JOURNAL OF PURE AND APPLIED MICROBIOLOGY, June 2015. Vol. **9**(2), p. 1339-1347

Study on Assessment of Sterility of Foley Catheters Used in Peshawar, Khyber Pakhtunkhwa

Zia ur Rahman*, Kamran Ahmad Chishti, Alija Baig, Farhat Ali Khan and Imran Khan

Sarhad University of Science & Information Technology Peshawar, Pakistan.

(Received: 11 February 2015; accepted: 19 March 2015)

To evaluate the microbiological sterility of selected Foley catheters as disposable medical devices. Random new packed samples of selected articles were obtained from open market and hospital pharmacy, and used samples from disposal waste of tertiary care hospitals in Peshawar, KPK. The Pharmaceutical sterility of these randomly sampled articles was assessed using United States Pharmacopoeia's standards for the sterility tests. The tests for evaluation of sterility were carried out in controlled aseptic environment using standard procedures and equipment. In case of newly packed Foley catheters collected from market and hospital pharmacy, microbial growth was observed in 20%, 24%, 44%, 31% and 22% of samples of sizes 8 Fr, 12 Fr, 18 Fr, 18 Fr, and 24 Fr respectively. While in case of Foley catheters collected from hospital disposal waste microbial growth was observed even after re-sterilization. Both bacterial and fungal growths were detected. Chances of microbiological contamination in disposable articles available in market are quite ample. It is therefore recommended that pharmaceutical manufacturers of such articles must strictly comply with GMP guidelines especially for sterilization, and standards established for Single use devices like Foley catheters, and the re-sterilization of these medical devices is not safe and effective, so the hospital waste management should be make effective, so that the recollection and re-sterilization of such articles do not take place in practice.

Key words: Foley Catheters, Single Use Devices, Sterilization.

Disposable medical devices or single use medical devices such as electro cardio graphic pads, catheters, glucose test strips, syringes, are meant are to be used upon single patient and for a single procedure[1]. As per guidelines of centre for disease control (CDC) for infection control in health care personnel, 1998; the medical devices that enter normally sterile tissues or the vascular system or through which blood flows should be sterilized before use. Sterilization is the use of physical or chemical means to destroy all microbial life, including highly resistant bacterial endospores[2].

Catheters are thin flexible tube extruded from medical grade materials that can be inserted in body tissues (cavity, duct or vessel) for multiple functions, for example, for drainage and administration of fluids or access by surgical instruments/procedure[3]. Due to this reason they have become an essential part of hospital based, outpatient and home healthcare settings. Foley catheters are generally used to access the urinary tract, in both hospital and pre-hospital services.

Ethylene oxide (EO) and ionizing radiations are the common methods of sterilization of medical devices sensitive to heat and moisture[4,5]. However, in Pakistan, especially KPK, mostly EO sterilized catheters are available in open market, although some gamma irridiated imported brands are also available[6].

Since catheters are necessity of healthcare settings and most frequently used disposable devices; but if these devices are not properly sterilized, their use can put patients at risk for local and systemic complications; including local site infection, CRBSIs (catheter related blood stream infections), septic thrombophlebitis,

* To whom all correspondence should be addressed.
Tel.: +92-3339359267;
E-mail: zia .pharmacist@hotmail.com

endocarditis, lung abscess, osteomyelitis; depending on the body site where it is used; beside this the presence of rackets in pharmaceutical market of Pakistan also have been reported, who dealing with collection of disposable wastes from hospitals and clinical setups, and reprocessing it for the purpose of re-selling these articles as new in the market[7].

Epidemics of device-related infectious diseases appear to have increased in number since 1965, and most often have been related to Foley catheters, intravenous infusion devices. Foley catheters and intravenous infusion devices represent major sources of nosocomial septicemia[8,9]. Since disposable medical devices like catheters and needles which are in direct contact with human tissue and organs and they must be sterile prior to use in order to prevent related infectious consequences.

In Peshawar (KPK), various types of catheters are available in poly bag and blister packaging, with different sizes for adult and pediatric patients and used in hospital and outpatient healthcare settings[6]. The purpose of this study is to evaluate the microbial sterility of these articles used in hospital and outpatient health care settings.

MATERIALS AND METHODOLOGY

Sampling

Samples Collected From Market & Hospital Pharmacy

Samples of commonly used Foley catheter were randomly purchased from open market and hospital pharmacies of all manufacturers available in Peshawar, KPK from Dec 2014 to mid of Jan 2015. Both poly bag and blister pack available samples were collected that were either EO sterilized or gamma irridiated, details summarized in **Table 01**.

Samples Collection From Hospital Disposal Waste

Collection of used disposable foley catheters from waste disposal of a tertiary care hospital of Peshwawar, of above mentioned critaria. The details have been summarized in **Table 02.**

Media & other chemical substances

The sterility tests were carried as per guidelines of United States Pharmacopoeia[10] for the evaluation of pharmaceutical sterility of selected articles (for both new and used articles). Briefly, two media types were used i.e. Fluid Thioglycollate medium (FTM) and Soybean-Casein Digest Medium (SCD). Media were sterilized as per manufacturer guidelines and verified for sterility prior to use. Articles divided in selected parts were aseptically immersed completely in prescribed media (FTM and SCD) simultaneously. Immersed samples were incubated at 37'C and observed for bacterial growth overnight and then after 48 hours. Similarly, samples were incubated at 25 ^{o}C for 7 days to check fungal growth. Blank media served as negative controls for both kinds of tests. All the tests were done in triplicate. Tests were repeated for the samples showing either bacterial or fungal growth as per pharmacopoeia guidelines.

Sterilization Technique for Lab Re-processed Foley Catheters

For used devices collected from hospital disposal waste, to be lab re-processed for the purpose of sterility evaluation, 0.2% Peracetic acid (PAA) Immersion was selected as sterilization technique, because FDA cleared Peracetic acid as sterilant for sterilization of medical devices, in concentration of 0.2%, applied for a duration of 12 minutes at 50-56°C[11].

Characterization of Microbial Growth

Gram's staining and Endospore (Schaffer-Fulton method) staining technique[12] was carried out on the samples showing bacterial growth after 24 or 48 hours incubation.

RESULTS

Results of New Samples

After immersion of the selected samples in desired mediums and prescribed incubation period, the samples were observed for microbial growth, results are summarized in table 3.

Table 03 shows that from each manufacturer 3 samples were taken for each different type of item, each sample was subdivided in to 3 parts which served as samples and these parts includes most vulnerable parts of the device, i.e. balloon, middle flexible tube and bladder opening part, for incubation and further studies.

Results of Used Samples

Table 1. Description of selected new samples for study, from market and hospital pharmacy

S.N	Item description	Number of selected manufacturers	Samples selected from each manufacturer	Packaging material included	Manufacturing material included	Claimed method of sterilization
1	6 Fr (French size)	3	3	All blister Packed	Silicon coated latex, pure silicon	All ETO sterilized
2	8 Fr (French size)	5	3	All blister Packed	Silicon coated latex, pure silicon	All ETO steriized
3	10 Fr (French size)	4	3	All blister packed	Silicon coated latex, silicon elastomers	All ETO sterilized
4	12 Fr (French size)	6	3	All blister Packed	Silicon coated latex, silicon elastomers	All ETO sterilized
5	18 Fr (French size)	4	3	2 blister packed, 2 poly bag	Silicon coated latex, silicon elastomers	2 Gamma irradiated, 2 ETO sterilized
6	18 Fr (French size) *TCHS	1	6	All poly bag	Silicon coated latex	All ETO sterilized
7	24 Fr (French size)	5	3	All blister Packed	Silicon coated latex, silicon elastomers	All ETO sterilized

*TCHS (Tertiary Care Hosp. samples)

Used foley catheters of size 18, 20 and 22 Fr were collected in triplicate from waste disposal of a tertiary care hospital situated in Peshawar; and were evaluated for microbial growth; results are tabulated as given below.

Table 04 shows that bacterial growth was observed in all samples of 18 Fr, while endospores were found in two samples (out of three), and fungal growth was present in two samples.

Table 5 shows that bacterial growth was observed in all samples of 20 Fr, while endospores were found in one sample (out of three), and fungal growth was present in one sample

Table 6 shows that bacterial growth was observed in all samples of 22 Fr, while endospores were found in one sample (out of three), and fungal growth was present in one sample.

Results of Lab Re-processed items

After the evaluation of microbial growth in used disposable foley catheters collected from waste disposable of a tertiary care hospital, were re-processed (re sterilized) in lab using 0.2% peracetic acid as sterilant and SOPs of sterilization practice, and again evaluated for microbail growth. Results are tabulated as given below.

Table 7 data shows that after sterilization bacterial growth was found in only one sample, similarly only one sample contains endospores, no fungal growth was present and no changes in physical consistency of product were observed.

Table 8 data shows that after sterilization bacterial growth was found in only one sample, similarly only one sample contains endospores, fungal growth was not observed and changes in physical consistency of product were observed.

Table 9 data shows that after sterilization bacterial growth was found in only one sample, similarly two sample (out of three) contains endospores, no fungal growth was present in samples and changes in physical consistency of product were observed.

DISCUSSIONS

The results presented in table 3 illustrate the microbial growth in sterilized disposable (single use) Foley catheters that have been collected from market and hospital pharmacy as new packed sterilized items (claimed to be not previously used). In under developed countries like Pakistan, there

is lack of compliance to the international standards of clinical waste management, where collections of these single used articles take place, which then recycled, packed and marketed by rackets in pharmaceutical market[7,13]. So there may be the possibility of collection of these disposable items from hospital disposle waste then repaked and re-selled. The Foley catheters in our study are single use medical devices and the regulatory bodies have clear cut guidelines on medical devices intended for single use (disposable); because, single use devices and specially devices with small lumens like foley catheters could not be properly sterilized and not safe to be resterilized and reused. For example Federal Drug Administration (FDA) said that "a single use device (SUD) is not intended to be reprocessed (cleaned, disinfected/sterilized) and used on another patient. The labeling may or may not identify the device as single use or disposable and does not include instructions for reprocessing"[1]. FDA also mentioned that in case if these SUDs are reprocessed by any hospital or company, it must meet the same standards and effectiveness as manufactured by the origional manufacturer for the first time[14]. Similarly Canadian standard association and health Canada states that medical devices labelled as single-use shall not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor, and still there is no licensed reprocessor cleared by FDA in developed country like canada, although USA have few[15,16], and one cannot imagine it in an under developed country. Canadian standards association also recommends that medical devices with small lumens, like catheters, that make them difficult to clean can put clients/patients/residents at risk, and should be designated single-use and not be reprocessed and re-used[17].

Interestingly it was found in our study that all samples, except one (which was gamma irradiated) resulted in positive microbial growth, were claimed to be ETO sterilized, as shown in table 3. Mostly these Foley catheters are marketed in our part of the world as ETO (ethylene oxide) sterilized, and there may be the possibility of ineffective ETO sterilization because this process efficiency and effectiveness is highly dependent on some of the factor like gas concentration, temperature, relative humidity (as water molecules carry ETO to reactive sites) and exposure time, if any of the factor is compromised the whole process is affected and ultimately the desired results (proper sterilization) are not obtained, and their use can put patients at risk for local and systemic infection complications[6,4]; as mentioned earlier the Foley catheters in our study consist of small lumens and it has been previously demonstrated that the effectiveness of ETO sterilization can also be altered by lumen length, lumen diameter, presence of inorganic salts, and organic materials[18,19]. For example, several studies have shown failure of ETO in inactivating contaminating spores in endoscope channels[20] or lumen test units[18], and residual ETO levels averaging 66.2 ppm even after the standard degassing time[21]. Similarly CDC reported that all medical devices having channels and small lumens like catheters and endoscopic instruments could not be disinfected or sterilized properly if the disinfectant or sterilant contact is inadequate and unreliable, because air pockets interfere with sterilization and disinfection process[22].

So the microbial growth observed during our study in packed samples collected from market and hospital pharmacy may be due to non-compliance with international guidelines of sterilization; as multiple studies in many countries have evaluated lack of compliance with established guidelines for disinfection and sterilization; Lowry

Table 2. Description of selected used samples for study, from hospital disposal waste

S.N	Item description	Number of selected manufacturers	Manufacturing material	Selected samples
1	18 Fr (French size)	N.A	Silicon coated latex	3
2	20 Fr (French size)	N.A	Silicon coated latex	3
3	22 Fr (French size)	N.A	Silicon coated latex	3

NA = Not applicable

Table 3. Description of Foley Catheter samples and developed microbiological growth after prescribed incubation period

S/N	Types of items	No of *Mfg(n)	Packaging material	No of samples (x) selectedfrom each Mfg	Each Sample parts(y) selected for test	Total number of each parts (nxy)Incubated	No of +ive samples	%Microbial Growth of samples	Sterilization type
1	8 Fr	05	Blister packed	03	03	45	09	20%	ETO
2	12 Fr	06	Blister packed	03	03	54	13	24%	ETO
3	18 Fr*TCHS	01	Plastic poly Bag	06	03	18	08	44%	ETO
4	18 Fr	04	Blister packed	03	03	36	11	31%	Gamma Irridiated
5	24 Fr	05	Blister packed	03	03	45	10	22%	ETO

Fr = French size, *TCHS (Tertiary Care Hosp. samples), Mfg (manufacturers)

PW *et al* in 1988 detected Seventeen cases of otitis media caused by Mycobacterium chelonae among patients seen at a single ear-nose-and-throat (ENT) office while using medical devices not properly sterilized. They concluded that outbreak underscores the need for high-level disinfection or sterilization of ENT instruments between examinations to prevent the transmission of pathological microbes[23]. McCarthy *et al* in 1999 during a study "infection control practices across the canada" concluded that improvements in infection control are desirable for dentists in all provinces and territories; infection control is required through better compliance with current recommendations for sterilization and disinfection[24]; and failure to comply with scientifically based guidelines has resulted in many outbreaks of infection[25].

Similarly regarding the results of lab reprocessed items that were collected from hospital disposal waste of a tertiary care hospital in Peshawar and then re-sterilized in Lab (using 0.2% PPA), both the viable bacterial growth and endospores were observed as shown in table 7, 8 and 9. The positive microbial growth may be due to the formation of biofilms in the lumen of urinary catheters because biofilms have been found and reported in urinary catheters, central venous catheters, and numerous medical devices[26]. The microorganisms resides within these biofilms can be resistant to sterilants by multiple mechanisms, and microbes resides within these masses are up to one thousand times more resistant to sterilants than are the same bacteria in suspension[27].David Stickler *et al* in a study demonstrated that urease producing bacteria's biofilms colonise catheters, and induce the deposition of calcium and magnesium crystals during catheter indewlling process, and then the biofilms starts to move down the lumenal surfaces of the catheters causing blockage of catheter's lumen[28]. Some catheter materials also have surface irregularities that increases the chances of the microbial adherence of certain species (e.g., S. epidermidis and C. albicans)[29]. Catheters made of these materials are especially vulnerable to microbial colonization. Due to the formation of the fibrin sheath, silastic catheters (Latex Foley Catheter with smooth, silicone exterior coating) are associated with higher risk of catheter infections than polyurethane

catheters[30]. Similarly, biofilm formation by C. albicans occurs more readily on silicone elastomer catheter surfaces than polyurethane catheters[31]. These arguments also supports our findings, as the new samples selected from market that had been shown microbial growth were either made of silicon coated latex or silicon elastomers; similar was the case of used disposable foley catheters collected from hospital disposale waste; that's why cleaning of the items is always recommended before processing for items intended to be reused, because it reduces the bioburden and removes foreign material (i.e., organic residue and inorganic salts) that interferes with the sterilization process by acting as a barrier to the sterilization agent[32]. The presence of these biofilms can have serious implications for immunocompromised patients and patients who have indwelling medical devices; so in the light of above mentioned references, the sterilization will not be effective and these medical devices would not be safe for use if these are being collected from hospital waste disposal and resterilized for the purpose of re-selling in market, as shown by our results after reporcessing of these articles collected from a hospital disposal waste.

Short Comings of Our Study

The shortcomings of this study include the limited pool of sample selection. Before this report no such work had been conducted in this regard in the region, so no comparison was made to such other studies. So additional research is needed for the evaluation of pharmaceutical sterility of such disposable medical devices, available in the market, which has been previously claimed as sterilized; as the non-sterility of such articles can lead to complicated infectious consequences

CONCLUSION

It has been concluded that there are chances of microbiological contamination in such

Table 4. Microbiological attributes of 18 Fr (french size) Foley Catheters

S/N	Article	manf. material in 24Hrs	Bacterial growth in 48Hrs	Bacterial growth Staining	Gram Staining	Endospore growth	Fungal
1	18 Fr	Silicon coated latex	Mild	Dense /Profuse	+ive	+ive	Present
2	18 Fr	Silicon coated latex	Mild	Dense /Profuse	+ive	-ive	Absent
3	18 Fr	Silicon coated latex	Mild	Dense/Profuse	+ive	+ive	Present

* Fr (French size)

Table 5. Microbiological attributes of 20 Fr (french size) Foley Catheters

S/N	Article	manf. material in 24Hrs	Bacterial growth in 48Hrs	Bacterial growth Staining	Gram Staining	Endospore growth	Fungal
1	20 Fr	Silicon coated latex	Mild	Dense /Profuse	+ive	+ive	Present
2	20 Fr	Silicon coated latex	Mild	Dense /Profuse	+ive	-ive	Absent
3	20 Fr	Silicon coated latex	Mild	Dense/Profuse	+ive	-ive	Absent

* Fr (French size)

Table 6. Microbiological attributes of 22 Fr (french size) Foley Catheters

S/N	Article	manf. material in 24Hrs	Bacterial growth in 48Hrs	Bacterial growth Staining	Gram Staining	Endospore growth	Fungal
1	22 Fr	Silicon coated latex	Mild	Dense /Profuse	+ive	-ive	Absent
2	22 Fr	Silicon coated latex	Mild	Dense /Profuse	+ive	+ive	Absent
3	22 Fr	Silicon coated latex	Mild	Dense/Profuse	+ive	-ive	Present

Table 7. Microbiological attributes of 18 Fr (french size) Foley Catheters

S/N	Article	manf.material	Sterilization method	Bacterial growth in 24Hrs	Bacterial growth in 48Hrs	Gram Staining	Endospore Staining	Fungal growth	Changes in physical consistency
1	18 Fr	Silicon coated latex	0.2% PPA	-ve	-ve	-ve	-ve	Absent	No change
2	18 Fr	Silicon coated latex	0.2% PPA	-ve	+ve	+ve	+ve	Absent	No change
3	18 Fr	Silicon coated latex	0.2% PPA	-ve	-ve	-ve	-ve	Absent	No change

* Fr (French size)

Table 8. Microbiological attributes of 20 Fr (french size) Foley Catheters

S/N	Article	manf.material	Sterilization method	Bacterial growth in 24Hrs	Bacterial growth in 48Hrs	Gram Staining	Endospore Staining	Fungal growth	Changes in physical consistency
1	20 Fr	Silicon coated latex	0.2% PPA	-ve	-ve	-ve	-ve	Absent	No change
2	20 Fr	Silicon coated latex	0.2% PPA	-ve	+ve	+ve	+ve	Absent	Surface stiffness
3	20 Fr	Silicon coated latex	0.2% PPA	-ve	-ve	-ve	-ve	Absent	No change

* Fr (French size)

Table 9. Microbiological attributes of 22 Fr (french size) Foley Catheters

S/N	Article	manf.material	Sterilization method	Bacterial growth in 24Hrs	Bacterial growth in 48Hrs	Gram Staining	Endospore Staining	Fungal growth	Changes in physical consistency
1	22 Fr	Silicon coated latex	0.2% PPA	-ve	-ve	-ve	+ve	Absent	No change
2	22 Fr	Silicon coated latex	0.2% PPA	-ve	+ve	+ve	+ve	Absent	No change
3	22 Fr	Silicon coated latex	0.2% PPA	-ve	-ve	-ve	-ve	Absent	Surface stiffness

Fr (French size)

disposable articles, so the pharmaceutical manufacturers of such articles must comply to the SOPs and GMP guidelines more precisely; and before bidding for the bulk purchase of such articles in hospital setups and even community setups, the quality control testing of random samples must be carried out to ensure the sterilization of these disposable items, and so to prevent the chances of local and systemic infections. Similarly the hospital waste management should be make effective, so that the recollection and resterilization of such articles do not take place in practice, as the resterilization of these medical devices is not safe and effective, so their use can put patient for the risk of infection complications, and inturn can increase the economic burden on health departments.

REFERENCES

1. FDA; Disposable devices; available at www.fda.gov/medicaldevices; accessed Mar 14; 2014
2. CDC (2012); Sterilization or Disinfection of medical devices; available at http://www.cdc.gov/HAI/prevent/sd_medicalDevices.html; accessed Mar 07 2014
3. Daniel T. Grint; Catheters, types, applications &potential complications; Ist edition; *Nova Biomedicals;* 2012.
4. Association for the Advancement of Medical Instrumentation; Ethylene oxide sterilization in health care facilities: Safety and effectiveness. AAMI. Arlington, VA, 2014 Edtion; available at http://www.aami.org/, accessed May 08 2014
5. Hansen JM, Shaffer HL. Sterilization and preservation by radiation sterilization; In: Block SS, ed. Disinfection, sterilization, and preservation. Philadelphia: Lippincott Williams & Wilkins, 2001:729-46
6. Rahman, Baig *et al*; Study on Assessment of Sterility of Foley Catheters, Intravenous Cannulas and Intravenous Infusion Sets used in Peshawar, KPK; *Journal of Pure and Applied Microbiology* 2014; **8**(6), p. 4503-4508.
7. Battersby A, R Feilden *et al* (1999:77:10); Sterilizable Syringes: excessive risk or cost-effective option; Bulletin of the world health organization.
8. Naomi P. O'Grady *et al*; Guidelines for the prevention of intra vascular catheter related infections; CDC; Aug 9, 2002/ 51(RR10); 1-26
9. Walter E. Stamm; Infections related to medical devices; *Ann Intern Med;* 1978; **89** (5-part-2); 764-769
10. USP (2009); USP32-NF27; May 2009 Edition; USA; pp 80
11. FDA (2009); FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices - March 2009; available at http://www.fda.gov/medicaldevices/deviceregulationandguidance/reprocessingofsingle-usedevices/ucm133514.htm; accessed Oct 4, 2014
12. Harley and Prescott: Laboratory Exercises in Microbiology, 5th Edition; pp 53-65, McGraw Hill, 2002
13. Syed Abdul Mujeeb, Arshad Altaf , Yvan Hutin *et al* ; recycling of injection equipment in Pakistan; Infection Control and Hospital Epidemiology; 2003; **24**(2).
14. FDA (2014); Reusing Disposable Medical Devices; available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121465.htm; accessed Sep 23, 2014.
15. Canadian Healthcare Association. The Reuse of Single-Use Medical Devices: Guidelines for Healthcare Facilities. Ottawa: CHA Press; 1996.239
16. Health Canada. Therapeutic Products Directorate. Reprocessing of Reusable and Single-Use Medical Devices. Letter to hospital administrators, July 30, 2004; 2004. [cited June 29, 2009]; Available from: http://www.hcsc.gc.ca/dhpmps/mdim/activit/announceannonce/reprocess_retraitement_let-eng.php.
17. Canadian Standards Association. CAN/CSA Z314.8-08, Section 5.1.5. Decontamination of Reusable Medical Devices. Mississauga, Ont.: Canadian Standards Association; 2008
18. Alfa MJ, DeGagne P, Olson N, Puchalski T. Comparison of ion plasma, vaporized hydrogen peroxide and 100% ethylene oxide sterilizers to the 12/88 ethylene oxide gas sterilizer. *Infect. Control Hosp. Epidemiol.* 1996; **17**:92-100.
19. Alfa MJ, Olson N, Degagne P, Hizon R. New low temperature sterilization technologies: microbicidal activity and clinical efficacy. In: Rutala WA, ed. Disinfection, sterilization, and antisepsis in healthcare. Champlain, New York: Polyscience Publications, 1998: 67-78.
20. Holler C, Martiny H, Christiansen B, Ruden H, Gundermann KO. The efficacy of low temperature plasma (LTP) sterilization, a new sterilization technique. *Zentralbl. Hyg. Umweltmed.* 1993; **194**:380-91.
21. Vesley D, Langholz AC, Rohlfing SR, Foltz WE.

Fluorimetric detection of a Bacillus stearothermophilus spore-bound enzyme, ±-D-glucosidase, for rapid identification of flash sterilization failure. *Appl. Environ. Microbiol.* 1992; **58**:717-9.

22. CDC (2008); Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 ; available at http://www.cdc.gov/hicpac/Disinfection_Sterilization/table_1.html; accessed Aug 16 2014
23. Lowry PW, Jarvis WR, Oberle AD, *et al*. Mycobacterium chelonae causing otitis media in an ear-nose-and-throat practice. *N Engl J Med* 1988; **319**: 978-82.
24. McCarthy GM, Koval JJ, John MA, MacDonald JK Infection control practices across Canada: do dentists follow the recommendations? *J Can Dent Assoc,* 1999; **65**:506-11.
25. Spach DH, Silverstein FE, Stamm WE Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med* 1993; **118**:117-28.
26. Donlan RM. Biofilms: microbial life on surfaces. *Emerg Infect Dis* 2002; **8**: 881–90
27. Vickery K, Pajkos A, Cossart Y. Removal of biofilm from endoscopes: Evaluation of detergent efficiency. *Am. J. Infect. Control* 2004; **32**:170-6.
28. David Stickler, Robert Young *et al*; Why are Foley Catheters so Vulnerable to Encrustation and Blockage by Crystalline Bacterial Biofilms; *Urol Res* 2003; **31**:306-11
29. Hawser SP, Douglas LJ. Biofilm formation by Candida species on the surface of catheter materials in vitro. *Infect Immun* 1994; **62**: 915–21
30. Mehall JR, Saltzman DA, Jackson RJ, Smith SD. Fibrin sheath enhances central venous catheter infection. *Crit Care Med* 2002; **30**:908–12
31. Hawser SP, Douglas LJ. Biofilm formation by Candida species on the surface of catheter materials in vitro. *Infect Immun* 1994; **62**: 915–21
32. Roberts CG. Studies on the bioburden on medical devices and the importance of cleaning. In: Rutala WA, ed. Disinfection, sterilization and antisepsis: principles and practices in healthcare facilities. Washington, DC: Association for Professional in Infection Control and Epidemiology, 2001:63-9.