nerve blocks
• Peripheral nerve stimulation
• Neurosurgeries
• Cardiac surgeries (valve/pacemaker replacements etc)
• Musculoskeletal injections (tenotomy, tendon and articular injections etc)
• Ultrasound guided procedures
• Biopsies
• Cannulation, Catheterization
• Injections, Ablations, Surgeries
• Aspirations, Drainages

Why is this so challenging?

• Ultrasound use proliferated to other departments
• Surface probes used in number of semi-critical and critical procedures devices

• Reprocessing intracavity probes is complex; surface probe reprocessing is more complex
IPs & Sonographers working together

Sonographers need your help!

Together a standard of care for all patients throughout healthcare can be ensured.

Communicate
Talk to your sonographers to identify which departments perform ultrasound procedures and what your current policies are.

Collaborate
Work together to standardize policies across all departments.

Take leadership
Identify training areas and conduct periodic training and assessments.

Ensure policies address all infection control aspects including gel and probe cover use, especially for surface probes.

Keep pace with new technology and guidelines.

Work together to drive change
Thank you

Questions?