HPV: Do you know the facts?

In June of 2012 the MHRA reported a fatality caused by the possible cross contamination of Hepatitis B from a transoesophageal echocardiography probe (Ref: MDA/2012/037 in June 2012). This fatality has brought current decontamination protocols within the healthcare industry under scrutiny. Procedures involving endovaginal cavity ultrasound equipment are of particular concern, due to the prevalence and potential contamination risk of Human Papillomavirus (HPV).

Human Papillomavirus

It is estimated that 75-80% of females and males are affected by HPV in their life time. High-risk genotype HPV strains 16 and 18 are responsible for roughly 70% of all cervical cancers.[1,2]

The point of convergence on the transmission of HPV is predominantly focused on the female gender. However, the alarming prevalence of HPV linked to men through oral sex is becoming widely recognised within the medical field. HPV forms in the epithelial cells of the body which include the mucosa of the throat, mouth, tonsils and tongue. The Centers for Disease and Prevention (United States) quote in the Bay State Banner:

"almost 12,000 new cases (oral cancers) are confirmed each year, and men bear the brunt of the illness at 80 percent of the diagnoses". [3]

For women, the possible risk of HPV transmission lies within a standard procedure used widely within obstetrics, gynaecology, IVF and emergency departments: endovaginal cavity ultrasound.

Current disinfectant procedures vary between hospitals and clinics. The majority choose to cover instruments with a sheath or condom, followed by disinfection with quaternary ammonium compound (QAC) based solutions.

A prospective study was conducted within the gynaecology department of Lyon University Hospital (France) to test the efficacy of their disinfectant procedures. Within the ward a sheath was used on the trans-vaginal probe followed by disinfection with a QAC based wipe. Out of the 200 samples taken after disinfection 6 samples contained high-risk HPV types. In addition, swabs were taken before the ultrasound examination. 6 samples out of 217 tested positive for HPV with 4 of these being the high-risk genotype. No breaks were detected on the sheaths used nor were any bodily fluids detected on the probes. This study reveals that under standard disinfectant procedures using QACs there was potential for cross contamination of the HPV virus between patients.[4]

When examining the mode of action of QAC solutions as a disinfectant, QAC has limited biocidal efficacy on non-enveloped viruses. HPV is a small non-enveloped virus. Therefore the standard disinfectant method of using QAC fails to protect patients against nosocomial transmission.[5]

Following the MHRA device bulletin on managing medical devices (section 9.1.1) any medical device in contact with mucous membranes, broken or intact, are recommended to be cleaned followed by sterilisation or high-level disinfection.

Due to "observed leakage rates of 0.9%-2% for condoms and 8%-81% for commercial probe covers", cleaning followed by high-level disinfection is also recommended by the American Institute of Ultrasound in Medicine for intra-cavity ultrasound transducers. High-level disinfection with glutaraldehyde, hydrogen peroxide and peracetic acid has been noted, however equipment damage and adverse health effects to the end user are an issue of concern.[6]

A further study has been conducted within the Emergency Department of the Chinese University of Hong Kong (Ma STC, Yeung AC, Chan PKS, *et al. Emerg Med J* (2012)).[7]

This study examined barrier methods on transvaginal sonography (TVS) probes. Barrier methods involved the use of a condom, removal of any lubricating agent with tissue paper followed by disinfection with T-Spray; a QAC-based disinfecting detergent.

Two parts of the study were undertaken; first, a surveillance on the routine disinfection of the TVS probe over a two-month

[1] 'The facts: what you should know about HPV, cervical cancer and genital warts' www.fpcouncil.com/sites/fpcouncil.com/files/files/HPV%20Private%20Practice%20Toolkit/HPV%20College%20Slide%20Kit.pdf
[2] 'World Health Organisation' 'Human Papillomavirus and Related Cancers' www.hpvcentre.net/statistics/reports/IND.pdf
[3] 'The Bay State Banner' 'HPV Viruses Linked to Growth in Oral Cancers' http://baystatebanner.com/news/2013/aug/12/hpv-viruses-linked-growth-oral-cancers
[4] 'High Risk HPV Contamination of Endocavity Vaginal Ultrasound Probes: An Underestimated Route of Nosocomial Infection?' www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0048137
[5] World Health Organization, 'Biologicals', 'Human Papillomavirus' www.who.int/biologicals/areas/human_papillomavirus/en
[6] American Institute of Ultrasound in Medicine, 'Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers Between Patients' Page 9 www.aium.org/resources/guidelines/reproductiveMed.pdf
[7] 'Transvaginal Ultrasound Probe Contamination by the Human Papillomavirus in the Emergency Department' www.group.bmj.com

period where swabs were taken twice daily (08:00hrs and 20:00hrs) took place.

Second, four swabs were taken at different interval periods. TVS procedures were performed for women showing signs of early pregnancy complications (swab 1 from the patient to check for HPV detection, swab 2 taken before patient contact, swab 3 after condom removal and swab 4 after probe disinfection).

This procedure, using the QAC-based disinfecting detergent, demonstrated inadequate elimination of the HPV virus. In the first part of the study, 9 out of 120 surveillance samples tested HPV DNA positive. In the second part, 14 out of 76 patients were found to be positive HPV carriers from swab 1. After TVS disinfection (swab 4) 3 samples were returned from the 14 women testing HPV DNA positive. This study showed that either staff failed to disinfect the TVS probes properly in between patients or the QAC-based disinfectant used (T-Spray) was inadequate in removing HPV DNA.

Following these results, the University immediately changed its disinfectant procedure of using a QAC-based disinfectant (T-Spray) to a sporicidal disinfectant: The Tristel Trio Wipes System.[8]

Tristel Trio Wipes System

The Tristel chemistry uses the acidification of sodium chlorite to generate chlorine dioxide (ClO_2). No hydrochloric acid is used and no chloride ion is produced, making the chemistry safer to the end user as well as the environment. Toxicology studies have been conducted in the United Kingdom and the United States. These have shown no reactions or contraindications when Tristel chlorine dioxide chemistry has been tested for eye irritation, skin irritation, skin sensitisation and acute oral toxicity.

Chlorine dioxide inactivates non-enveloped viruses and offers the highest level of disinfection. Chlorine dioxide is a powerful oxidising agent – an electron receiver. This means that the chlorine dioxide molecule is in constant search for an additional electron. When a bacterial cell comes into contact with chlorine dioxide, it donates an electron from its cell wall. This creates a breach in the cell wall through which cell contents pass in an attempt to bring the concentrations on either side of the cell membrane to equilibrium. The cell dies through lysis.

Pathogens are unable to build up resistance to chlorine dioxide. In contrast to other disinfectants, no rotation is needed and the strength of chlorine dioxide does not need to be increased over time.

The Tristel Trio Wipes System is a three-part decontamination system which includes:

- A cleaning wipe impregnated with an enzymatic detergent used to remove soil and organic matter from the device.
- A sporicidal wipe impregnated with a citric acid solution activated with a foam composed of sodium chlorite. When activated with the foam, the wipe produces a sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal chlorine dioxide (ClO_2) chemistry, effective in 30 seconds.
- A sterile rinse wipe impregnated with deionised water used to remove any chemistry left on the device.

The Tristel Sporicidal Wipe is effective against many organisms. These include *Bacillus subtilis*, *Mycobacterium terrae* (TB), *Enterococcus hirae*, *Staphylococcus aureus*, Vancomycin-resistant *Enterococci* (VRE), *Candida albicans*, Adenovirus, Polyomavirus SV40 (HPV), HIV, Hepatitis B and Hepatitis C.

The Tristel Trio Wipes System also provides manual or automated traceability and is recommended for the decontamination of heat-sensitive, non-lumened medical devices. These include transvaginal ultrasound probes, transrectal ultrasound probes, and other instruments such as nasendoscopes, TOEs or TEEs, laryngoscope blades, intubation endoscopes, manometry catheters and some ophthalmic instruments. When using the Tristel Trio Wipes System, the decontamination process can be completed in the consultation room in a matter of minutes, offering flexibility to the user.

Tristel's proprietary chlorine dioxide chemistry has an exceptional health and safety record spanning for more than 20 years. The Tristel Trio Wipes System offer a complete solution to the users for the decontamination of semi-critical medical devices and deliver Tristel's chlorine chemistry in a quick and effective way.

Picture 1: *Tristel Trio Wipes System.*

[8] 'Transvaginal Ultrasound Probe Contamination by the Human Papillomavirus in the Emergency Department' Available at www.group.bmj.com

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For Tristel patent information please visit: http://www.our-patents.info/tristel

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