Current issues in reprocessing of medical / surgical instruments in CSSD / TSSU

Martin Kiernan
Visiting Clinical Fellow
University of West London

Clinical Director, GAMA Healthcare

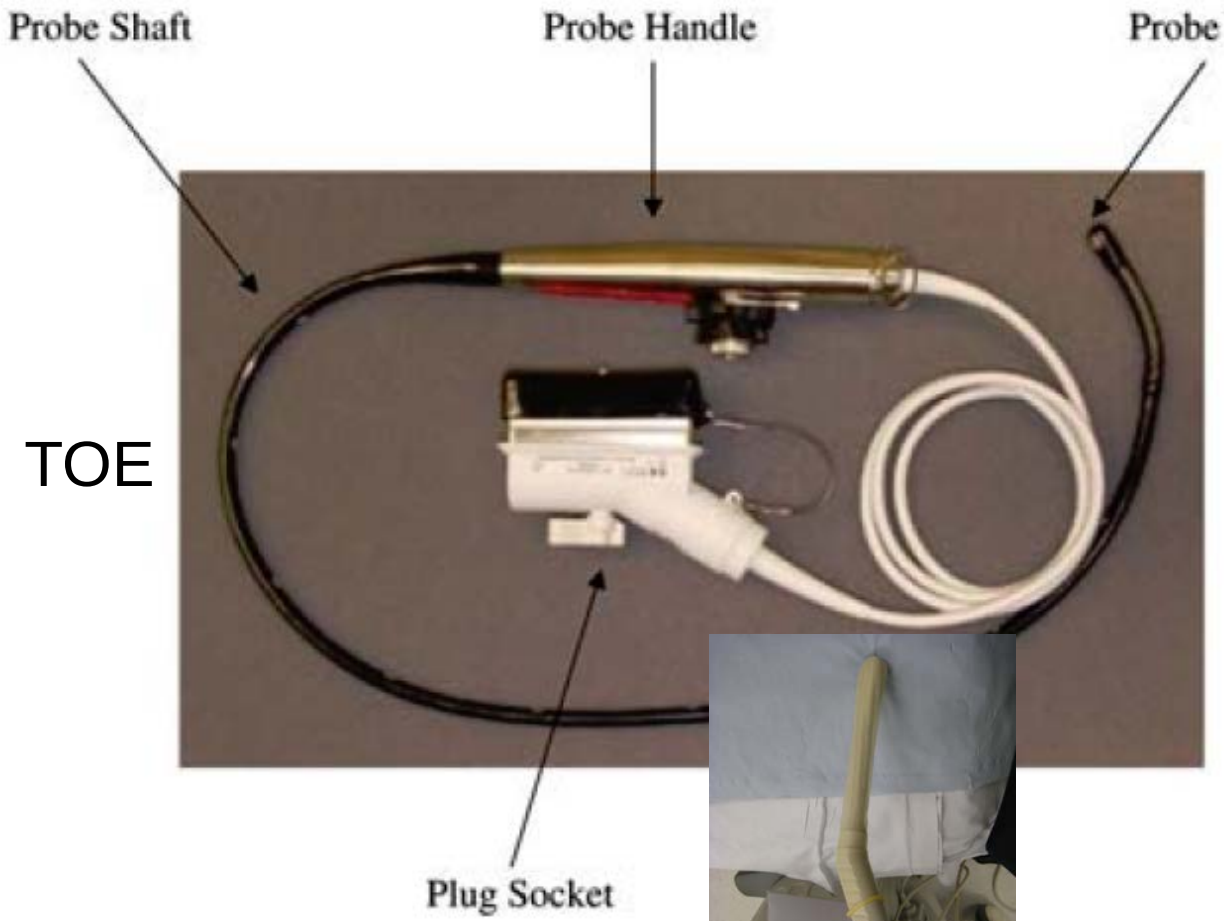
Current Issues

- Decontamination of Probes
- Single use items

Learning Objectives

- The attendee will be able to
  - Explain the risks associated with the use of intracavity probes
  - Recommend a suitable method for decontamination of intracavity probes
  - Apply an audit tool to the practice of decontamination of intracavity probes

Probes are increasing in use



TOE

Transrectal

Transvaginal

21 July 2011 Last updated at 15:13

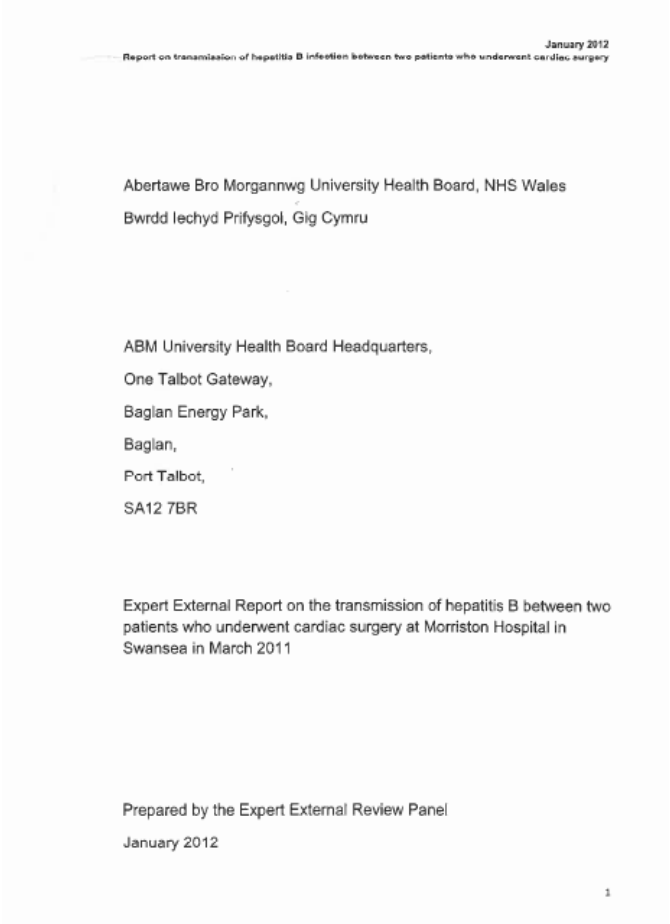
Morriston Hospital heart patients at hepatitis B risk

An investigation has started and people have been sent letters asking them to get in touch so they can be given blood tests

More than 150 patients who underwent heart surgery in Swansea earlier this year have been told they may have been exposed to the hepatitis B virus.

Managers said there was a "low risk" involving patients who had surgery at the cardiothoracic unit at Morriston Hospital between 11 March and 17 April.

A patient treated at the unit at this time was later diagnosed with an acute hepatitis B infection and died.



January 2012

Report on transmission of hepatitis B infection between two patients who underwent cardiac surgery

Abertawe Bro Morgannwg University Health Board, NHS Wales

Bwrdd Iechyd Prifysgol, Gig Cymru

ABM University Health Board Headquarters,

One Talbot Gateway,

Baglan Energy Park,

Baglan,

Port Talbot,

SA12 7BR

Expert External Report on the transmission of hepatitis B between two patients who underwent cardiac surgery at Morriston Hospital in Swansea in March 2011

Prepared by the Expert External Review Panel

January 2012

1

Medical Device Alert

Ref: MDA/2012/037 Issued: 28 June 2012 at 14:00

Device

Reusable transoesophageal echocardiography, transvaginal and transrectal ultrasound probes (transducers).

All models.

All manufacturers.

Problem

The MHRA is aware of an incident where the death of a patient from hepatitis B infection may have been associated with a failure to appropriately decontaminate a transoesophageal echocardiography probe between each patient use.

The MHRA is issuing this alert to advise users to appropriately decontaminate all types of reusable ultrasound probes.

Action by

Trust decontamination leads.

Healthcare professionals using these devices and staff responsible for reprocessing medical devices.

CAS deadlines

Action underway: 11 July 2012

Action complete: 19 July 2012

Note: These deadlines are for systems to be in place to ensure the actions are undertaken.

Action

Review, and if necessary update, local procedures for all ultrasound probes that are used within body cavities to ensure that they are decontaminated appropriately between each patient use, in accordance with the manufacturer's instructions.

Ensure that staff who decontaminate medical devices are appropriately trained and fully aware of their responsibilities.

Be aware of the MHRA's guidance document 'Managing Medical Devices' (available from our website www.mhra.gov.uk).

Be aware of the Department of Health's publications (England only): Choice Framework for local Policy and Procedures 01-06 – Decontamination of flexible endoscopes: Operational management manual 13536:1.0. Available from Space for Health, sign-in required: http://www.spaceforhealth.nhs.uk/England/topics/choice-framework-local-policy-and-protocols-01-06-%E2%80%93-decontamination-flexible-endoscopes

Also be aware of similar advice as/when published by the devolved administrations.

Journal of Hospital Infection xxx (2012) 1–8

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevierhealth.com/journals/jhin

Review

Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis

S. Leroy*

Epidemiology of Emerging Diseases Unit, Institut Pasteur, Paris, France

Methods: Systematic review and meta-analysis.

Results: From the 867 potentially eligible references, 32 articles were finally included. Very few cases with an established route of contamination had been reported. Indeed, apart from occurrence of outbreaks, it is difficult if not impossible to detect viral contamination through the use of endovaginal/rectal ultrasound probes. However, there was a pooled prevalence of 12.9% (95% confidence interval: 1.7–24.3) for pathogenic bacteria, and 1.0% (0.0–10.0) for frequently occurring virus (human papillomavirus, herpes simplex virus, and cytomegalovirus) for endovaginal/rectal probes, both after low-level disinfection. The pooled prevalence of infected patients after transrectal ultrasound and guided biopsies was estimated to be 3.1% (1.6–4.3).

Conclusions: There appears to be a risk of transmitting bacterial or viral infections via endovaginal/rectal ultrasound transducer, and the present meta-analysis provides an estimate of this risk. Further research with sophisticated modelling is warranted to quantify the risk.

Table I
Characteristics of the included studies

Authors	Year	Country	*N*	Design	Type of infection	Antibiotics given
Keizur *et al.*[24]	1993	USA	272	Retrospective	Sepsis, *Burkholderia cepacia*	No
Enlund and Varenhorst[21]	1997	Sweden	426	Prospective	Fever	No
Sieber *et al.*[39]	1997	USA	4439	Prospective	UTI	Yes
Rodríguez and Terris[34]	1998	USA	128	Prospective	Infection	N/A
Aron *et al.*[19]	2000	India	231	Prospective	Infection	Yes
Griffith *et al.*[22]	2002	USA	400	Prospective	UTI	Yes
Raaijmakers *et al.*[33]	2002	The Netherlands	5802	Prospective[a]	Infection	N/A
Berger *et al.*[41]	2004	Austria	4303	Prospective	Fever	N/A
Donzella *et al.*[20]	2004	USA	739	Prospective	Epididymitis	Yes
Otrock *et al.*[30]	2004	Lebanon	207	Retrospective	UTI	Yes
Sabbagh *et al.*[35]	2004	Canada	363	Prospective	Infection	Yes
Sheikh *et al.*[36]	2005	Kuwait	300	Prospective	Septicaemia	Yes
Lee *et al.*[27]	2006	UK	100	Prospective	Infection	N/A
Puig *et al.*[32]	2006	Spain	1018	Prospective	Major and minor infection	Yes
Shen *et al.*[37]	2006	China	80	Retrospective	Infection	No
Feliciano *et al.*[42]	2008	USA	1273	Prospective	Fever	Yes
Lessa *et al.*[28]	2008	USA	528	Prospective	Infection	No
Miura *et al.*[29]	2008	Japan	665	Retrospective	Septic shock	Yes
Shigehara *et al.*[38]	2008	Japan	457	Prospective	Acute prostatitis	Yes
Yamamoto *et al.*[40]	2008	Japan	243	Prospective	Acute prostatitis	N/A
Hadway *et al.*[23]	2009	UK	256	Prospective	Urosepsis, bacteraemia	Yes
Ozden *et al.*[31]	2009	Turkey	1339	Retrospective	Acute prostatitis	Yes
Kim *et al.*[25]	2010	Korea	878	Retrospective	Acute prostatitis, sepsis, bacteraemia	No
Koc *et al.*[26]	2010	Turkey	180	Prospective	UTI	N/A
Amis *et al.*[15]	2000	UK	72[b]	Prospective	Bacteria/virus on the probe	—
Syles *et al.*[17]	2006	UK	50[b]	Prospective	Bacteria on the probe	—
Bataillon *et al.*[18]	2010	France	34[b]	Prospective	Bacteria on the probe	—
Kac *et al.*[16]	2010	France	440	Prospective[a]	Bacteria/virus on the probe	—

N/A, not available; UTI, urinary tract infection.
[a] The studies by Koc *et al.* and Raajmakers *et al.* were multi-centre, all others, single-centre.
[b] Number of probes studied.

OPEN ACCESS Freely available online

PLOS | ONE

Persistence of Microbial Contamination on Transvaginal Ultrasound Probes despite Low-Level Disinfection Procedure

Fatima M'Zali[1]*, Carole Bounizra[1], Sandrine Leroy[2], Yahia Mekki[3], Claudine Quentin-Noury[1], Michael Kann[1]

1 Université Bordeaux Segalen, Microbiologie Fondamentale et Pathogénicité Unité Mixte de Recherche 5234, Bordeaux, France, 2 Centre Hospitalier Universitaire de Nimes, Service de Biostatistique, Epidémiologie Clinique, Santé Publique, Informatique Médicale, Nîmes, France, 3 Laboratoire de Virologie, Centre de Biologie et Pathologie Est, Hospices Civils de Lyon, Lyon, France

Abstract

Aim of the Study: In many countries, Low Level Disinfection (LLD) of covered transvaginal ultrasound probes is recommended between patients' examinations. The aim of this study was to evaluate the antimicrobial efficacy of LLD under routine conditions on a range of microorganisms.

Materials and Methods: Samples were taken over a six month period in a private French Radiology Center. 300 specimens derived from endovaginal ultrasound probes were analyzed after disinfection of the probe with wipes impregnated with a quaternary ammonium compound and chlorhexidine. Human papillomavirus (HPV) was sought in the first set of s100 samples, *Chlamydia trachomatis* and mycoplasmas were searched in the second set of 100 samples, bacteria and fungi in the third 100 set samples. HPV, *C. trachomatis* and mycoplasmas were detected by PCR amplification. PCR positive samples were subjected to a nuclease treatment before an additional PCR assay to assess the likely viable microorganisms. Bacteria and fungi were investigated by conventional methods.

Results: A substantial persistence of microorganisms was observed on the disinfected probes: HPV DNA was found on 13% of the samples and 7% in nuclease-resistant form. *C. trachomatis* DNA was detected on 20% of the probes by primary PCR but only 2% after nuclease treatment, while mycoplasma DNA was amplified in 8% and 4%, respectively. Commensal and/or environmental bacterial flora was present on 86% of the probes, occasionally in mixed culture, and at various levels (10-> 3000 CFU/probe); *Staphylococcus aureus* was cultured from 4% of the probes (10-560 CFU/probe). No fungi were isolated.

Conclusion: Our findings raise concerns about the efficacy of impregnated towels as a sole mean for disinfection of ultrasound probes. Although the ultrasound probes are used with disposable covers, our results highlight the potential risk of cross contamination between patients during ultrasound examination and emphasize the need for reviewing the disinfection procedure.

Citation: M'Zali F, Bounizra C, Leroy S, Mekki Y, Quentin-Noury C, et al. (2014) Persistence of Microbial Contamination on Transvaginal Ultrasound Probes despite Low-Level Disinfection Procedure. PLoS ONE 9(4): e93368. doi:10.1371/journal.pone.0093368

Persistence of Contamination
M'Zali et al (2014)

- Sheaths used over probe
- Probe removed and visually examined
- Wiped with tissue to remove gel
- Wiped with disinfectant impregnated wipe (QAC/chlorhexidine)
- Sampled for HPV, C. trachomatis and bacteria
- Post disinfection
  - HPV was recovered from 7% of the probes
  - C. trachomatis from 2% of the probes
  - Staph. aureus from 4% of the probes

European Journal of Echocardiography (2011) 12; I17 – I23

Guidelines for transoesophageal echocardiographic probe cleaning and disinfection from the British Society of Echocardiography†,‡

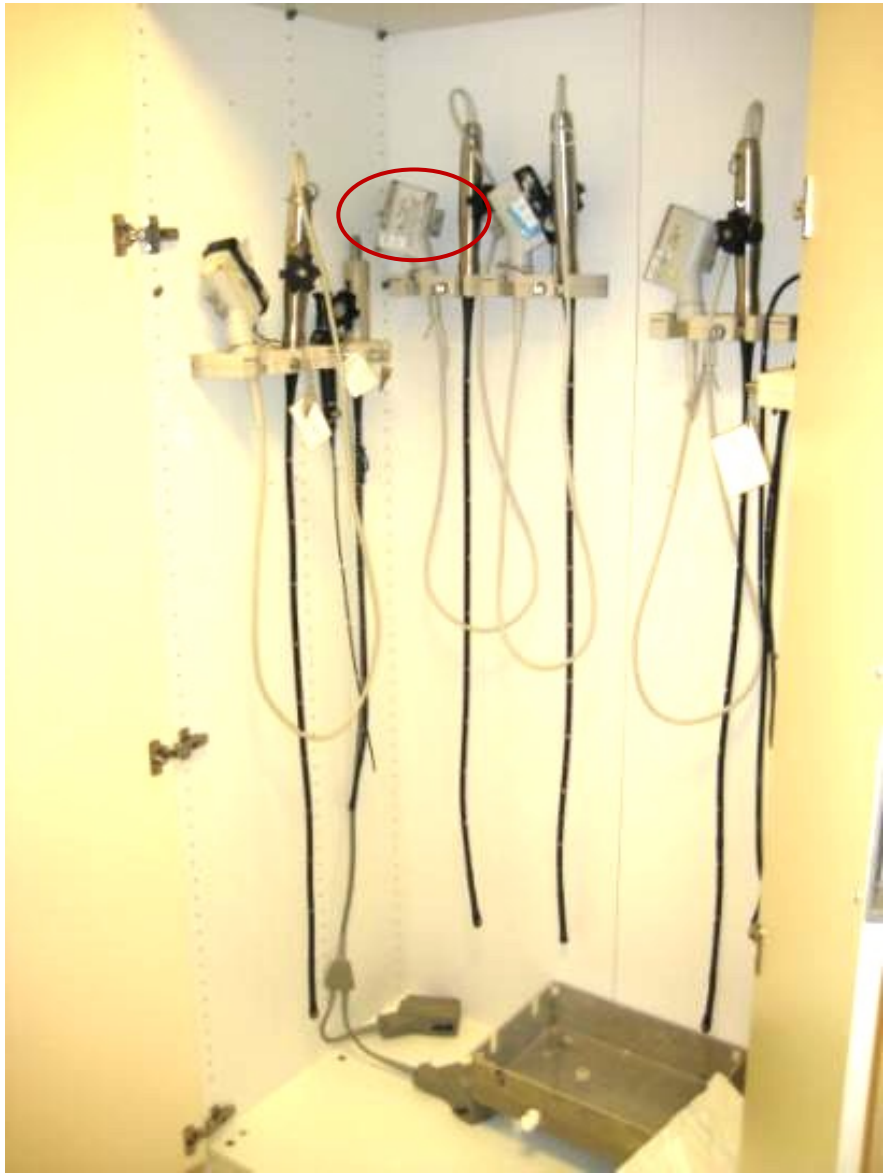
P. Kanagala[1], C. Bradley[2], P. Hoffman[3], and R.P. Steeds[4]*

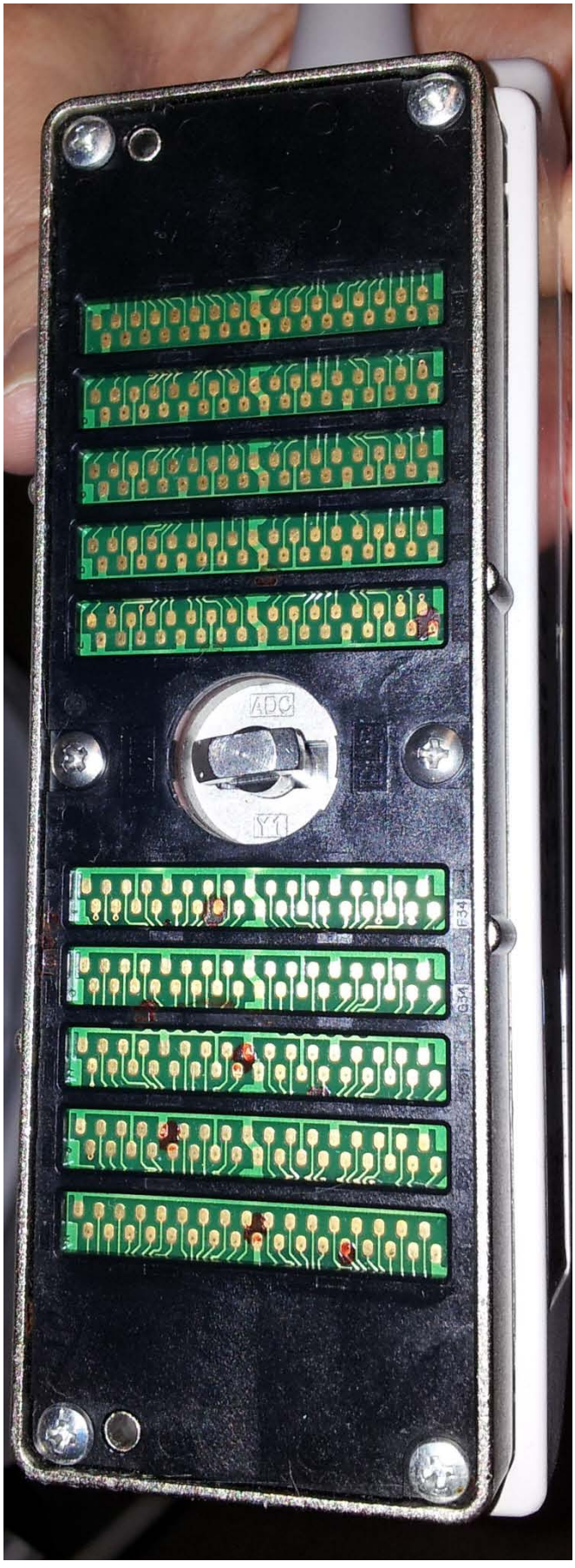
[1]Glenfield Hospital, Leicester, UK; [2]Hospital Infection Research Laboratory, Queen Elizabeth Hospital, Birmingham, UK; [3]Laboratory for Healthcare Infection, Health Protection Agency, London, UK; and [4]Department of Cardiology, University Hospital Birmingham NHS Foundation Trust, Queen Elizabeth Hospital, Birmingham B15 2TH, UK

Accepted after revision May 2011

The clinical utility of transoesophageal echocardiography (TOE) is well established. Being a semi-invasive procedure, however, the potential for transmission of infection between sequential patients exists. This has implications for the protection of both patients and medical staff. Guidelines for disinfection during gastrointestinal endoscopy (GIE) have been in place for many years.[1,2] Unfortunately, similar guidance is lacking with respect to TOE. Although traversing the same body cavities and sharing many similarities with upper GIE, there are fundamental structural and procedural differences with TOE which merit special consideration in establishing a decontamination protocol. This document provides recommendations for TOE probe decontamination based on the available evidence, expert opinion, and modification of the current British Society of Gastroenterology guidelines.

TOE PROBES AS FOUND

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Y1
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Insights Imaging (2016) 7:841–847
DOI 10.1007/s13244-016-0528-z

ORIGINAL ARTICLE

Infection prevention and ultrasound probe decontamination practices in Europe: a survey of the European Society of Radiology

Christiane Marita Nyhsen[1] · Hilary Humphreys[2] · Carlos Nicolau[3] · Gerhard Mostbeck[4] · Michel Claudon[5]

Received: 4 August 2016 / Revised: 19 September 2016 / Accepted: 3 October 2016 / Published online: 24 October 2016

Abstract

Objectives Although ultrasound (US) is considered one of

Methods An online survey was sent to all 22,000 full E members.

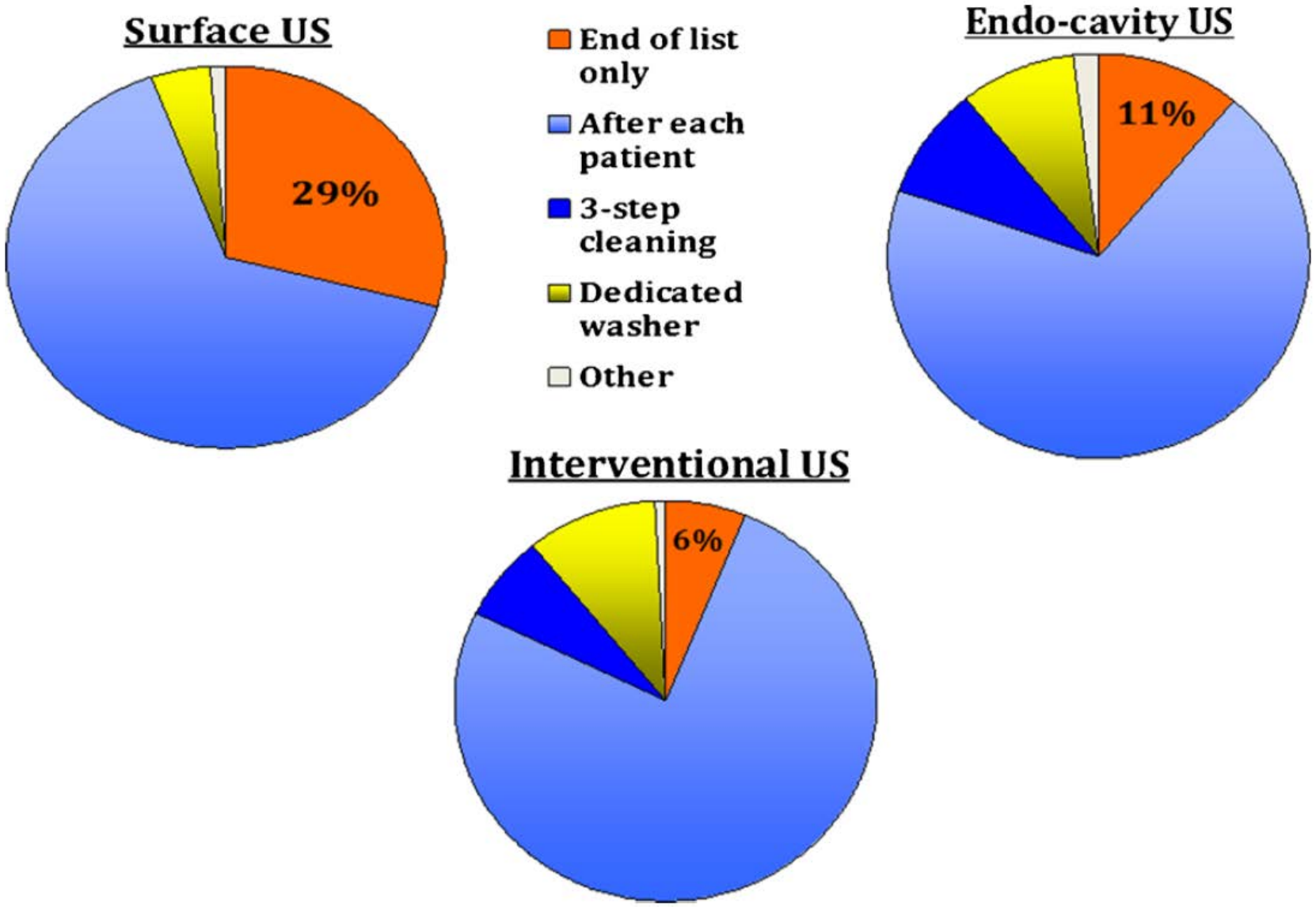


Fig. 1 US probe decontamination

Contents lists available at SciVerse ScienceDirect

Clinical Radiology

journal homepage: www.clinicalradiologyonline.net

Decontamination of transvaginal ultrasound probes: Review of national practice and need for national guidelines

R.A. Gray*, P.L. Williams, P.A. Dubbins, P.J. Jenks

Derriford Hospital, Crownhill, Plymouth, Devon, UK

CONCLUSION: While the decontamination of other endoluminal medical devices (e.g., flexible endoscopes) is well defined and regulated, the decontamination of TVUS probes has no such guidance. There appears to be incomplete understanding of the level of risk posed by TVUS probes, and in some cases, this has resulted in highly questionable practices regarding TVUS hygiene. There is an urgent need to develop evidence-based national guidance for TVUS probe decontamination.

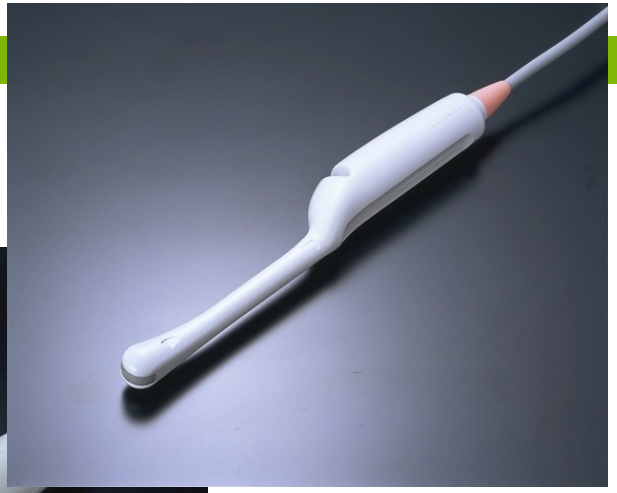
For the Purposes of Infection do You Consider TVUs to be:

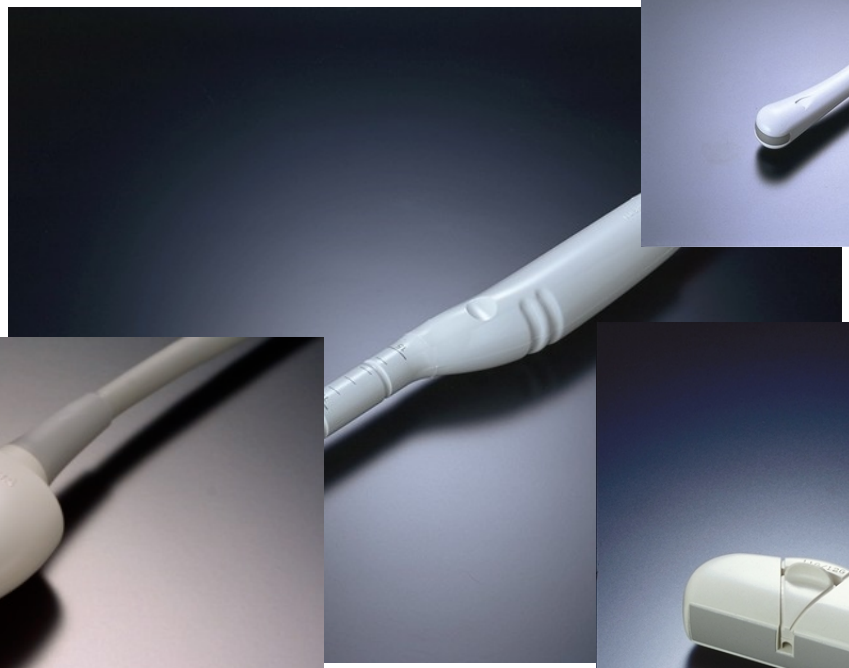
	NUMBER OF RESPONDENTS	%
High risk (direct contact with blood products)	36	53
Medium risk (contact with mucous membrane)	25	37
Low risk (contact with intact skin)	5	7
No risk	2	3

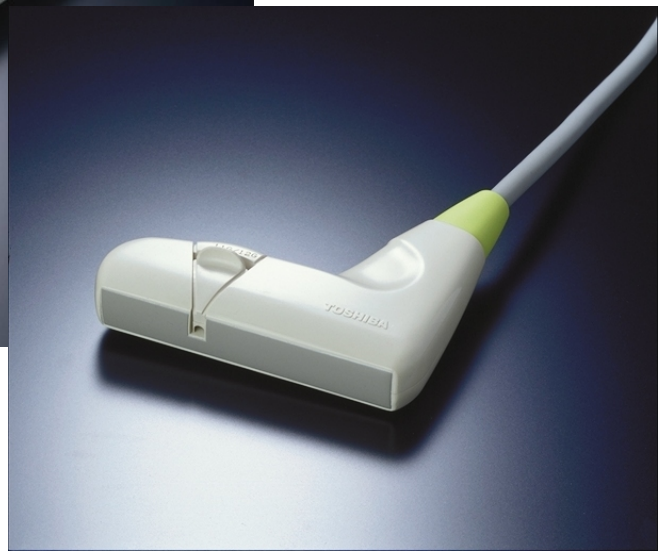
Probe Decontamination Problems

- Numerous patients seen in one session
- Often insufficient probes for one per patient
- Short periods only available for decontamination
- The probe, cable and plug socket cannot all be immersed in disinfectant
- Staff focus on the part of the probe in contact with the patient.
- Probes often heat sensitive
- Disinfectants may be damaging or ineffective
- Reluctance to unplug the probe
- Inadequate facilities for decontamination – risk of cross contamination

DIFFERENT TYPES OF PROBES







Medical Devices Directives

- Manufacturers are obliged to provide full details on how to decontaminate the reusable devices they supply. This should include compatibility with heat pressure, moisture, processing chemicals (e.g. detergents, disinfectants) and ultrasonics

- ISO EN 17664:2004 (Last revised 2008 - currently under revision) may apply
  - The principles may be applied when considering the information to be supplied with medical devices which only require disinfection prior to re-use

Spaulding Classification

Risk category	Recommended level	Device Examples
High (Critical) **Items that are involved with a break in the skin or mucous membrane or entering a sterile body cavity**	Sterilization	Surgical instruments, implants/prostheses, rigid endoscopes, syringes, needles
Intermediate (Semi-critical) **Items in contact with mucous membranes or body fluids**	Disinfection (high level)	Respiratory equipment, non-invasive flexible endoscopes, bedpans, urine bottles
Low (Non-critical) **Items in contact with intact skin**	Cleaning (visibly clean)	Blood pressure cuffs, stethoscopes, environmental surfaces

PROCESS OPTIONS

- Sterilization
  - Steam
  - Low temperature e.g. plasma, hydrogen peroxide
  - (Immersion in chemicals)
- Disinfection
  - Thermal washer
  - Chemical disinfectants

CONSIDERATIONS WHEN CHOOSING A DISINFECTANT

- Range of activity
- Rate of kill/turnaround time
- Health and safety issues
- Compatibility
- Inactivation by organic matter
- Ease of use
- Cost

Agents used

Leroy S. J Hosp Inf (2013)

- The most commonly recommended agents (glutaraldehyde, aldehydes and quaternary agents) are used because of transducer surface compatibility rather than the effectiveness of these agents' disinfecting properties
- Glutaraldehyde or other aldehydes are questioned because they may shorten the transducer life and because they can generate adverse events for workers and patients (i.e. chemical damage to the mucosa if the device is insufficiently rinsed), and for procedure (e.g. damage of gametes and embryos in the case of in vitro fertilization).

METHODS OF DISINFECTION

- Use of wipes
- Immersion in chemical disinfectant
- Automated system

IMMERSION IN DISINFECTANT

- Compatibility
- Efficacy
- Contact time
- Not all parts of the probe can be immersed so must be disinfected separately

USE OF WIPES

- Compatibility
- Efficacy
- Contact time
- Standardisation of wiping
- Coverage of all surfaces

HPV

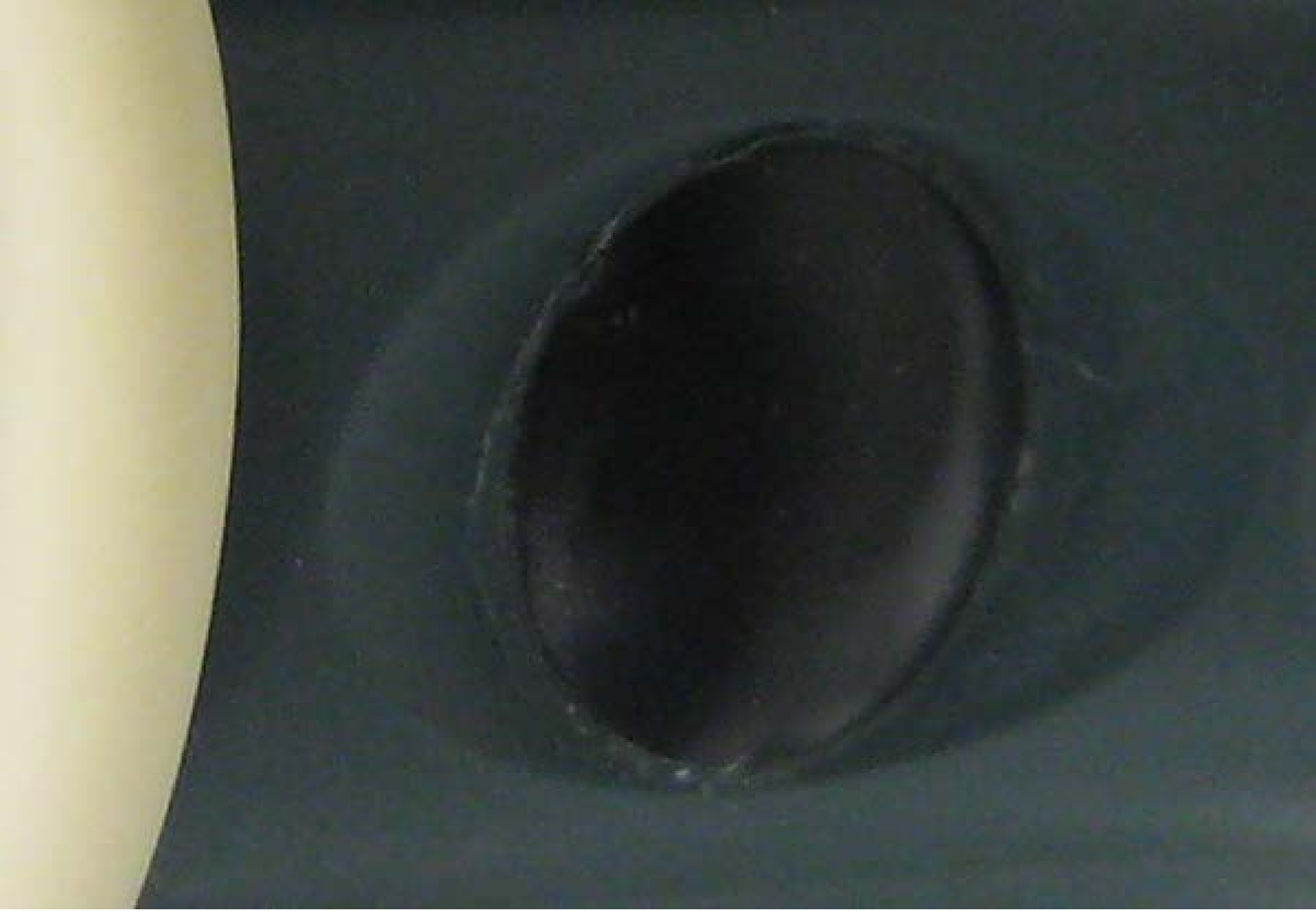
UV-C

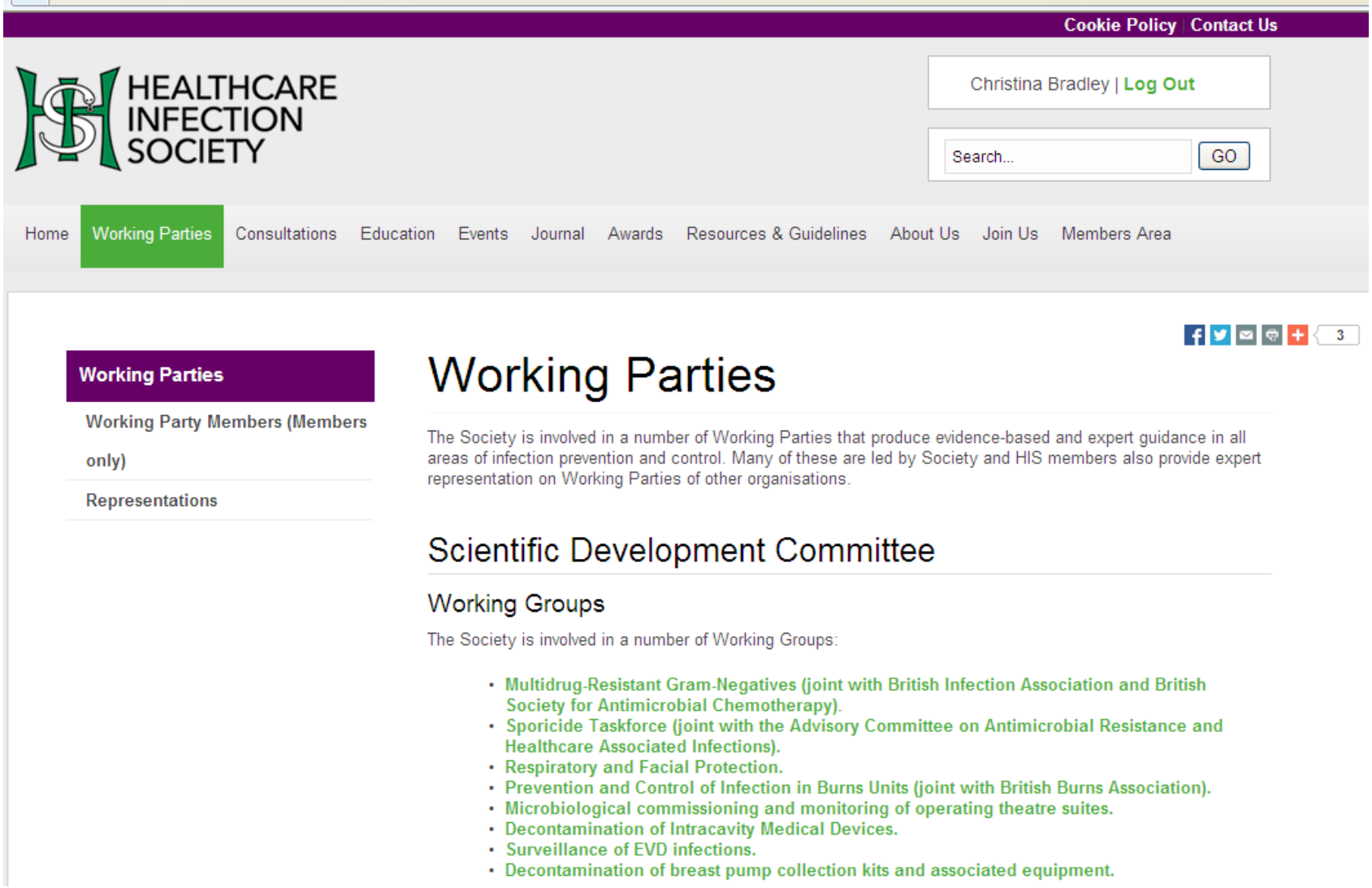
Automated Methods

- Is the process compatible with the probe?
- Is cleaning part of the process?
- Will the system accommodate all of the probe?
- Has the system been tested for microbial efficacy? Are test reports available?
- How is the system validated? What frequency?
  - Physical parameters or microbiological testing
- What assurance of a successful cycle is given?

USE OF PROBE SHEATHS

- Useful to reduce the amount of gel on the probe and to enhance the image.
- Use does not negate the need for decontamination
  - Do not cover all surfaces of the probe
  - Not easy to remove without contamination of probe
- How do you know the sheath is intact?
  - Overall rate of probe cover perforation is 1-9%
  - Some evidence that condoms may have a lower perforation rate however compatibility issues mean that they cannot be formally recommended
    - Leroy, J Hosp Inf (2013)





HIS Working Party on Decontamination of Intracavity Medical Devices

AUDIT

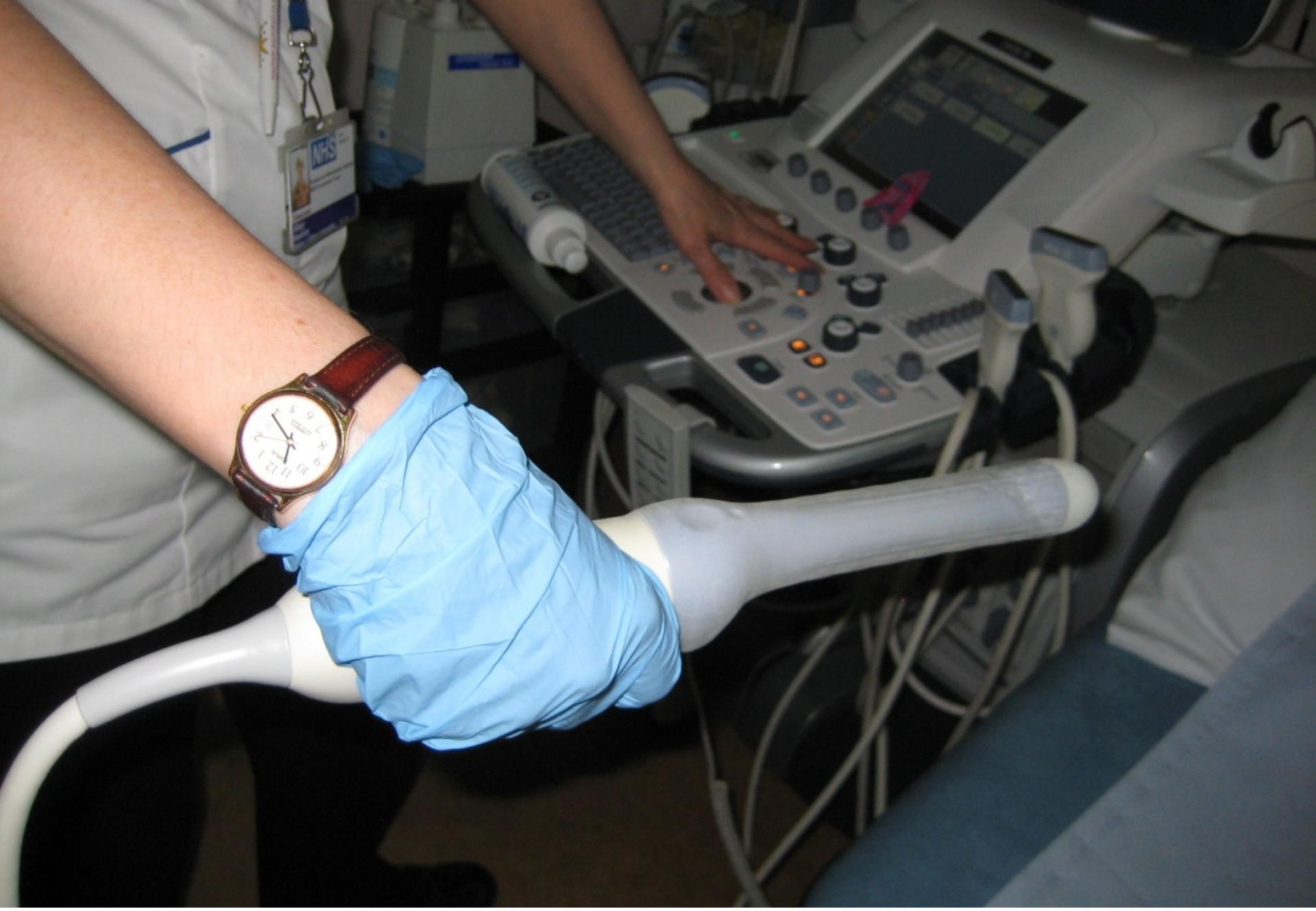
UNACCEPTABLE - ACTION REQUIRED	Sheath only or sheath and detergent clean
ESSENTIAL REQUIREMENTS	Cleaned and all surfaces that make patient or staff hand contact exposed to an effective disinfectant for the required contact time
BEST PRACTICE	Use of manual cleaning followed by an automated system that gives controls assurance of the decontamination procedure and decontaminates all surfaces that make patient or staff hand contact

AUDIT

- Facilities
- Cleaning
- Disinfection
- Storage
- Traceability system
- Documentation
- Training

GLOVES

- Do not remove the need for handwashing – they can develop holes + hands can get contaminated if glove removal technique not perfect.
- Gloves are personal protective equipment “PPE”
- Personal protective equipment does not always equate with patient protective equipment.
- There are many occasions where contaminated gloves can make contact with surfaces that will later contaminate fresh gloves before patient contact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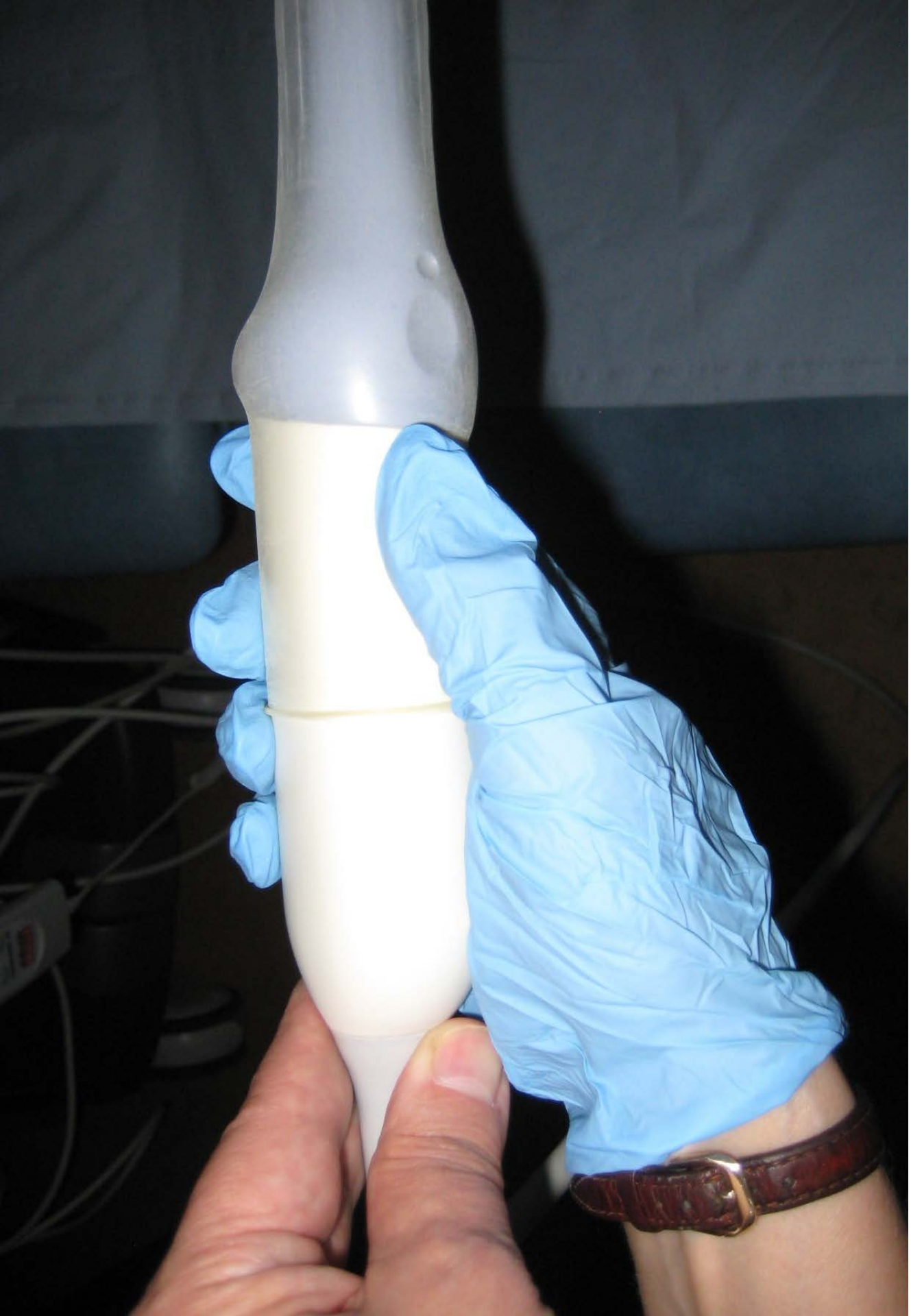
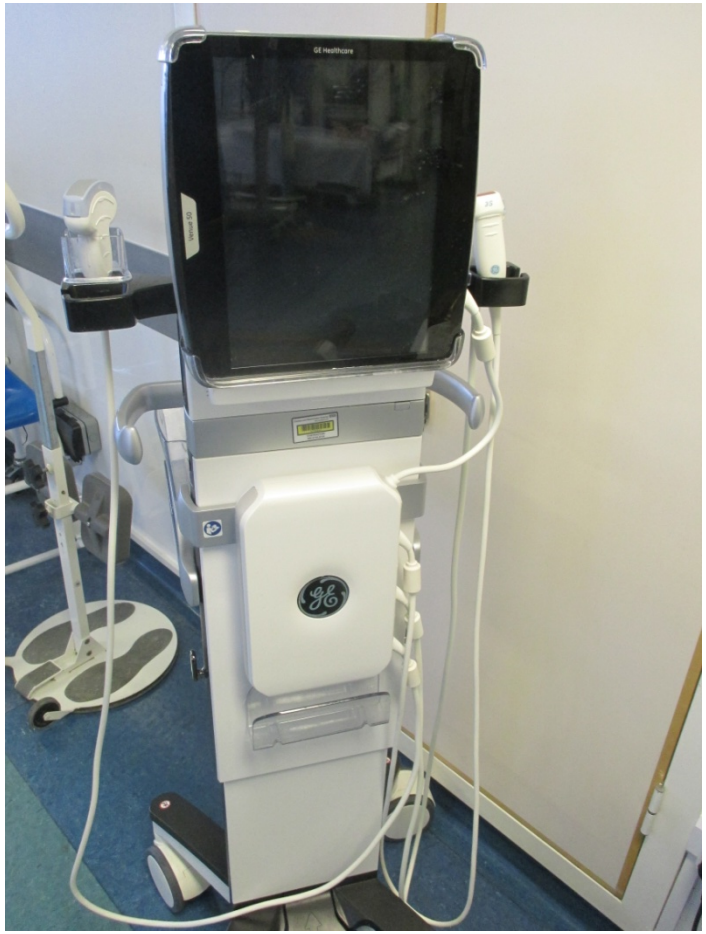
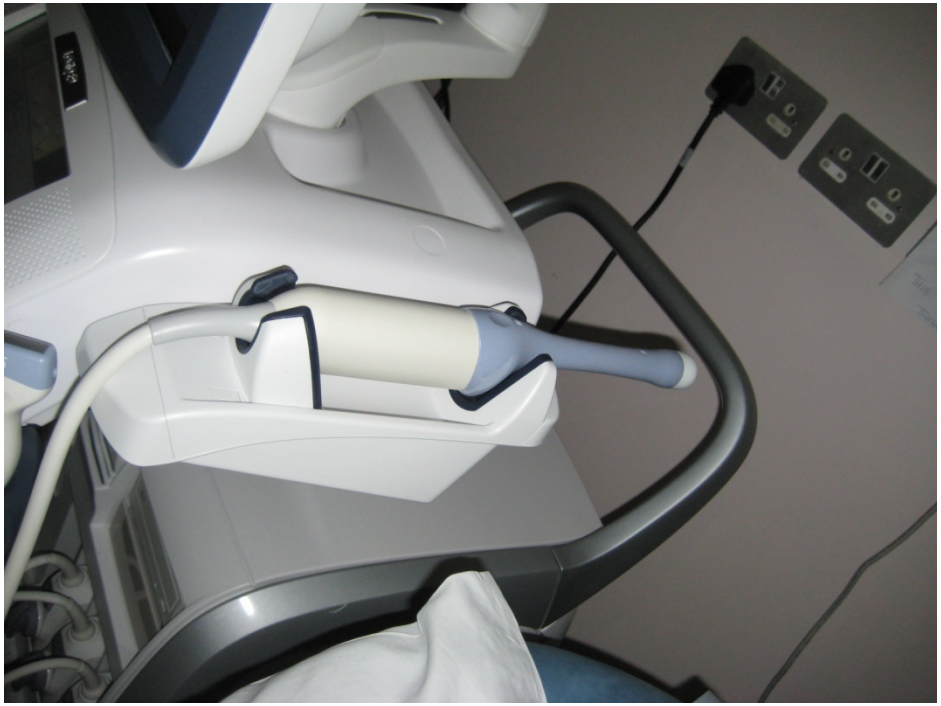


DIFFICULT TO CLEAN SURFACES

TOUCH SCREEN – SMOOTH SURFACE



DIRTY OR CLEAN?



DIRTY TO CLEAN FLOW

- Designated clean and dirty surfaces
- No point in decontaminating something if it is then put down on the surface it was just picked-up from. It will get recontaminated.
- If a facility is in use by more than one person, users should know where in the decontamination process it has reached by where it is in the room

SUMMARY

- Important to ensure
  - Staff receive comprehensive training
  - Cleaning takes place prior to sterilization or disinfection
  - All surfaces of the probe are exposed during the decontamination procedure
  - An effective disinfectant is used at the correct concentration
  - Validation takes place (if automated system used)
  - A traceability system is in place

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REUSABLE MEDICAL DEVICE

- A medical device made for reuse must work as well as it did on its first use every time that it is reprocessed. The manufacturer will validate the device for reuse and provide adequate reprocessing instructions when the device is placed on the market.
- ISO 17664 is relevant

SINGLE USE MEDICAL DEVICE

- A single use device may be made in such a way that any reprocessing may damage it or alter it to the extent of making it unsafe to reuse. If the device has been designed for single use, the manufacturer need not undertake any reprocessing validation studies and is therefore not required to provide such information.

SAFETY ISSUES

- Reprocessing single use devices may compromise its intended function
- Single use devices may not be designed to allow thorough decontamination
- Reprocessing a single use device may alter its characteristics so that it no longer complies with the original manufacturers specifications and therefore the performance may be compromised
- Single use devices have not undergone extensive testing, validation and documentation to ensure the device is safe to reuse

SAFETY OF PACEMAKER REUSE

- 18 studies with outcome of pacemaker reuse (2270 patients)
  - Patients with infection 1.97% - Not significant compared with new devices
  - Malfunction 0.68% - significant
- Low rate of infection but higher rate of malfunction
  - USA 2011

TRANSMISSION OF INFECTION

- Greatest concern
- Risk may increase due to inability to access all micro-organisms
- May be due to design e.g. narrow lumens and materials

ACINETOBACTER – LURKING IN THE VENTILATOR TUBING?

- 66 isolates of A. baumanii in respiratory samples in 2011
- Stopped reuse of single use of ventilator tubing
- 2 isolates of A. baumanii in respiratory samples in 2011
- Washer disinfector was damaging the tubing so temperature was lowered

- Free paper ICAN Conference 2012

MICROBIAL CONTAMINATION ON REPROCESSED VITRECTOMY PROBES

- 979 sampled
- 57 (5.8%) positive growth
  - 25 ethylene oxide
  - 16 hydrogen peroxide plasma
  - 16 LTSF
- Staphylococcus, Pseudomonas, Bacillus subtilis
- Practice of reuse not recommended

- Brazil 2012

INABILITY TO DECONTAMINATE

- Access to all surfaces e.g. acute angles, coils, long or narrow lumens, specialist surface coatings
- Validation of complete removal of all micro-organisms

ASSESSMENT OF DECONTAMINATION OF SINGLE USE DEVICES

- Reusable and single use devices soiled with radio-labelled blood and micro-organisms (including bacterial spores) by simulation of clinical use
- Single use
  - Biopsy forceps, papillotome
- Reusable
  - Biopsy forceps, papillotome, stone retrieval basket
- Cleaned following manufacturers instructions for reusable devices
- Disinfected in 2% glutaraldehyde
- Sterilized using steam or ethylene oxide
    - Heeg et al (2001) ICHE 22 542

ASSESSMENT OF DECONTAMINATION OF SINGLE USE DEVICES

- RESULTS
- Cleaning
  - Soil remained on all devices after cleaning
- Disinfection
  - Reusable devices – >5 $\log_{10}$ reduction in test bacteria
  - Single use devices - < 5 $\log_{10}$ reduction in test bacteria
- Sterilization
  - Bacterial spores remained on all devices
  - Single use devices were physically damaged by steam

  - Heeg et al (2001) ICHE 22(9) 542

CHEMICAL RESIDUES

- Materials may absorb or adsorb certain chemicals
  - glutaraldehyde, ethylene oxide

MATERIAL ALTERATION

- Exposure to chemicals may cause corrosion and/or changes in the device materials
- Exposure to elevated temperatures may alter the properties or cause degradation of the device materials e.g. plastics may soften, crack or become brittle

MECHANICAL FAILURE

- Devices may experience stress during each cycle of reuse leading to fatigue induced failure and fracturing e.g. single use drill burrs, saw blades, craniotomy knives

ENDOTOXINS

- Breakdown products of gram negative bacteria
- May remain on instruments after cleaning
- Sterilization process will not inactivate endotoxins

SAFETY vs COST

- Reduce spending on reprocessing non cost effective single use items releasing more funds for patient care, more expensive reusable devices and reducing the amount of clinical waste.
- Some items must be single use e.g. needles, dressings, syringes, gloves etc.

DEVICE ASSESSMENT GROUP

- Infection Control Doctor
- Infection Control Nurse
- Procurement Officer
- Member of the Ethical Committee
- Processor(s)
- Risk Management Officer (or equivalent)
- User

SINGLE USE “REUSE” CATEGORIES

- Unused items requiring sterilization following damage to pack or opening in error eg pacemaker
- Items used for more than one procedure on the same patient eg insulin syringes
- Items used on more than one patient after reprocessing

REUSE OF SINGLE USE ITEMS INFECTION RISK (1)

- High
  - In contact with a break in the skin or mucous membrane
- Class 1
  - Very high risk – Intravascular, intraventricular, intraoptic devices
  - Difficult to clean, heat labile, sterilization necessary
  - Infections may be severe and difficult to treat e.g., endocarditis, meningitis
- Class 2
  - Usually cleanable, heat tolerant, sterilization necessary e.g., surgical instruments

REUSE OF SINGLE USE ITEMS INFECTION RISK (2)

- Intermediate
  - In contact with intact mucous membranes, usually cleanable, disinfection is usually adequate
- Low
  - In contact with intact skin, usually cleanable, disinfection (or often cleaning alone) is adequate

CAN THE ITEM BE SUITABLY REPROCESSED AND REUSED (1)

- Can it be cleaned?
- Can it be adequately decontaminated ie cleaned/disinfected/sterilized with respect to the infection risk it poses to the patient?

CAN THE ITEM BE SUITABLY REPROCESSED AND REUSED (2)

- Is the item structurally or functionally damaged during reprocessing due to pressure, high temperature or chemicals?
- Are harmful residues present after processing?

CAN THE ITEM BE SUITABLY REPROCESSED AND REUSED (3)

- Is the reprocessor put at any additional or significant risk whilst processing (or disposing of) the item e.g. exposure to infectious material, hazardous chemicals or sharps?

- Are suitable processing equipment, facilities and expertise available?

CAN THE ITEM BE SUITABLY REPROCESSED AND REUSED (4)

- Is it possible to assess if the item is suitable for reuse by visual inspection or testing?
- If so can the number of reuses be identified by tagging or bar coding?
- Is sterility important? Can this be ensured by wrapping or processing at point of use?

IS REPROCESSING COST EFFECTIVE (1)

- Initial cost of the item

- Processing costs including labour
  - Transport – to and from the processor
  - Cleaning
  - Disinfection/sterilization
  - Packaging
  - Documentation
  - Testing/validation

IS REPROCESSING COST EFFECTIVE (2)

- Recording/tracking
- Additional equipment (if required)
- Training of processing staff
- Additional safety measures
  - Personal protective equipment
  - Exhaust systems
  - Health checks
  - Monitoring devices
- Disposal of single use item as single use

REPROCESSING OF SINGLE USE DEVICES - FDA (12.03.2013)

- Reprocessing and reusing single-use devices (SUDs) can save costs and reduce medical waste

- Before medical devices can be reprocessed and reused, a third-party or hospital reprocessor must comply with the same requirements that apply to original equipment manufacturers, including
  - Submitting documents for premarket notification or approval
  - Registering reprocessing firms and listing all products
  - Submitting adverse event reports
  - Tracking devices whose failure could have serious outcomes
  - Correcting or removing from the market unsafe devices
  - Meeting manufacturing and labelling requirements

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/

SINGLE USE ITEMS

DO NOT REUSE. Synonyms for this are Single-use or Use only once.

- Single use items *do not need to have decontamination instructions*

SO YOU ARE ON YOUR OWN

- Single use items are *not validated for safety* after decontamination

SO THERE IS A RISK OF FAILURE

- The *party who reprocesses* a single use item *becomes a manufacturer* under European law

LEGALLY RESPONSIBLE FOR THE INTEGRITY OF THE DEVICE

CONCLUSION

- Is there a risk to patient safety?
- The legal consequences should be considered
- Reprocessing will depend on careful costing taking into account all the variables
- Reprocessing should be validated
- Advice should be sought from a Device Assessment Group and a risk assessment carried out

REFERENCES

- Medical Devices Directive (1993)93/42/EEC
- MHRA. (2013) Single use medical devices – implications and consequences of reuse. www.gov.uk
- Heeg et al (2001) ICHE 22 542
- FDA Guidance (2013)
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices