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Inspection of selected medical device routine cleaning procedures: detection of residual proteins in the clinical setting in Gauteng hospitals

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INSPECTION OF SELECTED MEDICAL DEVICE ROUTINE CLEANING PROCEDURES: DETECTION OF RESIDUAL PROTEINS IN THE CLINICAL SETTING IN GAUTENG HOSPITALS

SJ JARDINE

A research dissertation submitted to the
Faculty of Health Sciences, University of the Witwatersrand, Johannesburg
fulfilment of the requirements for the degree
of
Master of Science in Nursing

Johannesburg, 2015

DECLARATION

I, SJ Jardine, declare that this research dissertation is my own work. It is being submitted for the degree of Master of Science (in Nursing) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

Signature ……..

……day of …… 2015

Protocol Number: M130345

DEDICATION

I dedicate this work to all the nurses and nurse tutors who have upheld the nurses' pledge and have devoted their lives to improving patient care.

ACKNOWLEDGEMENTS

I would like to thank all my mentors over the years that have guided my life and nursing career (that includes you Malcolm).

Thank you also to the team of supervisors who have overseen this project who are all dedicated to improved patient care (Viv Herbert, Prof Duse and Shelly Schmollgruber).

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Thank you to the hospital groups private and public for allowing me to conduct this research, and of course to the staff who participated.

To my loved ones thank you for your patience.

To all of you I will always be grateful.

ABSTRACT

Background:

Patients undergo surgical and medical procedures daily in hospitals and clinics in South Africa to treat various health problems. Medical devices are used to perform these procedures. It is possible that dirty medical devices could transmit healthcare associated infections, so it is critical that medical devices are cleaned, disinfected or sterilized according to validated procedures. Medical devices should be visually inspected to verify that they are indeed clean. Not all patient soils are visible to the naked eye so cleaning should be verified using additional methods. One such method is to test the device for protein residues.

The aim of this study was to establish if selected hospitals in Gauteng (South Africa) have standard operating procedures for cleaning medical devices, if their cleaning procedures are based on international validated procedures and to investigate if selected medical devices have protein residuals left on them after undergoing routine cleaning procedures. The results of this study could be used to help establish South African medical device cleaning guidelines.

A descriptive, multiple case study design was utilised in order to understand the phenomenon of medical device cleaning within its real life context in 5 hospitals in Gauteng (South Africa). The researcher established if the hospitals had medical device cleaning standard operating procedures at a unit level. The researcher observed and documented how specific medical devices were routinely cleaned (namely; flexible gastroscope, Yankhauer suction nozzle, needle holder, diathermy forceps, laryngoscope blades and vaginal speculum). Those devices were then visually inspected for soil and photographed. A marked (traceable) Crile's forceps provided by the researcher was soiled with Browne's soil test (artificial test soil). The Crile forceps and the aforementioned

medical devices were then be swabbed with a sterile swab and that swab was tested for protein residues with a ninhydrin protein residual test.

Results

Only 3% percent of the staff at unit level was aware of medical device cleaning SOP's. Not all medical devices were cleaned in accordance with internationally validated cleaning procedures. The percentage of medical devices that tested positive for proteins varied per device and per hospital. Overall 16% percent of medical devices tested positive for residual proteins post routine cleaning. Only 12% of the medical devices that were kept moist tested positive for residual proteins, whereas 19% of the medical devices that were not kept moist tested positive for residual proteins. The commercially available Ninhydrin test kit (Browne Ltd, UK) was able to effectively detect residual proteins on medical devices in this research to a similar degree found in previous research. The findings in this research however suggest that the ninhydrin test method may not be ideal for testing gastroscopes for residual protein (a more sensitive test may be more effective), and that medical devices should be tested regularly for residual proteins as visually inspecting them for soils is simply unreliable.

Conclusion

Medical devices should be decontaminated according to hospital SOP's that are based on validated cleaning procedures and MIFU in order for them to be cleaned effectively. Cleaning of medical devices should be verified using residual protein tests as visual inspection alone is not effective enough. South African guideline should be established for cleaning of medical devices that are in line with internationally validated procedures, MIFU and that advocate the use of protein residual tests to verify cleaning efficacy.

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LIST OF ACRONYMS

AAMI	Association for the Advancement of Medical Instrumentation
AORN	Association of Operating Room Nurses
CDC	Centres for Disease Control and Prevention
CJD	Creutzfeldt-Jakob Disease
CSSD	Central Sterile Services Departments
CSSD TECH	Central Sterile Services Departments Technician
EN	Enrolled Nurse
ENA	Enrolled Nursing Assistant
FDA	Food and Drug Administration
HCAI	Healthcare Associated Infection
HIV	Human Immunodeficiency Virus
ICU	Intensive Care Unit
ISO	International Standards Organisation
MIFU	Manufacturer's Instruction for Use
NHS	National Health System
NON HCW	Non Health Care Worker
OPA	Ortho-Phthalic Dialdehyde
PCD	Process Challenge Device
RN	Registered Nurse
SANAC	South African National Aids Council
SOCL	Structured Observation Check List
SOP	Standard Operating Procedure
STI	Sexually Transmitted Infection
STN	Student Nurse
TB	Tuberculosis
TSE	Transmissible Spongiform Encephalopathies
vCJD	variant Creutzfeldt-Jakob Disease
WHO	World Health Organisation