PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Reducing catheter associated urinary tract infections in hospitals: study protocol for a multi-site randomised controlled study
AUTHORS	Mitchell, Brett; Fasugba, Oyebola; Gardner, Anne; Koerner, Jane; Collignon, Peter; Cheng, Allen; Graves, Nicholas; Morey, Peter; Gregory, Victoria

VERSION 1 – REVIEW

REVIEWER	Victor D Rosenthal International Nosocomial Infection Control Consortium (INICC), Argentina
REVIEW RETURNED	11-Sep-2017

GENERAL COMMENTS	Specific comments Background 1. The introduction should provide updated data on the incidence rates of catheter-associated urinary tract infection (CAUTI) in developed and developing countries to set the current benchmark. The authors do not mention the incidence rate of CAUTIs and their adverse effects (extra length of stay, attributable mortality, extra costs, etc). So, the authors should cite and benchmark the following worldwide references, where CAUTI rates in adult ICUs were validated and determined by applying the surveillance methods and definitions of the US Centers for Disease Control and Prevention National Healthcare Safety Network (CDC NHSN): • In order to introduce an international benchmark on catheter-associated urinary tract infection in the ICUs, it is advisable to include a comment on and cite the incidence of HAI rates reported in the last published US report in 2015. [Dudeck MA, Edwards JR, Allen-Bridson K, et al. National Healthcare Safety Network report, data summary for 2013, Device-associated Module. Am J Infect Control. 2015;43(3):206-221.], and also to comment on the results of the data from 50 low and middle income countries by the International Nosocomial Infection Control Consortium (INICC) in 2016. • The International Nosocomial Infection Control Consortium (INICC) surveillance study, conducted from January 2010 to December 2015, in 703 intensive care units in low and middle income countries from Latin America, Europe, Eastern Mediterranean, Southeast Asia, and Western Pacific. During the 6-year study period, using CDC-NHSN definitions for health care-associated infection, prospective data were collected from 861,284 patients hospitalized in ICUs for an aggregate of 3,506,562 days. Although device use in INICC ICUs was similar to that reported from

	CDC-NHSN ICUs, device-associated health care-associated infection rates were higher in the INICC ICUs than in the last CDC-NHSN report: in the INICC medical-surgical ICUs, the pooled rate of catheter-associated urinary tract infection was 5.07 versus 1.7 per 1,000 catheter-days. [Rosenthal VD, Al-Abdely HM, El-Kholy AA, et al. International Nosocomial Infection Control Consortium report, data summary of 50 countries for 2010-2015: Device-associated Module. Am J Infect Control 2016.] Discussion 2. The topic of the prevention of the incidence of CAUTIs has been discussed in the literature from low and middle income countries, and the implementation of bundles and other different infection control measures were assessed in different recent studies. Specifically, the authors should include as reference the INICC multidimensional infection control approach that includes six elements whose effectiveness was assessed in low and middle income countries: (1) a bundle of interventions, (2) education, (3) outcome surveillance, (4) process surveillance, (5) feedback on healthcare-associated infection rates and their consequences, and (6) performance feedback. It is to be noted that the INICC is a nonprofit organization that provides free education, training, and basic and cost-effective tools and resources, including standardized forms and an online platform, to tackle this problem effectively and systematically. It is recommended that the following citation references be included: i. Rosenthal VD, Todi SK, Alvarez-Moreno C, et al. Impact of a multidimensional infection control strategy on catheter-associated urinary tract infection rates in the adult intensive care units of 15 developing countries: findings of the International Nosocomial Infection Control Consortium (INICC). Infection 2012;40:517-26. ii. Rosenthal VD, Ramachandran B, Duenas L, et al. Findings of the International Nosocomial Infection Control Consortium (INICC), Part I: Effectiveness of a multidimensional infection control approach on catheter-associated urinary tract infection rates in pediatric intensive care units of 6 developing countries. Infect Control Hosp Epidemiol 2012;33:696-703. iii. Leblebicioglu H, Ersoz G, Rosenthal VD, et al. Impact of a multidimensional infection control approach on catheter-associated urinary tract infection rates in adult intensive care units in 10 cities of Turkey: International Nosocomial Infection Control Consortium findings (INICC). Am J Infect Control 2013;41:885-91. iv. Kanj SS, Zahreddine N, Rosenthal VD, Alamuddin L, Kanafani Z, Molaeb B. Impact of a multidimensional infection control approach on catheter-associated urinary tract infection rates in an adult intensive care unit in Lebanon: International Nosocomial Infection Control Consortium (INICC) findings. Int J Infect Dis 2013;17:e686-90.

REVIEWER	Pat Stone Columbia University, USA
REVIEW RETURNED	21-Sep-2017

GENERAL COMMENTS	The bullets efficacy, but the aim states effectiveness. Usual care is not well explained. Furthermore, with the introduction of chlorehexadine for meatal cleaning, all nurses will undergo education about insertion. Therefore, it is not clear if any decrease in outcomes is related to the increased focus on proper catheter insertion technique or the chlorehexadine itself. This at the very least needs to be addressed as a limitation, it would be better to address in the trial itself. The research costs of planning and implementing the intervention should not be part of the costs considered in the cost effectiveness analysis. The cost-effectiveness analysis should follow standard guidelines such as CHEERS

REVIEWER	Doreen McClurg NMAHP RU Glasgow Caledonian University Glasgow G40BA
REVIEW RETURNED	25-Sep-2017

GENERAL COMMENTS	Thank you for undertaking this important trial. It is important to reduce the number of CAUTIs and should the use of Chlorhexidine be shown to reduce infections compared to saline then this would be easily introduced into everyday practice (no not if negative). My main concern is actually getting everyone on board a the three sites (I was a bit confused as at times it seems to discuss more sites but that may be within the larger hospital) and monitoring use and outcomes. Although training was mentioned this could be made a bit more clear as to who was being trained, everyone who inserts catheters, and how is this going to be undertaken and who was going to monitor fidelity? Apart from this the protocol is well structured and easy to follow. I wish the authors success.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
Comment: The introduction should provide updated data on the incidence rates of catheter-associated urinary tract infection (CAUTI) in developed and developing countries to set the current benchmark

Response: Agree. Included data from INICC work. Addition made in introduction, including addition of reference no 3

Comment: The topic of the prevention of the incidence of CAUTIs has been discussed in the literature from low and middle income countries, and the implementation of bundles and other different infection control measures were assessed in different recent studies. Specifically, the authors should include as reference the INICC multidimensional infection control approach that includes six elements whose effectiveness was assessed in low and middle income countries

Response: We agree of the importance of the INICC work and have included some of the suggested references in the revision. As the reviewer indicates, the INICC work has included a bundle approach to CAUTI prevention, in low and middle income countries. Our study is focussed on one element of insertion, where a gap in the literature currently exists. Similarly, our study is to be conducted in a high income country. We have sought to find a balance between the aims of our study and including some of the suggested references of the INICC where applicable. We have made reference to and referenced INICC work in the introduction. Addition of references 7 and 8.

Reviewer 2
The bullets efficacy, but the aim states effectiveness

Response: agreed and amended

Comment: Usual care is not well explained.

Response: Agree, ‘usual’ is superfluous and confusing. It has been removed. The term usual has been removed (p.16 under ‘strengths’)

Comment: Furthermore, with the introduction of chlorehexadine for meatal cleaning, all nurses will undergo education about insertion. Therefore, it is not clear if any decrease in outcomes is related to the increased focus on proper catheter insertion technique or the chlorehexadine itself. This at the very least needs to be addressed as a limitation, it would be better to address in the trial itself

Response: This is an important point which we have considered and now made clearer in the manuscript. Education is limited to just the use of chlorhexidine (rather than saline), not about other elements of catheter insertion or management. Similarly, ‘system’ measures such as the replacing /adding chlorhexidine to catheter pack is being undertaken. We have added clarity around education on page 16, under ‘implementing the intervention’ We have included education as potential limitation (page 17, under ‘limitations).

Comment: The research costs of planning and implementing the intervention should not be part of the costs considered in the cost effectiveness analysis. The cost-effectiveness analysis should follow standard guidelines such as CHEERS

Response: Agree with point raised. When reporting results from the cost effectiveness analysis, standard guidelines will be used. No action required.

Reviewer 3
My main concern is actually getting everyone on board a the three sites and monitoring use and outcomes. Although training was mentioned this could be made a bit more clear as to who was being trained, everyone who inserts catheters, and how is this going to be undertaken and who was going to monitor fidelity?

Response: This is an important point. Education is limited to just the use of chlorhexidine (rather than saline), not about other elements of catheter insertion or management. Similarly, 'system' measures such as the replacing /adding chlorhexidine to catheter pack is being undertaken We have added clarity around implementing the intervention on page 16.

VERSION 2 – REVIEW

REVIEWER	Pat Stone Columbia University USA No Competing Interest
REVIEW RETURNED	13-Oct-2017

GENERAL COMMENTS	Response is adequate

REVIEWER	Doreen McClurg Glasgow Caledonian University Glasgow G40BA No Competing Interest
REVIEW RETURNED	16-Oct-2017

GENERAL COMMENTS	None