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The Sterility Evaluation of New and Lab Reprocessed Pharmaceutical Disposable Syringes in Peshawar, KPK

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

Sarhad University of Science & Information Technology Peshawar, Pakistan.

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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. Whilst the study also included the determination of the microbial status of the used disposable syringes collected from the Hospital waste and the sterile status of the Lab re processed Disposable syringes. 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. More over for the Lab reprocessing the SOP was developed under the light of the standard guide lines. Microbial growth was observed both in ethylene oxide and radiation sterilized (manufacturer's claim) syringes. 1ml 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 where as the lab reprocessed Disposable syringes also showed comprehensive growth of both bacterial and fungal growth. 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. The point worthy to mention over here is that the Disposable syringes which were lab reprocessed also shown considerable growth of the microbial organisms which strengthen the fact that SUDs should not be reprocessed as these items cannot with stands to the high temperature of Auto clave and because of the complex structure and narrow lumen the chemical sterilization cannot guarantee these items safety for the reuse.

Key words: 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 users[1].

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

* To whom all correspondence should be addressed.
E-mail: alijabaig@yahoo.com

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 controls[2].

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 auto clave 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 iatrogenisis[3].

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 year[4]. 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 body[4].

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. Moreover it was also determined that whether or not the re-cycling of these items are safe enough to reuse them.

MATERIALS AND 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 01**.

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 lines[5].

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 staining [6] 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

Table 1. Description of newly packed selected item for study

S.N	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/N	Types of items	No of *Mfg / Hospital (n)	Packaging material each Mfg / Hospital	No of items(x) selectedfrom for test	Each item parts(y) selected	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. Bird eye View of Microbiological attributes of different new D/ Syringes observed during study.

S/N	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	1mlD/S*	Foreign	Mild	Dense /Profuse	Rubber Plunger,needle assembly	+ive	-ive	Absent
2	1mlD/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/SHospital 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	10mlD/S	Foreign	Mild	Dense /profuse	RubberPlunger ,needle assembly	+ive	-ive	Absent

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

Table 4. Microbiological attributes of 1ml and 3ml used Disposable syringes

S/N	Article	mfg Name	Physical status of collected articles	Bacterial growth in 24Hrs	Bacterial growth in 48Hrs	Gram Staining	Endospore Staining	Fungal growth	Parts involved
1	1ml D/S*	N/A	Intact parts, no wearing and Tearing	Mild	Dense /Profuse	+ive	+ive	absent	Rubber Piston, Needle, Luer Lock
2	1ml D/S	N/A*	Intact parts, no wearing and Tearing	Mild	Dense /Profuse	+ive	+ive	present	Rubber Piston, Needle, Luer Lock
3	1ml D/S	N/A	Intact parts, no wearing and Tearing	Moderate	Dense/Profuse	+ive	-ive	present	Rubber piston , Needle, Luer Lock
4	3ml D/ S*	*N/A	Intact parts, no wearing and Tearing	Mild	Dense /Profuse	+ive	+ive	Present	Rubber Piston, Needle, Luer Lock
5	3ml D/ S	N/A	Intact parts, no wearing and Tearing	Moderate	Dense /Profuse	+ive	-ive	Absent	Rubber Piston, Needle, Luer Lock
6	3ml D/ S	N/A	Intact parts, no wearing and Tearing	Moderate	Dense/Profuse	+ive	+ive	Absent	Rubber piston , Needle, Luer Lock

* D/ S (Disposable syringes), N/A (Not Applicable)

Table 5. Microbiological attributes of 5ml and 10 ml used disposable syringes

S/N	Article	Mfg . material	Physical status of collected articles	Bacterial growth in 24Hrs	Bacterial growth in 48Hrs	Gram staining	Endospore Staining	Fungal growth	Parts used as a sample
1	5ml D/S*	*N/A	Intact parts, no wearing and Tearing	Moderate	Dense /Profuse	+ive	-ive	present	Rubber Piston, Needle, Luer Lock
2	5ml D/S	N/A	Intact parts, no wearing and Tearing	Moderate	Dense /Profuse	+ive	-ive	Absent	Rubber Piston, Needle, Luer Lock
3	5ml D/S	N/A	Intact parts, no wearing and Tearing	Mild	Dense/Profuse	+ive	+ive	Present	Rubber Piston, Needle, Luer Lock
4	10ml D/S*	*N/A	Intact parts, no wearing and Tearing	Moderate	Dense /Profuse	+ive	-ive	present	Rubber Piston, Needle, Luer Lock
5	10ml D/S	N/A	Intact parts, no wearing and Tearing	Moderate	Dense /Profuse	+ive	-ive	Absent	Rubber Piston, Needle, Luer Lock
6	10ml D/S	N/A	Intact parts, no wearing and Tearing	Mild	Dense/Profuse	+ive	+ive	Absent	Rubber Piston, Needle, Luer Lock

* D/ S (disposable Syringes), *N/A (Not Applicable)

Table 6. Microbiological attributes of 1ml and 3ml Lab reprocessed Disposable syringes.

S/N	Article	mfg Name	Physical status of collected articles	Bacterial growth in 24Hrs	Bacterial growth in 48Hrs	Gram Staining	Endospore Staining	Fungal growth	Parts involved	Method of Disinfection	Changes in physical Parameter after Lab reprocessing
1	1ml D/S*	N/A	Intact parts, no wearing and Tearing	Absent	Dense /Profuse	+ive	+ive	absent	Needle,Luer Lock	0.2% *PAA	NO
2	1ml D/S	N/A*	Intact parts, no wearing and Tearing	Mild	Dense /Profuse	+ive	-ive	present	Rubber Piston	0.2% PAA	NO
3	1ml D/S	N/A	Intact parts, no wearing and Tearing	Mild	Dense/Profuse	+ive	+ive	Absent	Rubber piston	0.2% PAA	NO
	3ml D/S *	N/A	Intact parts, no wearing and Tearing	Mild	Dense /Profuse	+ive	-ive	absent	Needle rubber piston	0.2% *PAA	NO
	3ml D/S	N/A*	Intact parts, no wearing and Tearing	absent	Dense /Profuse	+ive	+ive	present	Rubber piston , Needle	0.2% PAA	NO
	3ml D/S	N/A	Intact parts, no wearing and Tearing	absent	absent	-ive	-ive	absent	———-	0.2% PAA	NO

* D/ S (Disposable syringes), N/A (Not Applicable), PAA (Per Acetic Acid)

Table 7. Microbiological attributes of 5ml and 10ml Lab reprocessed Disposable syringes.

S/N	Article	mfg Name	Physical status of collected articles	Bacterial growth in	Bacterial growth in	Gram Staining	Endospore Staining 24Hrs	Fungal growth 48Hrs	Parts involved	Method of Disinfection	Changes in physical Parameter after Lab reprocessing
1	5ml D/S *	N/A	Intact parts, no wearing and Tearing	Mild	Dense /Profuse	+ive	-ive	Present	Needle, Luer Lock	0.2% *PAA	NO
2	5ml D/S	N/A*	Intact parts, no wearing and Tearing	Absent	Absent	-ive	-ive	Absent	———	0.2% PAA	NO
3	5ml D/S	N/A	Intact parts, no wearing and Tearing	Moderate	Dense/Profuse	+ive	+ive	Absent	Rubber piston	0.2% PAA	NO
4	10ml D/S *	N/A	Intact parts, no wearing and Tearing	Mild	Dense /Profuse	+ive	+ive	absent	Needle	0.2% *PAA	NO
5	10ml D/S	N/A*	Intact parts, no wearing and Tearing	moderate	Dense /Profuse	+ive	-ive	Absent	Rubber ,needle	0.2% PAA	NO
6	10ml D/S	N/A	Intact parts, no wearing and Tearing	Absent	absent	-ive	-ive	present	Luer Lock, Rubber Piston	0.2% PAA	NO

* D/ S (Disposable syringes), N/A (Not Applicable) PAA (Per Acetic Acid)

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 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.

Used Disposable Syringes

Used Disposable syringes of different sizes were collected from waste disposal of different tertiary care hospitals situated in Peshawar; and were evaluated for microbial growth when tested in triplicate as per USP guideline; results are tabulated as given below.

Results of Used Disposable items

Table 04 shows that bacterial growth was observed in all 1ml used Disposable syringes collected from the hospital while endospores were found in two out of three items; similarly fungal growth was observed in two Out of three Items tested. While this table shows that bacterial growth was observed in all samples of 3ml D/S, while endospores were found in two item samples and fungal growth was present in one item sample.

Table 05 shows that bacterial growth was observed in all samples of 5ml used disposable syringes, while endospores were found in one item sample and fungal growth was present in two items tested whereas the table 05 shows that bacterial growth was observed in all samples of 10ml used disposable syringes, while endospores and fungal growth were found in one item each.

Note: it is pertinent to mention here that the used disposable syringes showed bacterial growth in form of mix culture comprised of cocci, and rode shape and curved shaped bacilli.

Disinfection Technique for Lab Re-processed Disposable syringes

For used devices collected from hospital disposal waste, to be lab re-processed for the purpose of post reprocessing microbial evaluation, HLD (High Level of Disinfection) was selected as process, because sterilization process cannot be adopted for reprocessing as the disposable syringes does not with stand to the high temperatures and get a distorted shape. The HLD technique is adopted as an internal protocol of reprocessing for the used items (Disposable syringes) in the light of international PIDAC guide lines [7].

Lab Re-processed items

After the evaluation of microbial growth in used disposable syringes, collected from disposable waste of a tertiary care hospital, were cleaned and re-processed in lab using 0.2% PAA(Per Acetic Acid) as a HLD (High Level Disinfectant) [7] and revaluated for microbial growth. Results are tabulated below.

Results of Lab Re-processed items

Table 06 data shows that after HLD (High Level Disinfection) with 0.2% PAA that one item sample showed bacterial growth, endospore presence in needle and luer lock parts while the fungus growth was absent while in another sample(Rubber Piston) bacterial growth and fungus was present but no endospore were found during studies. Similarly in triplicate samples one of the item sample showed bacterial growth with endospore presence yet the fungus growth was absent. Yet the table 06 data shows that after HLD (High Level Disinfection) with 0.2% PAA that one item samples (Needle, Rubber Piston) showed bacterial growth while endospore and fungal growth were absent. In another item samples (Rubber Piston, Needle) bacterial growth , fungal growth and endospore were present ,like wise in triplicate one item samples (Needle, Luer Lock ,Piston) were found free of any microbial presence.

Table 07 data shows that after HLD (High Level Disinfection) with 0.2% PAA that one item samples (Needle, Luer Lock) showed bacterial growth and fungal growth while endospores were absent. In another item samples (Rubber Piston, Needle, Luer Lock) bacterial growth, fungal growth and endospore were absent, like wise in triplicate one item sample (Rubber Piston) were found positive with bacterial growth and endospores yet the Bacterial growth was absent. Whereas table 07 data shows that after HLD (High Level Disinfection) with 0.2% PAA that one item sample (Needle) showed bacterial growth and endospores while

fungal growth was absent. In another item samples (Rubber Piston, Needle) bacterial growth was present yet the fungal growth and endospores were absent, like wise in triplicate one item samples (Rubber Piston , Luer Lock) were found free of bacterial growth and endospores yet the Fungal growth was present.

NOTE: Above tabulated data shows that after HLD (High Level Disinfection) with 0.2% PAA some of the samples (Parts of the syringes) showed microbial growth while some of the samples after reprocessing showed no growth. The most important point is that those parts which are exclusively vulnerable to the growth of the Biofilm and having direct contact NLN (Narrow Lumen Needle) or indirect contact (Rubber Piston , Luer Lock) with patient blood, showed microbial growth even when reprocessed.

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 cGMP[8],NICE Clinical Guideline[9] and FDA guidelines[10]. 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 lines (7, 8, and 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 WHO[11]. 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 growth[12].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 assembly[13].

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 test[14]. 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 Philippines[14].

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 consumers[14].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 hospitals[15]. 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 procedure[14] 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 gas[16], 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 regard[17]. These lines may also strengthen our argument that there is reprocessing of the disposable items in different parts of the world.

Satirically Pakistan despite of having a status of developing country entered in the 21st century have shown no improvement in the field of health for giving better quality health facilities to the general public and the earnestness of the matter can be gauge from the recently published in the leading newspaper of the KPK (Khyber Pukhtoonkhwa)province the Daily "AAJ " according to which the Leady Reading Hospital Peshawar (the leading tertiary Care Hospital) is producing approximately 100,000 disposable syringes per day as solid medical waste yet the safe disposal of such high quantity flagrant waste is carrying a big question mark and posing a great threat to the health of the general population if they are dealt by the black market runners[18]. This article unearthed that the disposal items used by the patients are reportedly reused after reprocessing. The article highlighted that there are illegal private medical practices and Health care centers in the local community without having NOC from the municipal corporation and relevant health departments so the clinical waste which they are producing are not properly discarded as per laws and regulations. The article imparts that the poor hospital clinical waste management is not restricted to the Peshawar only because in all densely populated cities of the KPK including Kohat, Noshera, and Mardan the same hazard is prevailing[18]. The question which raise here is that whether in Pakistan we have any law which ensure the safe and proper disposal of the Hospital waste in the country or not, the answer is yes. The Pakistan has the Environmental Protection Act 1997 which bound every health care center that the hazardous waste produced in 24 hours should be immediately ashed as per international guidelines, this law also emphasizes that a committee should be constituted under the supervision of the Health secretary who periodically review and amend the rules and regulations regarding the safe disposal of the precarious hospital waste in light of the international guidelines. Moreover another law in this regard which is framed in Pakistan is Hazardous Substance Rule 2000, according to which every health care setting whether provincially or Federally governed, is legally bound to make arrangements in their facilities for the safe disposal of the hospital waste in such a way that the surrounding environment and the general public health should not be compromised at all[18]. Because it is obvious that simple burning of the clinical waste does not fulfill the requirement of the safe disposal because this produce the fume and smoke which equally noxious and a serious health hazard for the green belt and general public of the vicinity as well as for the Health care team working in the facility and these vulnerable may suffer from these smokes complicated lungs, skin and gastro intestinal disorders. It is worth mentioning here that in all three Teaching Hospitals of the Peshawar (Khyber Teaching Hospital, Hayatabad Medical Complex, and Leady Reading Hospital) solid waste disposal equipment is recently installed by spending a huge amount of 3.2 million rupees, Yet it is heart pinching that no proper arrangements are done to deal with the smoke, produced due to the disposal of the clinical waste through these inestimable installations and seems to be just an eye wash, which is really health hampering because this smoke consist of dangerous gases like sulphur dioxide , furans and Nitrogen dioxide[18].One of the astonishing fact which came out of this article is that an official of the Ministry Of Health KPK on

the condition of anonymity reveled that Leady Reading Hospital (2000 Bed Facility) average 1200Kg , Khyber Teaching Hospital(1500 Bed Facility) 500kg , Hayatabad Medical complex (700 Bed Facility)300kg and City Hospital Peshawar (250 Bed Facility) bringing forth 150kg of the solid waste (including clinical waste) per day, as per finding of the survey done in the year 2007.According to an independent survey report in Peshawar 2000 kg of highly noxious hospital waste is generated per day which is not discarded as per international guide lines and the reason for this is not the financial constrain but it is due to the lack of the cognizance in the relevant departments giving an deaf ear and turning a blind eye to this serious health issue[18]. According to an American published research report Hospitals are not meant to only provide the health care to the ailing fragments of the society yet they are suppose to make astringent arrangements to ensure that hospital environment should not be the source of spreading diseases to the ambulatory, admitted patients as well as to the healthier individuals who come to the hospital to visit their loved ones [18].

The issue of the hospital waste /clinical waste is of so great concern that Peshawar High Court in this regard issued an order through which the environmental ministry KPK was directed to make sure that all the Government and private Health care settings of the province are safely managing their solid waste /clinical waste and the required waste disposal equipments are well connected in these facilities and incase of non compliance the law shall take its course in full letter and spirit. Although after such orders by the honorable court some quarters specifically government sector did show some improvement, yet a huge chunk of private health care settings are still on the way of non compliance and have unsatisfactory means of their waste disposal. This article also bring out in to open that these non compliant setups having close ties to the black market contractors (dealing in hospital solid/ clinical waste Purchase) who are loading and dumping this waste from these clinical setups and from where it is sold to those who are illegally reprocessing and remarketing these clinical items which are intended by law to be SUDs (Single Use Devices)[18].

Studies in Pakistan show that large hospitals generate about 2.0 kg of waste per bed per day. Out Of which 0.5 kg can be categorized as biomedical risk waste. There are many small hospitals and clinics which also produce risky surgical and pharmaceutical waste in huge quantities so in Pakistan daily Medical Waste Production (MWP) from both public & private sector hospitals is estimated as 0.8 million tons[19]. Un ethical disposal practices results in illegal reuse of discarded syringes, IV tubes, blood bags and other equipment through Black markets(As discussed above that Black Market are active in Pakistan and busy in illegal sale of reprocessed Disposable Syringes), which are not intended for either sterilization or reuse .In Pakistan there are about 92,000 beds in public sector hospitals, while its Population 160 million will rise to 250million by year 2025[19].Taking into account these facts If no well established segregation system, dumping of hospital waste with municipal waste, Maintenance and monitoring issues of incinerator technology, Lapses in Landfill designs, and Issues related to behaviors change are not properly addressed the amount of Hospital Waste generated will increase to alarming level due to day by day increase in population and healthcare facilities that's why it was emphasized that Implementation of HWM (Hospital Waste Management) Rules framed in 2005 Ministry of Health Pakistan, must be implemented at all District levels in order to enforce the law in all hospitals for effective pathological, infectious, and pharmaceutical waste disposal so that to reduce the burden of diseases and to prevent reuse of these items, yet the situation is otherwise round[19].

The role efficacy and the input of PIDAC-IPC (Provincial Infectious Diseases Advisory Committee on Infection Prevention and Control, which is a multidisciplinary committee of health care professionals with expertise and experience in Infection Prevention and Control) is very substantial and remarkable. The committee trim advises to Public Health Ontario on the prevention and control of health related issues ensuring the entire health care system for safety of both clients/ patients/residents and health care teams. So this body developed an important document regarding Single used devices safe application and covered multiple aspects to prevent the spread of infectious Blood borne diseases[20]. According to those guide

line provided by the body Health care settings must not endogenously reprocess single use medical devices. Critical devices (items invested in sterile tissues) and semi critical devices (Equipment/device that comes in contact with non-intact skin or mucous membranes but does not penetrate them) labeled as single use must not be reprocessed and re-used unless otherwise done by a licensed reprocessor. Pont of interest is that Currently there are no licensed reprocessors in Canada except there are reprocessors in the USA licensed by the United States Food and Drug Administration (USFDA) [20]. According to law Health care settings that wish to have their single-use medical equipment/devices reprocessed by a licensed reprocessor should ensure that the reprocessors facilities and procedures are certified by a regulatory authority to ensure the cleanliness, sterility, safety and functionality of the reprocessed equipment/devices as per international guidelines to assure reprocessed items functionality and integrity[20] as proven by our studies that SUDs such as disposable syringes cannot be reprocessed by using conventional methods.

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 budg*et al*location 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 individual[21].

For example the health budget of Pakistan allocated for the financial year 2013- 2014 was 25 billion[22]. Similarly Bangladesh allocated health budget for the fiscal year 2013-2014 was Tk (Takka) 94.95b which is around 4.7% of the total budget[23].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)337billion allocated to health sector for fiscal year 2014 – 2015 which is ironically 9.7% less than the health budg*et al*located in financial year 2013-2014 which was INR 373billion[24]. 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 budget[21].

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 constrains 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 conditions[25].

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 manufacturer[26]. 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 menace[26] 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.

CONCLUSION

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 highly trained and 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 and protocols of Hospital waste disposal and destruction, 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, as shown by our studies that even the High Level Disinfection did not sufficiently made these items free from germs and spores and by taking such measures the black markets and the rackets dealing with the used syringes collection, reprocessing and remarketing would be greatly discouraged.

It would be of worth that all health care providers are imparted with the proper training to make them well aware of the safe use and disposal of the critical disposal items like disposable syringes. So much so in under developing and developing countries astringent Health regulatory authority should be put in place so that no space what so ever should be granted to the quackery which is a source of spreading blood born diseases by following un ethical Health practices.

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.

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