‘Endoscope Decontamination’

‘A Tube in a Hole??’

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Note – This presentation is my personal interpretation and not NHS Wales policy.
Hospital Acquired Infections

What is the Problem? Why we decontaminate.

In 1990 – It was accepted Infection happens, live with it and reduce where possible.

In 2016 – Infection is intolerable!! Legislation, Government target Bad publicity etc
A Flexible Endoscope

A Common Sense device?

- Highly technical
- Heat labile
- Easily damaged
- Difficult to clean
- Source of contamination
Decontamination

The Challenge?

The levels of HAI that can be attributed to ineffective decontamination processes are difficult to accurately determine.

Effective decontamination requires the attainment of Acceptable standards at all stages of the life-cycle.
The Legal Framework

Flexible endoscopes and their accessories are classified as medical devices under the Medical Devices Directive (93/42/EEC7 and 2007/47/EEC8). The Medical Device Regulations 2002 (MDR) implemented the EC Medical Devices Directives into UK law (Consumer Protection Act and HSWA).

Manufacturers’ instructions for reprocessing should be followed.

The patient risks associated with inadequate endoscope decontamination have been documented in many journal articles and “more endoscopes have been associated with hospital-acquired infections than any other device”.

We are not Killing People?

Then an Incident??

Northern Ireland/Swansea + more??

“...critics say the official reports understate the rate of infection. A patient won’t necessarily link a fever to an earlier procedure-and medical institutions aren’t eager to report the cases they do know about.”
Northern Ireland 2004?

In June 2004 an incident occurred in a Trust in Northern Ireland. The failure to decontaminate adequately an endoscope raised concern about the possible risk of exposure of patients to blood borne virus infection. The incident resulted in a patient notification exercise being undertaken and prompted a review of endoscope decontamination throughout Northern Ireland (NI).

Practises were reviewed across the UK and standards were generally no different in England/Scotland/Wales or NI.
However are we cleaning the device

The Issues:

Is the endoscope appropriately cleaned?

Is each lumen appropriately cleaned?

Irrigation – Manual/Automated methods

No debris present

Appropriate flow rates down each channel

Knowledge of the scope

Automated scope recognition

Channel Patency
Is the Endoscope Appropriately Cleaned?

If each channel is inappropriately cleaned, residues such as blood tissues, cells and micro-organisms remain to potentially reduce the efficacy of the disinfection process.

Additionally there is a need to check each channel is undamaged and free of debris (bodily or any other matter) picked up during manual cleaning.
Is the Endoscope Appropriately Cleaned?

Combined Manual & Automated Process to render the device decontaminated.

However, we need to ensure all aspects are appropriate??
Appropriate use of the Manual Clean Brush

Is the brush size compatible with the channel?

Are ‘Bristle brushes’ efficient?

Are brushes the source of re-contamination?

Is the brush the cause of internal damage?
Effectiveness of Cleaning

Factors that influence:

- Brushing Strokes
- Chemicals
- Irrigation
- Technique
- Brush Type

<table>
<thead>
<tr>
<th>Brushing Strokes</th>
<th>Brushing Alone</th>
<th>Brushing with Irrigation</th>
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<tbody>
<tr>
<td>1</td>
<td>1.5</td>
<td>2.4</td>
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<td>5</td>
<td>2.8</td>
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<td>10</td>
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Approximate Log Reduction against known microbial challenge
Appropriate use of the Manual Clean Brush

Comparison exercise undertaken, single pass of a ‘pull-thro brush and a bristle brush – 4mm surrogate using an appropriately manual wash dilution.

Before
Appropriate use of the Manual Clean Brush

Comparison exercise undertaken, single pass of a ‘pull-thro brush and a bristle brush – 4mm surrogate using an appropriately manual wash dilution.

After
What we have?

The Scope lumen

The Manual Brush
Engineering a Solution

The Manual System?

Brush Technology - Integrity

Irrigators
The Use of Irrigators?

Assist scope technician during the manual cleaning process of a flexible endoscope. Provides hands free continuous flushing of endoscope channels which in turn reduces repetitive motion normally done manually by technician while enhancing endoscope cleaning protocol.

Quietly for a preset time set by user the system recirculates the enzymatic detergent filled sink the channels of the scope
When you think things are going well.

An Incident Occurs on your patch

How Safe are the brushes!!!
Channel Patency?

AERs for endoscopes should be fitted with means to ensure that each of the lumens is patent so that disinfectant and rinse solutions will flow through each lumen, even those that have a control wire.

A test is required to demonstrate if an endoscope lumen becomes disconnected, totally obstructed or partially obstructed, it will be detected.
17.11 For each lumen (air/water, biopsy, elevator as relevant), connect a 1.5 m length of tubing of the appropriate diameter and run an operating cycle. On completion of the cycle replace one of the tubes with a similar tube that has a Luer-lock male connection. A hypodermic needle of the appropriate size, with sheath attached and the end cut off for safety reasons, is attached to the 1 mm inner-diameter tube. Other small lumen test pieces may be used, attached to the 1.5 m tube, as long as they present a partial blockage to fluid flow. Another operating cycle should then be run. Repeat the test, changing the position of the partially obstructed tube on each test.

17.12 Needles from size 21 to 32 will be required to determine at commissioning which size is suitable for each lumen to give an indication of partial blockage. Figure 3 gives an illustration of a suitable test piece.
So What Do We Find?

Good!

Bad!

Halfway In-between!
So What Do We Find?

Disconnections – When tested, most AER manufacturers will recognise total disconnection during cycle.

Total Obstruction - When tested, most AER manufacturers will recognise total obstruction during cycle.

Halfway In-between – Do AER’s sense partial blockages????
Partial Blockage

• Some AERs may have a very sensitive lumen blocking system. Scope recognition will indicate if there is the slightest deviation compared to predefined values.
Do current systems provide the assurance we need??

AER’s are set up to work between tolerances, however the operational reality is.

• Calibration of measured pressures can drift.
• Sensitivities can vary as a result of where the blockage is positioned.
• Can be over sensitive – downtime!!
• Is the accuracy transferred to every channel?
• Is the accuracy transferred to every scope?
Important factors!!!

AER’s should be set up with the configured information from endoscope manufacturers and AER manufacturers.

Compatible connectors.

Routine validation should verify patency recognition

Rigorous inspection of manual brushes.

Training

Review Testing methods?
PERCEPTION OF RISK in 2016?

**Hazard:** Potential source of harm

**Harm:** Physical injury/damage to health or property

**Risk:** Probability of occurrence of harm & severity

**Risk assessment:** Overall process comprising risk analysis and evaluation — CATTNAP

*(Cheapest available technique To narrowly avoid prosecution)*
Process Error?

Weakest Link?
Human Factors & Risks?

‘Incompetent people are 1% of the problem. The other 99% are good people trying to do a good job who make very simple mistakes and it's the processes that set them up to make these mistakes.’

There is an Inevitability of an Error/We are different!
User Priorities?

• EQUALITY

• PRIVACY/DIGNITY

• TIMELINESS

• COMFORT

• SAFETY/CLEANLINESS !!!!!!!!!!!!!!!!!!!!!

• RISK?
The Future?

Sterilization of Flexible Endoscopes – Hydrogen Peroxide/Plasma/UV??

Single Use

Robotic Equipment – DaVinci! HELP!!!!

Capsule Technology??

Virtual Endoscopy??
Have confidence in the NHS???
Many Thanks

Two Winning Teams!!!