

## A NOVEL, EVIDENCE-BASED METHOD FOR REPROCESSING CATHETERS USED FOR INTERMITTENT CATHETERISATION

### Hypothesis/Aims of study

Plain, uncoated PVC catheters for intermittent catheterisation (IC) have the potential to be cleaned and re-used multiple times. Up until about 15 years ago this was standard practice in the UK – adults and children were taught to wash their catheters with soapy water and store them in a small container between uses. Regulatory changes around 2000 stopped re-use because catheter manufacturers were required to provide tested cleaning instructions or label their catheters 'single-use'. Consequently, apart from a small number of metal catheters for women, single-use catheters became the only option for IC users. The UK's almost exclusive use of single-use catheters is not the case in comparable countries (1) or in developing nations. In addition to the potential cost savings from catheter re-use, patients have reported advantages to both multi-use and single-use catheters (2). For example, being able to re-use a catheter reduces the fear of running out of supplies. A simple, evidence-based cleaning method would allow catheters to be licensed for multi-use thereby offering patients a choice or mix of multi-use and single use catheters.

The purpose of this study was to explore and then test a simple, evidence-based cleaning method using laboratory testing and IC user input. Results may allow catheters to be licensed for multi-use thereby offering patients a choice of catheter type.

### Study design, materials and methods

Seven cleaning methods including soap and water, Milton solution (1% sodium hypochlorite & 16.5% sodium chloride), steam, boiling and vinegar were tested using standard laboratory procedures for their ability to remove commonly occurring uropathogens (including *E.Coli*, *Klebsiella Pneumoniae*, and *Enterococcus Faecalis*) from catheters soaked in contaminated artificial urine. Episcopic differential interference contrast microscopy (EDIC-M) was used to assess any cleaning related changes to the catheter surface. The most effective methods were soap & water and Milton. These were then tested by a panel of community-dwelling IC users (5 men and 4 women) recruited via local urology out-patients. Participants were instructed to clean and re-use their uncoated catheters once, then 7, 14 and, finally, 28 times. An iterative process was used to refine the methods for cleaning, drying, lubricating and storing catheters; participants met in focus groups (8 meetings over 14 months) with clinical nurse experts to share their impressions of the practical issues of catheter reuse. Industry and clinician members, interviewed face to face, highlighted that any cleaning method needed to be simple. Two consecutive naïve panels (10 men, 8 women) then tested the refined method. Throughout the testing, all participants returned their used catheters to the laboratory for microbiological and surface change analysis. Urinalysis was done at baseline and prior to each increase in number of catheter re-uses. The microbiological testing is reported elsewhere. At the end of the testing three men and three women were video recorded discussing their experiences.

### Results

Based on laboratory testing and IC user experience, the final method comprises a simple, two-step cleaning process (Figure 1) based on the Milton method (<http://www.milton-tm.com>): a soap and water wash followed by soaking for a minimum of 15 minutes in Milton solution. A luminal flush using a catheter tip syringe is used to ensure that the entire inner lumen is exposed to the Milton solution. Users reported that the method was easy to use, convenient and that they would consider re-use based on this approach (Table 1).

Some quotes from users on starting to reuse catheters are below:

#### *Quotes from Women:*

"The cleaning process was demonstrated at the first meeting and once I got home and read it through again it seemed very easy and straight forward and no I didn't have any problems with that -- I thought it was excellent"

"When I first started the trial I did find it a little bit of a nuisance sterilising the catheters but towards the end it became so much easier it just became part of regular life really."

#### *Quotes from men:*

"As far as the cleaning was concerned with reusable catheters I found the process straight forward right from the very beginning. As long as you had the equipment set out and had your routine quickly established I found no problem at all, it became an automatic process really just like brushing your teeth. "

"I got used to the procedure gradually and by the time I'd done it half a dozen times I improved on it and it became second nature."

### Interpretation of results

Our cleaning method is based on the Milton method and was found to be effective at removing bacteria from catheters and very acceptable to male and female IC users, both at home and away. Milton is a particularly acceptable cleaning method as it is safe and effective for use with baby products and is widely used in domestic settings. It does not require a heat or power source and can therefore be used in different locations e.g. the bathroom, and the items required are readily available and easily transportable. Users noted the need for well-designed resources for those who may wish to re-use catheters. With input from the IC user panel, a comprehensive, multi-media teaching kit has been developed.

The gender-specific resources to catheter re-use include:

1. Short video guides to cleaning the catheters and drying, lubricating and storing the catheters
2. Paper step by step guides to accompany the videos (Figure 1)
3. Booklets with additional key information to support users e.g. tips on re-using catheters away from home
4. User videos – participants from the testing above talking about their experiences

Concluding message

Together with IC users, an effective and acceptable method for cleaning uncoated PVC catheters, and supporting resources, has been developed. The availability of an evidence-based method for re-processing catheters provides catheter users with the desired flexibility for using multi-use catheters as well as single use catheters depending on their activities and circumstances. This method is now being tested with a large group of participants (3).



Disclosures

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