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Intermittent catheterisation: The devil is still in the details

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Short communication

In 2017, we raised our concerns with the 2014 Cochrane review 'Intermittent catheterisation for long-term bladder management' [1]. Subsequently, the 2017 Cochrane review by Prieto *et al.* [2] was withdrawn following our critique, which was published [3]. In October 2021, Prieto *et al.* published their new review [4]. Although this version stated our concerns, the authors failed to implement crucial changes. Therefore, we present our three main concerns with the current review below:

1. Definition of catheter-associated urinary tract infection (CAUTI): Although this review was published in 2021 and discussed the difficulties in adhering to the 2009 Infectious Diseases Society of America (IDSA) CAUTI definition [5], the authors still included studies that considered the National Institute on Disability and

Rehabilitation Research (NIDRR) 1992 UTI definition [6]. In our opinion, this is the most crucial concern with the current 2021 Cochrane review. The 1992 NIDRR definition directly conflicts with the 2009 IDSA definition. We have addressed this point in great detail in our letter to Cochrane in 2017 and in our short communication [3]. Prieto *et al.* stated that 'Sixteen trials reported symptomatic UTI as an outcome measure...' but none of these sixteen studies met the IDSA 2009 definition.

2. Data analyses: Prieto *et al.* stated that 'We conducted data collection and analysis in accordance with methods specified in the Cochrane Handbook for Systematic Reviews of Interventions...' However, Prieto *et al.* as done before in 2014, violated the Cochrane Handbook as it states that 'Meta-analysis is the statistical combination of results from two or more separate studies.' [7]

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Thus, analyses such as ‘Aseptic versus clean technique, Outcome 1: Symptomatic UTI’, ‘Single-use catheter (sterile) versus multiple-use catheter (clean), Outcome 1: Symptomatic UTI’, and ‘Hydrophilic-coated catheter (single use) versus uncoated catheter (single use), Outcome 1: Symptomatic UTI’ as well as ‘Outcome 3: Satisfaction’, of which none met the IDSA 2009 definition or did not follow the Cochrane Handbook, are invalid.

3. Conclusions: Prieto *et al.* should revise their conclusions given the paucity of randomised-controlled trials (RCTs) adhering to the IDSA 2009 definition. There is no conclusive evidence that the multiple-use of catheters manufactured for single-use is safe. As Cochrane reviews are highly influential in the medical community and to policy makers as well as health care insurance companies, we believe it is important that others are aware of the concerns our group has raised in detail with Cochrane. It is particularly important to note that the current results and conclusions of the 2021 Cochrane review on intermittent catheterisation (IC) could negatively impact medical care in developed and developing countries around the world.

The National Institute for Health and Care Excellence (NICE) stated that “to make an ‘off-licence’ recommendation for the use of these catheters, better quality evidence is needed”. Furthermore, NICE updated its clinical guideline to recommend only single-use catheters for IC [8].

Besides legal aspects of catheter use [9], it should be considered that the ‘catheter-only’ costs are not presenting the entire picture. Additional costs due to catheter-related complications, such as urethral trauma/lesions (and subsequent treatment), CAUTI, urosepsis and cardiovascular adverse events (i.e., SCI population) must be taken into consideration when comparing single-use versus multiple-use catheters that are manufactured for single-use.

Furthermore, there is no standardised and universally accepted cleaning method, which would be a necessary prerequisite for the multiple use of catheters [10]. Until appropriate RCTs, such as the ongoing COMPARE (NL8296 - Rotterdam, NL) and MultiCath (ISRCTN68472863 - Southampton, UK) trials, examine whether catheters designed as reusable are equivalent to single-use catheters, or well-done RCTs examine multiple-use of single-use catheters, healthcare providers should not recommend the multiple-use of single-use catheters.

Declaration of competing interest

Matthias Walter has received funding from Wellspect and Coloplast, and serves on advisory boards for Coloplast.

Michel Wyndaele serves on advisory boards for Coloplast.

Veronique Keppenne serves on advisory boards for Coloplast.

Desiree Vrijens serves on advisory boards for Coloplast.

Marcio A. Averbek has received funding from Coloplast, and serves/served on advisory board or is/was a consultant for Coloplast, GlaxoSmithKline (GSK), and Medtronic.

Charalampos Konstantinidis serves on advisory boards for Coloplast.

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Michael Kennelly serves on advisory boards for Coloplast.

Véronique Phé has served on advisory boards or as a consultant for Medtronic, Viatrix, Allergan, Hollister, Ambu and Astellas.

Francois Theron serves on advisory boards for Coloplast.

Andrei V. Krassioukov serves on advisory boards for Coloplast, Wellspect, and Craig Neilsen Foundation.

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