



The Mult/Cath study: Development and Clinical Trial of a Mixed (Multi/Single-use) Catheter Management Package for Users of Intermittent Catheters (IC)

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Trial website: www.soton.ac.uk/multicath Email multicath@soton.ac.uk



Background to the study

- Incomplete bladder emptying is a common urological problem
- Intermittent catheterisation (IC) is the gold standard treatment
- In the 1980s sterile, single-use, hydrophilic coated catheters became popular based on limited low-level evidence that they caused less urethral trauma and fewer UTIs
- There is no robust evidence that any type of IC catheter e.g. coated or uncoated, causes more UTI than another
- A lack of evidence-based cleaning guidelines led to the MHRA licensing all non-metal IC catheters for single use only
- There are advantages & disadvantages to single and multi-use



PHASE 1 – preparing for the trial

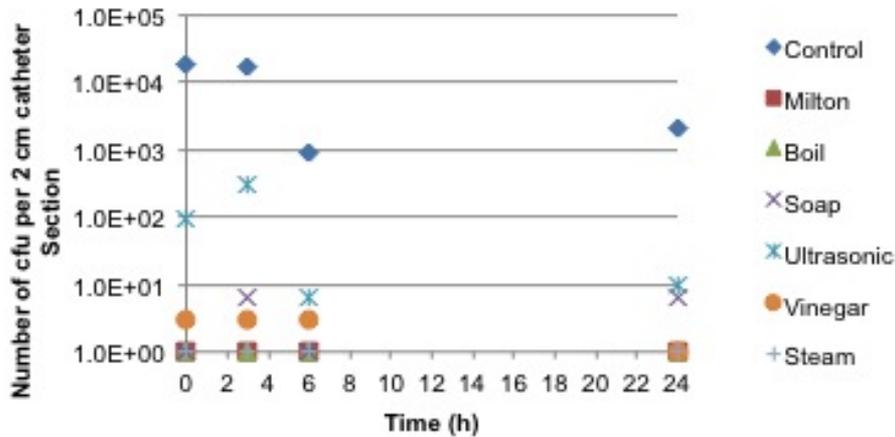
- Developed the cleaning method with panels of catheter users – how to clean (based on the Milton method*), dry, store and lubricate catheters for multi-use
- Interviewed catheter users - advantages and disadvantages of single and multi-use
- Prepared data collection tools - UTI symptoms
- Identified barriers and facilitators to a change in practice – health care professionals & industry representatives

* <http://milton-tm.com/en/consumer/sterilising-methods>

Laboratory testing

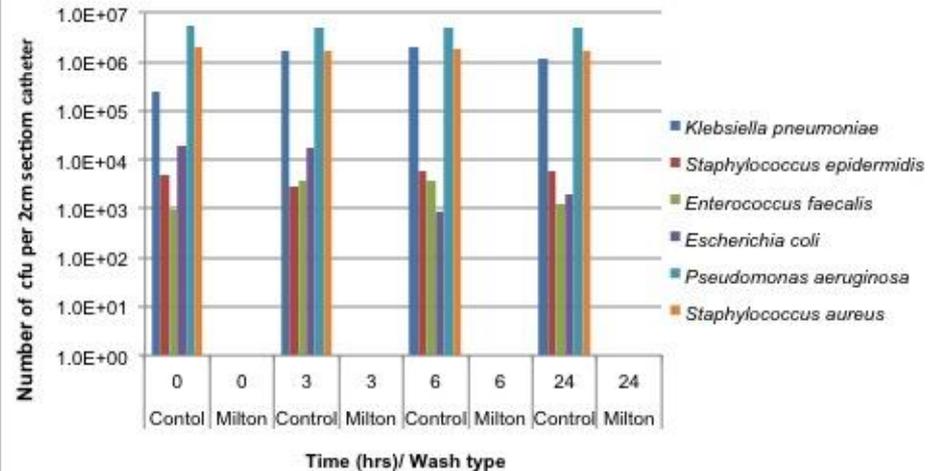
- A range of treatments were tested on various uropathogens and assessed using culture and advanced microscopy methods:
 - Milton (sodium hypochlorite)
 - Steam
 - Boiling
 - Soap & water
 - Ultrasonic cleaning bath
 - Vinegar
- Milton soak, steam sterilisation and boiling were most effective. Heat treatments could cause damage to catheter material or lead to evidence of bacterial colonisation.

Laboratory results



Effectiveness of all cleaning methods on the reduction of uropathogenic *E. coli*.

Comparison of treatment with Milton soak and control rinse with tap water for a range of uropathogens.



Clinical testing with user panels

- Panel tested a simple soap and water method and the Milton Method:
 - Step 1: soap and water rinse
 - Step 2: soak in Milton for at least 15 min
- User panel testing showed that simple cleaning with soap and water was less effective than the two-step Milton Method.
- All panel members had urine colonised with high numbers of bacteria.
- Where bacteria were found on catheters, these were generally the same species as in the urine.

Clinical testing results

No. times catheter reprocessed	Cleaning method tested	Total samples tested* (from men & women)	No. (%) samples with culturable bacteria
1 - 7	Soap & water only	225 (m=117; w=108)	58 (26)
	Milton Method	678 (m=306; w=378)	21 (3)
8 - 14	Milton Method	84 (m=36; w=48)	0 (0)
15 - 27	Milton Method	24 (m=6; w=2)	1 (4)
28+	Milton Method	63 (m=27; w=36)	0 (0)

*A total of three sections were analysed from each catheter.

Results show how the Milton Method was significantly more effective than soap and water alone.

The refined Milton method

- A simple, two-step cleaning process of a soap and water pre-wash → 15 minute Milton soak with luminal flush
- Teaching kit – gender specific ‘how to’ videos, step by step guides, user booklets with user tips.
- Users reported that the method was *easy to use, convenient, can be done anywhere, kit easy to transport* and would consider using it.

“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.”



2 Steps to Clean Your Catheter (Men)

First... WASH + RINSE



- Wash the catheter with soap - under the tap OR in a basin OR bowl of water (any soap will do). Use your hands or a dry wipe to clean along the length of the catheter and around the eye holes.



- Rinse the catheter inside and out under a running tap.

Then... FLUSH + SOAK



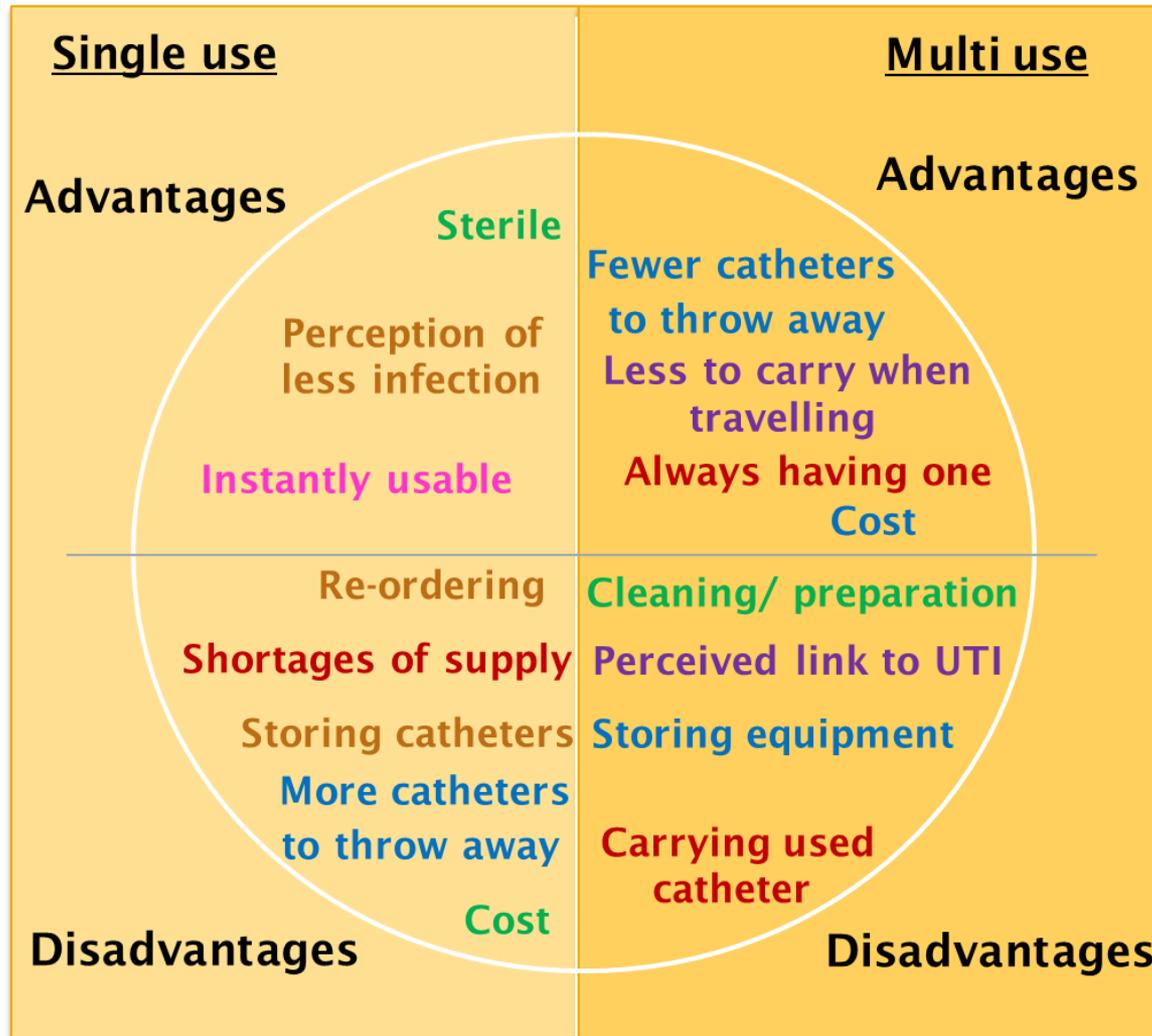
- Using the syringe put 6mls of Milton liquid in 1L of water (to the black line on the container)
- Connect the syringe (with adaptor) to the funnel end of the catheter.
- Place the catheter tip in the Milton. Use the syringe to suck Milton right through the catheter and flush it out
- Finally, suck Milton into the catheter again – don't worry about air bubbles in the syringe. Hold the funnel end in the Milton while you disconnect the syringe – this will make sure that the Milton remains inside the catheter.



1 litre = half
the container

- Soak the catheter for at least 15 minutes – make sure it is covered by the Milton and the lid is on the container.
- Wash your hands after handling Milton.

Understanding IC users' views – advantages and disadvantages of single use and multi-use



(Interviews with IC users n= 39)

Hear from catheter users | The MultiCath Trial |
University of Southampton

Understanding symptoms of UTI:

User reported signs & symptoms* (n=30)

Changes to urine	Change in bladder emptying	General symptoms	Pain/discomfort
>70%	About 50%	<30%	<30%
<ul style="list-style-type: none"> • Urine gets cloudy • Urine smells 	<ul style="list-style-type: none"> • Increased bladder activity • Leaking of urine 	<ul style="list-style-type: none"> • Not feeling well • Fever/feeling hot 	<ul style="list-style-type: none"> • Bladder discomfort • Back/kidney pain • Burning/pain when passing urine • Pain in penis

* Symptoms in this table were based on participants' self-diagnosis and not confirmed with urinalysis (NIDRR symptom set).

Strategies to manage UTI



- **Increase fluids**
- **Watch and wait**
- **Attention to hygiene**
- **Careful IC technique**
- **Self-medication**
- **Self-blame**



UTI: summary & conclusions

First study to explore IC users experiences of UTI.....

- Changes to urine most common signs perceived as UTI
- Terms used to describe UTI symptoms vary
- Coping strategies vary and self blame expressed
- UTI hard to determine where co-morbidities exist
- Imprecise detection has implications for over/under treatment of UTI
- Further work is needed to develop a valid self-report tool and to confirm symptoms with urinalysis.

Understanding clinicians' attitudes to re-use

Two distinct camps:

Most responders **with previous experience** of catheter re-use were accepting of the possibility of re-introduction of re-use ✓

Responders **with no experience** of catheter re-use thought it was a backwards step and were unhappy about the possibility of re-introduction of re-use ✗

Implement – clear guidelines/pathways with adequate training for clinicians who teach ISC

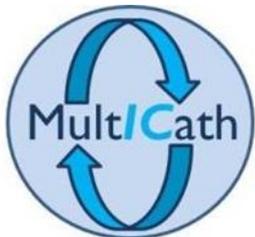
(Interviews n=19, survey responses n =206)

Conclusions: Interviews and survey

- **No increased UTI risk** - a re-usable catheter should not cause, or be believed to cause, an increase in risk to patient health (infection, stricture, bladder) compared to a single use catheter;
- **'Normalcy' should be maintained** - any increase in burden to the patient (threat to normalcy) in using a re-usable catheter should be commensurate with the perceived benefit held by patients and healthcare professionals;
- **Viability of supply** - the development, manufacture, distribution, supply, purchase and disposal of re-usable catheters must be financially viable for suppliers (manufacturers/distributors) and purchasers (NHS/patient)

Phase 1 Conclusion

- An effective **and** acceptable method for cleaning uncoated PVC catheters has been developed.
- **Mixed** use would be acceptable to users and gives them flexibility to choose a strategy to suit their needs and preferences.
- An evidence-based method for cleaning catheters could allow some catheters to be licensed for multi-use.
- Mixed use, using the Milton method, must now be tested with a large group of participants in a non-inferiority RCT.



www.southampton.ac.uk/multicath



Phase 2 - the Mult/Cath trial

Non-inferiority patient-randomised controlled trial (RCT)

Is mixed catheter use (single and multi-use) no worse than single use only?

- Sample Size: 520 Intermittent catheter users
- Multi-centre: Southampton, Bristol, Glasgow, Newcastle, London



Primary Outcome

Urinary Tract Infection



**Presence of
symptom(s)**

+

**Help-seeking
behaviour**

+

**Microbiologically
confirmed**





Secondary outcomes

- UTI (non-microbiologically confirmed)
- Bacteruria
- Rate of antibiotic prescription
- Micro-haematuria
- Bleeding
- Quality of life
- Patient user preference
- Cost





Take home messages

- The aim of the Mult/Cath programme is to **increase options** for intermittent catheter users
- Existing research shows that there are advantages from single-use and multi-use catheters → **mixed use may be optimal**
- **An open mind is important** to test safety and acceptability in the Mult/Cath trial
- Trial re-start planned for 2018

Welcome to the MultiCath Trial

Development and Clinical trial of a mixed (Multi/single-use) catheter management package for users of Intermittent Catheters starting in April 2016

The MultiCath Trial aims to find out whether using a mixture of re-usable catheters and single-use catheters is as safe and acceptable for intermittent catheterisation as using only single-use catheters.

The study is led by Professor Mandy Fader from the University of Southampton in collaboration with Bristol Urological Institute, Glasgow Caledonian University, Newcastle University, University College London and North Bristol Trust.



About the trial

Find out about the MultiCath Trial



Clinicians

Find out how to get involved



Patients

Find out how you can take part



FAQ's

Your questions answered



An introduction to the MultiCath Trial

Hear from Prof Mandy Fader



Papers

Articles and summary protocol



How to re-use catheters

Guidelines for men and women



Hear from catheter users

Men and women talk about re-using catheters

www.southampton.ac.uk/multicath

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