

Study on Sterility Assessment of Disposable Syringes used in Peshawar, KPK

Alija Baig*, Zia ur Rahman, Muhammad Khurram,
Farhat Ali Khan, Mujahid Sher and Imran Khan

Sarhad University of Science and Information Technology Peshawar, Pakistan.

(Received: 06 September 2014; accepted: 14 November 2014)

To evaluate the microbiological sterility of disposable syringes used in the Peshawar region of KPK, Pakistan. Our aim of study was to affirm that whether or not these Disposable syringes really meet the criteria of safety for which it is intended to be used. Random samples of disposable syringes were collected from local market and Government tertiary care hospitals in Peshawar, KPK. The sterility of these syringes was assessed using United States Pharmacopoeia's standards for the sterility tests. The tests for evaluation of sterility were carried out as per SOPs (standard operating procedures) applied for controlled environment and equipments in a microbiological lab. Microbial growth was observed both in ethylene oxide and radiation sterilized (manufacturer's claim) syringes. 1 ml Disposable syringes gamma radiated and ETO (ethylene oxide) treated showed microbial growth in 33% and 44% of selected samples respectively, similarly 53% and 51% of samples showed microbial contamination in 5ml Syringes of both local and Hospital collected items respectively. In case of 3ml and 10 ml syringes microbial growth was observed in 40% and 65% of samples respectively. It was interesting to find that microbial growth was observed in most vulnerable parts of syringes which are in direct contact with human body or medication like needle and plunger. Our study concluded that there are chances of microbial contamination in such disposable syringes and may have the deleterious effect on the health of the individuals so precautions must be observed to avert all those possibilities which may cause the contamination of these items.

Key words: item, Disposable syringes, Plunger, needle assembly, Ethylene Oxide, Sterilization.

Sterilization is a term referring to any process that eliminates or kills all forms of microbial life including transmissible agents. Sterilization can be achieved by applying Heat, chemicals, irradiation, high pressure, filtration or combinations of any one of them. Sterilization is necessary for the complete destruction or removal of all microorganisms (including spore-forming and non-spore-forming bacteria, viruses, fungi, and protozoa) that could contaminate pharmaceuticals or other materials and thereby constitute a health

hazard and if these products are used with these microbial contaminants they lead to serious blood born diseases and other infectious diseases to the users¹.

As per FDA (Food and Drug Administration) rules and regulation the SUD (single used device) should always be used for a single procedure for a single patient. Despite a lack of clear data that suggests that many injuries are occurring due to reprocessing practices," said David W. Feigal, M.D., director of FDA's Center for Devices and Radiological Health (CDRH), "FDA has concluded that the practice of reusing single-use devices needs additional attention and regulatory controls².

* To whom all correspondence should be addressed.
Tel.: +92-3469018911; +92- 3005869474
E-mail: alijabaig@yahoo.com

Though some of the hospitals disinfecting and sterilizing some of the Disposable or SUD (single used device) in order to save the money and reduce the hospital waste quantity, yet the FDA seriously have concern over this practice due to the fact that many of disposable items have complexity of the structure, may does not with stand to the autoclave temperature or these items may not be well sterilized by simple method as well as the simple disinfection methods does not effectively make them germs free as spore does survive by these methods. So the application of all these methods of disinfection and sterilization can leads to failure of either the process of sterilization or the item function failure by its structure deformation. The Classical example is D/Syringes which cannot with stand to the high temperature and undergoes structural deformation. Moreover this item by simple disinfection method cannot be made sterilized as it has the structural complexity and can be a source of spreading different serious infection.

As a matter of fact the disposable syringes are the most prime item which is used in case of any emergency situation both in inpatient and outpatient clinical settings for administering drugs and fluids, aspiration of the fluid from the body cavities, tissues, wounds or collection of blood samples for laboratory examination. So the credibility of the sterility of this item must be out of question to have an unambiguous lab results as well as to avoid the clinical complications associated with these D/ Syringes like myositis, phlebitis, bacterimia, blood born disease and Hospital acquired infections, as it can be a major contributing factor in the iatrogenesis³.

The disposable items reuse can be a source of spreading serious life threatening diseases like nosocomial infection or hospital acquired infection as In the United States, according to the Centers for Disease Control and Prevention roughly 1.7 million hospital acquired infections are reported, from all types of microorganisms, including bacteria, which is a contributing factor to 99,000 deaths each year⁴. While According to a European survey report in case of hospital admitted patient two third of the total deaths per year are due to hospital acquired infections. These hospital acquired complicated infections does include sever

pneumonia, UTI (Urinary tract infection), septicemia and may involve any other vital organs of the body⁴.

So having in mind such facts it's pertinent to mention that because of most frequent and common use of these Disposable syringes in the clinical practices, the safety of this item must be ascertained for good clinical outcomes.

Objective of the study

The objective of this study was to ensure that sterilized disposable syringes do meet the international criteria of sterilization, and they are safe when used in all clinical setups.

The focus of the study was different parts of D / syringes like Luer Lock, Needle Assembly and Rubber Plunger, which are more vulnerable to contamination.

Materials & Methodology

Sampling criteria

It is pertinent to mention here that there are dozens of sterilized disposable syringes of different local and foreign brands available in Peshawar, KPK Pakistan. The items which were sorted out between Dec 2013 to March 2014 are based on the facts that the selected Sizes, Shapes and brands are most commonly used in all clinical setups and they are easily available in Peshawar, KPK Pakistan; which carry tag of quality and cost effectiveness. During sorting Care was taken that collected items should have the variety in term of packing material as well as in different other physical parameters where as possible. During sorting the packing material physical condition was strictly examined and each item was observed with naked eye for any packaging perforation, dirt and all those things which could lead to the rejection of the collected item for the study, which is also true for the items collected from three different government tertiary care hospitals. From hospitals only one type/size of item was selected which is mostly used i.e. 5ml D/Syringes and these items are purchased in government tertiary care hospitals, by health department through MCC (medicine Coordinating Cell) bidding procedure, from the manufacturers which supply these items to the local market. The description of the selected items is tabulated below in table 1.

Media & other Chemical substances

The United States Pharmacopoeia (USP) Sterility tests methods are being selected for the

evaluation of pharmaceutical sterility of selected items as per USP 2009 guide lines⁵.

At the same time the aseptic procedures and the control environment was ensured for correct interpretation of the results. Two types of media had been selected for the sterility tests, i.e. Fluid Thioglycollate medium which support growth of anaerobic bacteria, and Soybean-Casein Digest Medium which support growth of both fungi and aerobic bacteria. The medium were sterilized (autoclaved) as per manufacturer guide lines, and sterility was confirmed by incubating the autoclaved medium for a specified period before processing. For the purpose of gram staining crystal violet, iodine, alcohol and safranin were used; whereas for endospore stain malachite green was used in the prescribed concentrations. Other chemicals included isopropyl alcohol, distilled water.

Samples were immersed adequately in respected medium using aseptic techniques and incubated at 37°C and observed for bacterial growth after 24 hours and 48 hours respectively. Similarly, samples were incubated at 25°C for 5 days to observe fungal growth. Positive and negative controls were applied for each test. All tests were performed in triplicate. Tests were repeated for the samples showing either bacterial or fungal growth, to confirm any chance of error in procedure or material.

Characterization of Microbial Growth

The samples which showed the presence of microbial growth by making test tube turbid, Gram staining and Endospore staining⁶ were performed for the characterization of the micro organisms. The microscopic examination was

performed for the identification of both bacteria and fungus in samples.

RESULTS

In Disposable syringes (both local and foreign brands) the microbial growth observed was of great importance in sense that the selected parts (samples) which showed growth are those having direct (needle assembly, Luer/ Lock) or indirect (rubber plunger) contact with the patient when get invested into body. The percent microbial growth observed in each type of item is tabulated below in **table 02**.

Each selected item (X) from each manufacturer (n) while the (n) in case of table 2(5) apply to number of hospitals, was divided in to 3 parts (Y) which served as samples, these three parts were Leuer Lock, Rubber Plunger and needle assembly, as they are the most vulnerable parts to contamination.

Microbial growth was observed both in ethylene oxide and radiation sterilized Disposable syringes. 1ml syringes (radiation sterilized) showed growth in 33% of samples and ETO sterilized syringes showed growth in 44% of selected samples, similarly 5ml disposable syringes of both local market and hospitals collected showed 53% and 51% of microbial growth in samples respectively. While In case of 3ml and 10 ml syringes microbial growth was observed in 40% and 65% of samples respectively.

To bore in mind the above mentioned findings of table 03, it is worth mentioning here that-microbial growth was detected in the selected parts (samples) of all items. Apart from bacterial

Table 1. Description of selected item for study

S. No	Item type	Packaging material	Number of manufacturers/ Hospitals	Claimed method of sterilization
1	1ml D/S	Plastic Bag	01	Gamma irradiated
2	1ml D/S	Blister pack	06	ETO
3	3ml D/S	Blister pack	06	ETO
4	5ml D/S	Blister pack	06	ETO
5	5ml D/S hospital items	Blister pack	03	ETO
6	10ml D/S	Blister pack	07	ETO

NA = Not applicable, * D/S (Disposable syringes), ETO (Ethylene oxide)

Table 2. Descriptions of samples developed percent microbiological growth after prescribed incubation period.

S No	Types of items	No of *Mfg / Hospital (n)	Packaging material	No of items(x) selected from each Mfg / Hospital	Each item parts(y) selected for test	Total number of each item parts served as samples = (nxy) incubated	No of +ive samples	%Microbial Growth of sample	Sterilization type
1	1ml D/S	01	Plastic poly Bag	03	03	09	03	33%	Gamma irradiated
2	1ml D/S	06	Blister Packed	03	03	54	24	44%	*ETO
3	3ml D/S	06	Blister Packed	03	03	54	22	40%	ETO
4	5ml D/S	06	Blister Packed	03	03	54	29	53%	ETO
5	5ml D/S *GHSI	03	Blister Packed	03	03	27	14	51%	ETO
6	10ml D/S	07	Blister Packed	03	03	63	41	65%	ETO

*GHSI (Govt .Hospitals selected items),*D/S (Disposable syringes), Mfg (manufacturers), ETO (ethylene oxide)

Table 3. Microbiological attributes of different D/ Syringes observed during study

S No.	Article	Manufactures L/F*	Bacterial growth in 24Hrs	Bacterial growth in 48Hrs	Samples (selected Part's) developed growth	Gram staining	Endospore Staining	Fungal growth
1	1ml D/S*	Foreign	Mild	Dense /Profuse	Rubber Plunger,needle assembly	+ive	-ive	Absent
2	1ml D/S	Local	Mild	Dense /Profuse	RubberPlunger,needle assembly	+ive	-ive	Absent
3	3ml D/S*	Local	Mild	Dense /Profuse	RubberPlunger,needle assembly, L/ lock*	+ive	-ive	Absent
4	3ml D/S	Foreign	Mild	Dense /Profuse	RubberPlunger,needle assembly,	+ive	-ive	Absent
5	5ml D/S*	Local	Mild	Dense /profuse	RubberPlunger ,needle assembly, L/ lock*	+ive	-ive	Present
6	5ml D/S	Foreign	Mild	Dense /profuse	RubberPlunger ,needle assembly	+ive	-ive	Absent
7	5ml D/S Hospital items	*N/A	Mild	Dense /profuse	RubberPlunger ,needle assembly	+ive	-ive	Present
8	10ml D/S*	Local	Mild	Dense /profuse	RubberPlunger, Needle assembly, L/ lock*	+ive	-ive	Present
9	10ml D/S	Foreign	Mild	Dense /profuse	RubberPlunger ,needle assembly	+ive	-ive	Absent

* D/S (Disposable syringe); N/A (Not Applicable); L/ Lock (Leur Lock)

growth (gram Positive) some of the samples of different items developed fungal growth as well and the part which developed fungal growth was the rubber plunger, which is amongst the most vulnerable part of the item and it was our area of more interest when the test was designed. Yet in all the above tabulated samples endospores were not found. It was interesting to find out that bacterial growth was observed both in samples of local and foreign manufacturers.

DISCUSSIONS

All clinical setup prefer to use disposable syringes because of the fact that these items are so easy, convenient and time saving specially in case of clinical emergencies, Yet these items does carry some risk factors both for health care providers as well as for the patient, if they are not properly manufactured, transported, stored, dispensed, used and discarded as per cGMP⁷, NICE Clinical Guidelines⁸ and FDA guidelines⁹. The disposable syringes discourages the conventional method of sterilization as the material of Disposable syringes which they are made up of, does not with stand to the high temperature of the sterilization and undergoes *Contortion*. In case of failure to follow above mentioned guide lines⁷⁻⁹ there will be an absolute chance of reusing these disposable syringes by just visible cleaning and disinfecting which could lead to serious blood borne diseases transmission. Unfortunately there are rackets in pharmaceutical market who are purchasing the used Disposable Syringes from clinical waste specifically in third world countries, reprocessing these items and make them available in the market and this is a irrefutable fact which cognizance is also taken by WHO¹⁰. In an interesting study which is done in Tanzania over the sterilized syringes and needles it is observed that 40% of the cultures obtained from these sterilized syringes and their needles yielded microbial growth¹¹. One can imagine now that how such items can be a source of transmitting blood borne deadly diseases, for example the transmission of hepatitis C and hepatitis B(transmitted by only 10 picolitres of blood) is strongly believed to be spread by use of poorly sterilized syringes and their needle assembly¹².

In a similar report it was revealed that one

of the East European country who supplied Disposable syringes to the international agency failed the sterility test¹³. It is worthy to mention here that the reports published in the news papers of Pakistan affirmatively highlighted the practices of reprocessing the disposable syringes and their availability in pharmaceutical bulk purchasing markets of Pakistan, china, South Africa and Philippines¹³.

One of the report, which is really an eye opener in this regard, which states that in Pakistan from hospital wards and Outpatient departments the clinical waste is routinely collected for the recollection of the disposable syringes with intend to sold it back to the middle man or directly to the manufacturer where these articles are reprocessed, packed and distributed in the pharmaceutical markets for selling to the consumers¹³. In like manner cases reported in a highly reputed government tertiary care hospital of Pakistan KPK province that on several occasions Disposable syringes when opened by the nursing staff, they found these items with plastic body and needle assembly in deformed shape; having packing without needle assembly; needles with blood stains and the most pinching point is that all these Disposable Syringes were brought by the patient attendants to the clinical setup from the pharmacies in the vicinity of the hospitals¹⁴. Although the man in the street has the strong perception that disposable syringes in its packing is safe and effective for use and its sterility is out of question yet the reality is other way round.

Ironically the samples of disposable syringes that developed growth in our study were claimed by the manufacturer to be sterilized, yet the Sterilization is a highly sensitive procedure and its practices can be improved with adequate training and using state of the art equipments. A study in the united republic of Tanzania showed that 50% reduction in the contamination rate of sterilized syringes taken place after strictly following the development and introduction of a program of sterilization training and procedure¹³.

As process of sterilization such as by ETO is greatly affected by the factors such as gas concentration, temperature, relative humidity and time of exposure to gas¹⁵, therefore require astringent in processes control and skilled personnel during manufacturing because failure

in this regard may compromise the quality of the product.

The issue of the disposable items used in the world is of serious concern that a letter in this regard was written by FDA director of office of compliance center for devices and radiological health for intimation to all the health care executives through president of American college of health care executives. The letter was aimed to bring in the notice of these higher ups about the reprocessing of the SUDs (single used disposable devices) by some of the manufacturers and the supply of these items to the health care centers. It was emphasized through the letter that all those health care facilities using reprocessed items should follow the FDA policies in this regard¹⁶. These lines may also strengthen our argument that there is reprocessing of the disposable items in different parts of the world.

The importance of this study in the light of economy of under developed countries of the world can be easily realized that many under developed countries having insignificant budget allocation for health sector to even meet the basic health needs of the general public.

According to a survey report of the transparency international, in Pakistan there is no national health insurance policy and 78% of the general public paying their health care expenses by themselves and sometime these expenses goes out of the reach of the individual¹⁷.

For example the health budget of Pakistan allocated for the financial year 2013- 2014 was 25 billion¹⁸. Similarly Bangladesh allocated health budget for the fiscal year 2013-2014 was Tk (Takka) 94.95b which is around 4.7% of the total budget¹⁹. This fact is admitted by the Bangladesh health minister himself that government for several years allocated much less amount for the health sector which led to the deprivation of the general public to get benefitted from the government hospitals regarding their basic health issues. Situation is not so different if we just take the example of the second most progressive economy of the south Asia that is India where INR (Indian rupee) 337 billion allocated to health sector for fiscal year 2014 – 2015 which is ironically 9.7% less than the health budget allocated in financial year 2013- 2014 which was INR 373 billion²⁰. These health budgets reveals that it is just a peanut keeping in view such densely

populated and poor countries of the world and its serious health issues such as AIDS, polio, hepatitis C, T.B and Dengue fever, These are some of the diseases striking the Pakistani population very hardly every day and need a lot of budgeting to control over these monsters which are shattering the financial status of the poorest of the poor of Pakistani population. Moreover in Pakistan diseases like Cancer, Diabetes, Heart diseases have largely replaced communicable diseases in last twenty years but there is a decrease in spending over the health sector from 1.5% of GDP to less than 1% which is reportedly less than 4% of the government total budget¹⁷.

So from these above mentioned bitter facts, it is obvious that even in coming times we cannot expect too much from the governments in this very important area and the suffering of the general community is going to be more serious due to their day by day growing health issues.

So in such case if there are mal practices in health care setting, like use of sub standard disposable syringes as evaluated by our study, will be a source of dissemination for the blood borne diseases leading to sickness of population by leaps and bounds which will further shrink the health resources of such countries having already a financial crunch and scarcity of the health facilities.

Limitation and Biases of study

The constraints of this study include very limited work that had been conducted in this regard and no extensive comparison was made with such other studies although a research was conducted on these items according to which the Disposable syringes developed microbial contamination with *Bacillus Subtilis* spores at the most inaccessible site, between plunger and barrel, processed under controlled conditions²¹.

In this regard the FDA regulations is of great interest according to which some of the SUDs (single use devices) like surgical drills, biopsy forceps, electrophysiology catheters, and Laparoscopy scissors may be reprocessed if the process is so effective that the reprocessed articles at the end have the efficacy and sterility as good as when they were made by the original manufacturer²². A similar report issued by the U.S Congress General Accounting Office (GAO) which also states that some of the SUDs can be reprocess

if the process is followed as per manufacturing standards in its full letter and spirit. Yet the report does agree that some of the reprocessed SUDs definitely carry the risk of spreading diseases and pose health hazards to the general community. So for all these reasons the FDA is enhancing its surveillance over the reprocessing of SUDs to have effective control over this menace²² and this statement does signify our study.

Hence in light of the above mentioned facts additional research is needed for the evaluation of pharmaceutical sterility of such disposable medical devices which have been claimed sterilized, because the non-sterility of such items can lead to Hazardous blood borne communicable infections in clinical practices.

CONCLUSIONS

It has been concluded that there are chances of microbiological contamination in disposable syringes available in local market as well as in hospital pharmacies. So the pharmaceutical manufacturers of such items must follow the SOPs and cGMP guidelines more precisely using state of the art machines for manufacturing and packaging of these items as well as use of skilled workers.

Besides that before bidding for the bulk purchase of such items in clinical setups and even in community pharmacy setups, the quality control parameters from manufacturing, to safe storage and transportation should be strictly followed by all concerned quarters to ensure the safety of these most abundantly used items in clinical practices so that patients are get benefited and clinician achieve better out come by averting the chances of iatrogenic effects and Nosocomial infections.

Moreover all the relevant quarters should make assure that these Disposable Syringes are properly discarded by adopting and strictly following international methods of disposal and destruction systems, in order to avert any chance of reuse of these disposable syringes by simply washing, disinfecting and repacking because disinfection does not have sporocidal effects and for these Disposable syringes effective recycling process such as autoclave cannot be used as these items cannot with stand to high temperature of the autoclave.

It is also a logical conclusion that if countries frame their laws and regulations in the light of FDA recommendations there can be an effective control over the manufacturing, use and safe disposal of SUD (Single used devices) like Disposable syringes and so all the mess due to its reuse can be eradicated if the law takes its course. By taking all these steps a reasonable fraction of the health allocated budget can be secure from wastage which may have a greater impact over the health reforms in poor countries facing scarcity of the resources.

REFERENCES

1. Center for Disease Control(CDC)., Sterilization or Disinfection of medical devices; available at http://www.cdc.gov/HAI/prevent/sd_medicalDevices.html; accessed Dec 24 2013.
2. Food and Drug Administration 2009 (FDA); Sterilization or Disinfection of medical devices; available at www.fda.gov/medicaldevices; accessed August 04 2014.
3. Starfield B; "Is US health really the best in the world?" JAMA 2000; **284**(4): 483–5
4. Pollack, Andrew; "Rising Threat of Infections Unfazed by Antibiotics"; New York Times, 2010.
5. United States Pharmacopoeia; USP32-NF27; May 2009 Edition; USA; pp 80.
6. Harley and Prescott: Laboratory Exercises in Microbiology; 5th Edition; pp 53-65, McGraw Hill, 2002.
7. MHRA (Medicine and Healthcare Products Regulatory Agency) 2014; Rules and Guidance for Pharmaceutical Manufacturers and Distributors; Pharmaceutical Press; 8th Edition.
8. NICE 1998; Waste management guidelines for health care facilities; available at; www.nice.org.uk/; accessed August 16 2014.
9. Food and Drug administration (FDA) 2014; Device regulation and guidance/post market requirements/quality systems regulations; available at; www.fda.gov/MedicalDevices; accessed August 04 2014
10. World Health Organization (WHO) 2014; Safe injection vital to health; available at; <http://www.who.int/gpv-cold-chain/safe/problem.htm>; accessed July 7 2013.
11. Gumodoka B et al; Injection practices in Mwanza Region, Tanzania: prescriptions, patient demand and sterility; *Tropical medicine and international health*; 1996; **1**: 874-880.

12. Singh J et al. Outbreak of viral hepatitis B in a rural community in India linked to inadequately sterilized needles and syringes; *Bulletin of the World Health Organization*; 1998; **76**: 93-98.
13. A.Battersby, R.Feilden et al; sterilizable syringes excessive risk or cost effective option; bulletin of the WHO; 1999; **77**: 812- 819.
14. Frontier Post; Sub-standard surgical items; North West Frontier Province, Pakistan; 1998.
15. AAMI. Arlington, VA 2014; Association for the Advancement of Medical Instrumentation; Ethylene oxide sterilization in health care facilities: Safety and effectiveness; available at; <http://www.aami.org/>; accessed May 23 2014
16. Food and Drug Administration (FDA); Department of Health & Human Services; available at; <http://www.fda.gov/medicaldevices/device/regulationandguidance/documents/ucm106350.htm>; accessed July 20, 2014.
17. IRIN Asia 17 May 2013; Challenges to improving health care in Pakistan LAHORE/DUBAI; available at; <http://www.irinnews.org/printreport.aspx?reportid=98055>; accessed march 13 2014.
18. The news tribe; Pakistan budget 2013-14 at a glance for a common person; available at; <http://www.thenewstribes.com>; accessed September 28 2104.
19. Dhaka tribune, Bangladesh health budget plummets; available at <http://www.dhakatribune.com>; accessed September 30 2104
20. Integrated Health Services (ihs); new govt & healthcare trends India; available at <http://www.ihs.com/products/global-insight/industry-economic-report.aspx?id=1065985237>; accessed September 30 2104
21. Rubbo S. D and Gardner J. F; Sterilization of Syringes by Ethylene Oxide. *Journal of Applied Bacteriology*; 1968; 31: 164–169.
22. Food and Drug Administration; Reusing Disposable Medical Device; available at; <http://www.fda.gov/medicaldevices/device/regulationandguidance/reprocessingofsingle-usedevices/ucm121465.htm>; accessed July 10 2014.