

Summer Training at



**Fortis Hospital, Mohali
(March 19- May 31, 2014)**

Reuse of Single Use Devices in Cath-Lab at Fortis Hospital Mohali

**By
Harshana Bist**

**Under the guidance of
Dr. Alok Kumar Mathur**

**MBA- Hospital & Health Management (MBA-HM)
2013-2015**



**The IIHMR University, Jaipur
2014**

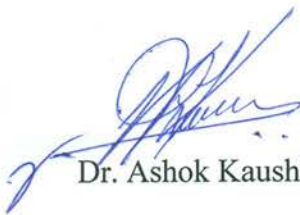
**INSTITUTE OF HEALTH
MANAGEMENT RESEARCH**
1, Prabhu Dayal Marg
Sanganer Airport, JAIPUR - 302 029, INDIA
Tel. : 3924700, 2791431-32
Fax : 91-141-3924738
E-mail : iihmr@iihmr.org
URL : <http://www.iihmr.org>
Gram : HEALTHINST

CERTIFICATE

This is to certify that Ms. Harshana Bist has completed her summer training at Fortis Hospital – Mohali, from 18th April to 31st May, 2014 and has successfully completed her project on “*Reprocessing of Single use devices (S.U.D's) for Reuse in Cath Lab.*” under my guidance and supervision.

All the data relating to the study was collected by herself and her approach to the study has been sincere and scientific and analytical. This work is partial fulfillment to the course requirements for the Post Graduate diploma in Health and Hospital Management with specialization in Hospital Management.

I wish her all the best for her future endeavors.



Dr. Ashok Kaushik

Dean(Academic & Student Affairs)

IIHMR Jaipur



Mr. Alok Mathur

Associate Professor

IIHMR Jaipur

CERTIFICATE

This is to certify that Dr. Harshana Bist, a student of IHMR-Jaipur PGDHM-18 has carried out a project on *"REUSE OF SINGLE USE DEVICES IN CATH. LAB AT FORTIS HOSPITAL MOHALI"*

This project work has been prepared by the student herself with utmost sincerity and this work has not been presented earlier for any academic activity.

I wish her all the very best & success in her further future endeavours.



Dr. Rishi. Mangat

Medical Co-ordinator

Cath-Lab



Mrs. Kanwal Inder Kaur Sandhu

Manager (Trainings)

Human Resource

ACKNOWLEDGEMENT

I take this opportunity to express my profound sense of gratitude and indebtedness to all those who helped me throughout the duration of the project.

I would like to acknowledge, First and foremost Dr. Rishi. Mangat (Medical co-ordinator, Cath Lab) for showing confidence in me and giving me such a wonderful topic to do my project in the last 10 days of my internship, without her support and guidance it would not have been possible. Then I would like to thank my mentor at Fortis Mohali, *Mrs. Kanwal Inder Sandhu* Training Manager H.R department for her consistent support, motivation and encouragement throughout the internship duration. She has been a Great source knowledge, information and inspiration to do work with utmost diligence and sincerity.

I would also like to thank Ms. Shivani. Garg (Zonal Head-H.R –North Zone) without whose permission I would not get this golden opportunity to do my internship in this esteemed hospital.

I would also like to thank my faculty at IIHMR-Jaipur and specially my Mentor- *Mr. A.K. Mathur* and also feel privileged to acknowledge *Mrs. Tanjul Saxena* (H.R- Lecturer) who although was not my official mentor continuously guided me all through the internship.

I would also wholeheartedly thank the entire staff at Fortis Mohali for being so supportive and helpful and removing time from their hectic schedules and giving all the required information, especially Cath Lab incharge Abhilekh sir, Nurses and technicians and CSSD staff .

At the end, I am thankful to God and my heartfelt gratitude to my parents and friends who supported me throughout the course.

THANK YOU ALL

Table of Contents :

SR.NO	TOPIC
1.	Section 1 : Observational Learning -Brief History of the Hospital - Overview of the Hospital -Overview of the Departments
2.	Section 2 : Project Report - Introduction - Objective - Need for study - SUD's, Reuse, Reprocessing Procedure - Review of literature
3.	Research Methodology - Research Question, Objectives - Data collection - Analysis & Interpretation - Findings & Recommendations
4.	References

ACRONYMS

FHM : Fortis hospital Mohali

Pts : Patients

SUD's ; Single use devices

ETO's : Ethylene dioxide Sterilised instruments

Cath.Lab : Catherisation lab

CCU – Critical/Coronary care Unit

PTCA :Percutaneous T Coronary Angioplasty

I. OBSERVATIONAL LEARNING

Section -1



FORTIS HEALTHCARE LIMITED: A brief History and present

Fortis Healthcare Limited ,is one of the fastest growing and India's second largest healthcare provider in the country. The company was founded by the visionary business leader, Late Dr. Parvinder Singh, the Managing Director of Ranbaxy Laboratories.

Fortis Hospital- Mohali was the first step towards realising his Dream, his vision regarding the Indian Healthcare industry.

- **Mission Statement:**

“ To create a world-class integrated healthcare delivery system in India, entailing the finest medical skills combined with compassionate patient care ”



- **Late Dr. Parvinder Singh**
Founder, Chairman Fortis Ltd

- **Vision Statement :**

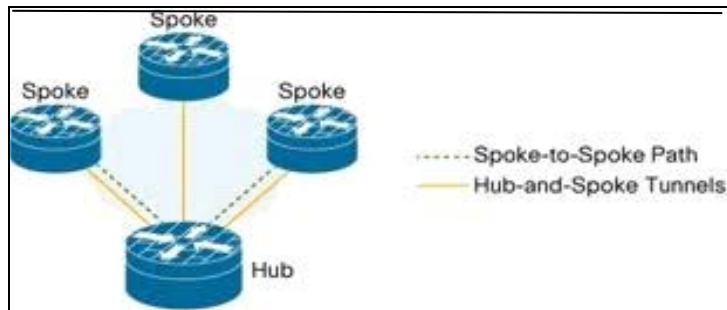
“Globally Respected Healthcare organization known for Clinical Excellence and Distinctive Patient Care.”

- FORTIS HEALTHCARE LTD. Was incorporated in 1996 to develop a world-class system of integrated healthcare delivery in India , comprising super-speciality areas along with multi-speciality care at the tertiary level.
- Late Dr.Parvinder Singh’s Dream was carried forward by his Sons, Malvinder.M.Singh and Shivender.M.Singh.
- Fortis is the manifestation of Dr.Parvinder Singhs ideology and has been vrapidly growing through a combination of acquisitions, Greenfield, Brown field and management contracts.
- Fortis is in collaboration with the renowned hospital Escorts and has created history by acquiring 10 Hospitals from Wockhardt, giving it a strong Pan India presence, this was one of the largest deal ever in the Healthcare industry.
- In 2005, Fortis announced its first International foray jointly with Mauritis based partner, and thus came into existence “**Fortis Clinique Darne** “

JOURNEY OF FORTIS:

- 1996 : Foundation of the vision
- 2001 : JUNE, : Cardiac centre Launched
- 2002 : AUGUST : Multi speciality wing
- 2005 : Acquiisition of 5 ESCORTS HOSPITALS
- 2009 : JANUARY, First International Hospital in partnership- MAURITIUS
- Latest acquisition ; 10 Wockhardt Hospitals Pan India

■ OPERATING MODEL :



Fortis operates on a Hub and Spoke model to Provide ,Multi-speciality and Tertiary level medical care.

HUB's – are the super-speciality Hospitals

SPOKE's – are the Multi speciality centres.

Patients who have the need are referred to these Hubs from the Multi speciality facilities in the Region, by embracing this system the patient benefits from the many available network facilities.

■ SOME HIGHLIGHTS :

- Fortis Hospital Mohali, is the Most advanced Hospital in the Tricity (Chandigarh, Mohali Panchkula)and the nearby regions, and has State-of Art Infrastructure and Technology and services. There are now 64 Fortis Hospitals across the globe.
- Fortis Hospital Mohali is the first Hospital that was started and the biggest in the tricity, ie a 350 Bedded Hospital with 250 Operational Beds and 7 Operation Theatres, 4 ICU's and a Round the clock Emergency Dept. and 24hrs Pharmacy along with Ambulance services.
- Recent Development is the FORTIS CANCER INSTITUTE at Mohali.
- Fortis Hospital Mohali has been awarded “ BEST DESIGN AWARD” By American Institute of Architecture 1999.
- Built-up Area of Fortis Hospital Mohali 400,000 sq.ft, with a investment of 155 Crores.

QUALITY FOCUS & ACCREDITATION :



Fortis Healthcare has been at the Forefront of providing quality healthcare services and has raised the bar of Quality Standards in the country. The hospital employs renowned medical talent from the healthcare industry.

- Due to their excellent Quality care standards & safety for patients 3 of Fortis's Hospitals have received the Prestigious JCI Accreditation (Joint Commission International)
- JCI- is the largest accreditor of Healthcare organisation in U.S
- In Addition to this, 6 Fortis hospitals in India have been given the highly Respected NABH Accreditation, which is the Highest national recognition for Quality, Patient care and Safety.
- On the other hand even the Labs have been given NABL accreditation



JCI- Joint Commission International :

- JCI accreditation is the Gold Standard for all the US and European hospitals, depicting the highest levels of Patient care and Safety
- The Mission of the Joint commission international is to improve the quality of Healthcare.
- It is awarded to those Hospitals which reflect the highest levels of Patient care and Safety.
- The accreditation standards are listed in the third edition of JCI, functionally divided to 7 Patient centred chapters & 6 Organisation management chapters.

PATIENT CENTERED STANDARDS	ORGANISATIONAL MANAGEMENT STANDARDS
1. Access to Care and Continuity of care	1. Quality improvement and patient safety
2. Patient and family Rights	2. Prevention and control of infections
3. Assesment of Patients	3. Governance, leadership and direction
4. Care of Patients	4. Facility management and safety staff
5. Anesthesia and surgical care	5. Staff qualifications and education
6. Medication Management and use	6. Management of communication and information
7. Patient and family education	

- NABH-



National Accreditation Board for Hospitals & Healthcare providers

- NABH is a constituent board of Quality council of India, structured to cater to much desired needs of the consumers and to set Benchmarks for Progress of health industry.
- The standards provide framework for quality assurance and performance improvement of hospitals.
- The Standard focus is on Patient safety and quality of care.
- There 10 Chapters in the NABH book, which comprise of two Major aspects of Healthcare delivery.

Patient Centered	Organisation centred
1. Access , Assesment and Continuity of care.	6. Continous Quality Improvement
2. Care of Patients	7. Responsibility of Management
3. Management of Medication	8. Facility Management and Safety
4. Patient Rights and Education	9. Human Resource management
5. Hospital infection control	10. Information Management system

Certificate of Accreditations, Fortis Mohali :

- Awarded JCI Accreditation on 15TH June, 2007
- Re-Accreditation July, 2008, 2013
- Awarded NABH Accreditation on 16th June, 2008
- Re-Accreditation June, 2011
- NABH audit 9th-11th May, 20



Hospital Overview :

- **FHM** – is divided into 2 Blocks, A - block & B – block, and now recent development is the Fortis Cancer Institute, which maybe named C – block.
- Further, again the Departments are divided Floor wise, which is as follows,

- **Basement** : Materials, Stores, H.R, House-keeping , MRD, Biomedical engineering dept, CSSD, Laundry, Food & Beverage dept.
- **Ground Floor** : Reception, Registration, OPD's Blood Bank, X-ray, NICU, General ICU, Patient waiting areas, IDBI Bank+ATM ,cafeteria, CCD, Prayer Room, Childrens play area, Dietetics,PWD-Patient welfare dept.Emergency. Lab, Nuclear Medicine, Clinic Rejuve. Pharmacy
- **1st Floor** : Opds, Wards, CMO office, MICU
- **2nd Floor** : MSOT,CCU, Cath LaB, PCR, ORTH.OT
- **3rd Floor** : Executive offices, Café Jamjaajee,Paalna Library. Auditorium, Finance, Marketing, Media & Communication, IT,CSR, FOS, QA Dept.
- In all there are 27 Depts in the Hospital.
- Some Depts. At FHM are Outsourced, like :
 - IVF- Dr. Pai & his Team (Mumbai)
 - Lab : SRL
 - Ultrasound,CT,MRI : Dr.Chawla
 - Dental : Axiss Dental

And latest addition is Physiotherapy Dept. outsourced to Dr.Balaji

Overview of FHM Department wise ;

➤ **OPD – Out Patient Department ;**

The OPD at FHM is a Muliti –speciality centre bringing to the patients all the required specialities under one roof.It consists of the following specialities like Cardiology, Dentistry,ENT, Gastroenterology, Endocrinology, internal Medicine, child specialist, Gynaecology.Neurology,Opthalmology,Orthopaedics, Psychiatry, Pulmonology, Rheumatology,Urology,Radiology,Lab, Nuclear medicine,Pathology .

It also has Home Based Rehabilitation Programmes and also has a Rhabilitation centre-cum inn providing a world class ambience along with Patient care.

➤ **Preventive Health Care : *CLINIC REJUVE***

Fortis firmly believes in Prevention is better than cure,,and this is done here at Clinic Rejuve ,where preventive Healthcare packages are given to pts and their family members at discounted rates to help them identify High-Risk pts and guide them towards better and healthy living, and providing them with required Medical help or Medication, and try to decrease lifestyle diseases by guiding towards healthy living.

➤ **Radiology** : Fortis can boast about having one of the most Advanced Radiology dept with skilled technicians and with the latest and most advanced machines. The Dept. has facilities like 64 Slice CT Scan, MRI,Mammography, X-Ray Ultrasound.

➤ **Nuclear Medicine** : This Dept. uses Safe,Painless, cost-effective method to image body with specialised diagnostic Gamma Cameras,in order to identify organ function and find out if presence of any disease.

➤ **Pathology** : SRL Ranbaxy manages the Path Lab at FHM . One of Asia's leading clinical testing facilities, SRL follows the protocol of College of American Pathologists Staffed with highly skilled technicians and equipped with digital analysers and complete automation in Biochemistry, Hematology Serology, Microbiology and Pathology and these services are rendered round the clock 24x7,and has also been Awarded NABL

➤ **Physiotherapy** : FHM has a dedicated Physiotherapy dept.which facilitates quick rehabilitation and pain management plus manage pts with musculoskeletal, cardiothoracic and neurological conditions. They also aid in Geriatric care from Degenerative diseases and provide Rehabilitation post trauma /surgery.

➤ **Dietetics** : The goal of the Diet clinic is to provide diet consultation to patients and their attendants and satisfy their diet related queries. This dept organises specific individual counselling and diet education to the pts based on the clinical parameters and Doctors prescription.

➤ **IPD :** FHM has a total capacity of 350 beds out of which 315 are functional. The functions of IPD are to Admit/Discharge/Transfer pts. Collect patient information and coordinate the admission with the other functions of the hospital. Arrange for the billing accept reservations, Disseminate information. It has a Reception desk all the above procedures are done.

➤ **OT'S** – there are 3 Main OT's Cardiac-OT, MS-OT, Ortho-OT ,

Cardiac OT : Bringing breakthrough technologies to the operating room, and setting international standards in its cardiac facilities, FHM has one of the most state of art OT with the most advanced lung and heart machines and many such devices. Cardiac OT has been constructed around a central sterile core which has the provision of storing all the sterile items to be used in the OT. It also has a Stas lab for immediate ABG & Electrolyte and steam sterilizer . The OT is directly connected with CSSD through a Dumb waiter lifter to transfer items.

Cardiac CATH Lab : FHM has 3 Cath labs that function Round the clock 24hrs and 7 days supported by a sophisticated CCU . It has some world class equipments like, COROSCOPE - by Siemens used for electrophysiological monitoring and INNOVA 2000 – by GE a digital imaging system , one of its kind in the world.

MSOT : Multispeciality Operation theatre

FHM is equipped with high-tech OT's where high risk surgical procedures are performed by a dedicated team of experts. There are 4 Major and one Minor OT .

There is a Exclusive OT for Joint Replacements

A State-of-Art Neuro OT has been commissioned and is only of its kind in the region.

On an average 15-20 cases are done in MSOT from 8am to 8pm , however Emergency services are available round the clock.

CCU : Critical Care Unit :

CCU is managed by experts in critical care, with patient to nurse ratio 1:1. Trained intensivists are adept in all emergency techniques such as airway management, IV, Anaesthesia etc

➤ **EMERGENCY DEPT.**

The Dept. of Emergency Medicine at FHM is adept with the most modern life support systems and manned by highly qualified paramedics with knowledge and skills to evaluate and stabilize pts who seek emergency medical care, especially those with potentially lethal and serious conditions.

The Dept is equipped to Handle all emergency cases like,

Cardiac emergencies : Chest pain, heart attacks, angina

Neuro. Emergency : Stroke, shock

Medical emergencies : Poisoning, abdominal pain, lung problem, liver, kidney

Surgical emergencies : appendicitis, lacerations, cuts, wounds, fractures, trauma, RTA's

➤ **Wards :**

The Wards at FHM are, A1, A2, A3, A4 Latest additions A6 (Cancer institute block)

A1 A2 are located on the first floor,

A1 Multi-speciality unit which have a capacity of 33 which includes 2 deluxe rooms, and one presidential suite

A2 Cardiac unit, bed capacity of 38 with one presidential room and 5 Double rooms and 10 single rooms.

A3 is Multispeciality again, with 47 beds

A4 A5A6 have also been made now.

➤ **Fortis PAALNA:**

FHM has launched a complete Obstetrics and Maternity division. It aims at offering young expectant mothers an excellent experience of childbirth and care. FHM aims to make the delivery safe comfortable, stress free and Memorable.

➤ **Pharmacy :**

Pharmacy is one of the most important unit in the hospital. FHM has In Patient Pharmacy on 2nd floor, and the Out Patient Pharmacy on the Ground floor. The Chemist shop is right at the entrance that operates 24x7 and the aim of this Dept is to provide standard medicines to pts .The entire medicine and medical disposable requirements of OPD pts and discharged IPD Patients are met by the Pharmacy Dept.

➤ **CSSD : CENTRAL STERILE SUPPLY DEPARTMENT**

Ensuring high standard of sterilisation and disinfection to minimize the incidence of hospital acquired infection rate, is one of the most essential feature at FHM.

The objective of the Central Sterile supply Dept. is to provide all the hospital departments served adequate supply of sterilised goods conforming to highest standards of sterilisation from a central place thus reducing the overall cost and contributing towards reduction in the incidence of hospital acquired infection. Destruction of all micro-organisms including their spores by chemical or physical means.

Sterilization methods used :

- 1) Steam Sterilization
- 2) Ethylene Oxide Gas Sterilization

To minimize the time as well as distance , CSSD is connected with Cardiac units and OT,s through two dumb waiter lifts. One is used to transfer the sterile goods, and one for transportation of contaminated goods.

The Dept is divided into 3 zones,

- 1.Decontamination Area
- 2.Semi-sterile Area
- 3.Sterile Area

There are timings for supplying and taking of the goods at CSSD, for Wards and others

Mornings 8.15am to 11am

Evenings 2-30pm to 5pm

While foe Emergency /OT's there is no time restriction (Inventory stock is kept in the Ratio 3:1 to Avoid any kind of shortage)

➤ **PWD : Patient welfare Dept :**

Since its inception Fortis Healthcare has been aspiring to track patient satisfaction and feedback through our Patient Welfare Program. Fortis healthcare has an established PWD and the welfare officers, termed as the pink ladies – due to their uniforms act as liaisons between the patients/customers and the hospital. They are patients advocates or representatives striving to provide solutions to any problem they may encounter here at Fortis.

➤ **Human Resource Dept.**

The Human Resource Dept. deals with the effective management and development of the most valuable Resource i.e. the Human component of the organisation. In FHM it is located in the Basement with the Zonal Head, 4 managers, 3 executives and a GDA.

Some of the important functions of HR are,

Manpower planning, Recruitment and Selection, Training and Career Development, Periodic Employee Performance Appraisal, Employee Rights/Welfare/Grievance, Wage and salary administration, rewards, incentives, Trainings, Job description and Job Analysis, employee engagements programmes- Fortis idol, FHM Nach Baliye, Doctor/Nurse/Staff of the month etc. Thus this Dept is one of the key depts for functioning of the hospital.

➤ **IT- Information Technology**

The mission of the dept. to implement and support the IT related infrastructure required to achieve the target of being a near paperless and film less institute. The Major tasks include Systems support, looking after the installation and routine maintenance of the Computer systems and networking at FHM Mohali.

There's, IT Help desk, nos. 6050, 6055, there are 13 servers, 450 work stations, call centre, etc. Backups and internet are also maintained by this dept.

The Softwares used here at FHM are, MEDTRAK and PYROGEN.

Pyrogen : operational only in the accounts and Pharmacy Dept.

Medtrak: is operational in all the depts at FHM

Fortis was one of the first few hospitals to use HIS Hospital information system.

➤ **FINANCE :**

One of the Most integral dept. of the the hospital, which is responsible for Revenue collection, calculation and all money related matters, Purchases, allowances or salary of Employees, Situated on the 3rd floor of Block B.

➤ **Marketing :**

FHM is the first of its kind of Hospital in this region, and FHL has been formed with the sole objective of providing total integrated healthcare by establishing State-of-Art Health delivery system. This dept along with Media and communication, creates awareness through Ad, Banners, Hoardings Press releases and interviews on Radio and Seminars.

➤ **CSR : Corporate Social Responsibility**

For the upliftment and betterment of Society, this has now become a Mandatory issue, 2% of the profits are supposed to be used for CSR activities for the welfare of the people. FHM also is doing its bit, and has 21 programmes running like ,

CHETNA : To provide help to the underprivileged girl child

ACTFAST : To spread awareness about HIV/AIDS

SAARTHAK : To extend support to cancer patients

SAHAYAK : A programme for Dialysis Patients

NANHI CHAH : To celebrate birth of a girl child and plant tree saplings

Friends of Fortis, Rural Outreach camp, Blood Donation Camps, Free Health check ups etc to name a few.

➤ **F&B –Food and Breverage Dept :**

This is again a vital part of the Hospital as it provides the restricted and special diet to the patients as per requirements. It is responsible for pre-preparation, Preparation, service, clearance of Food and Beverages.

➤ **MATERIALS/ STORES/PURCHASE :**

This dept is responsible for purchase storage of Medical Consumables, Stationary, Medical equipments, Pharmacy stores, its aim is to provide right item at the right time at the right price and quantity. Here at Fortis we have a CBU-Central Buying Unit that procures all the orders. Functions of this dept. are Procurement, Storage, Distribution,

➤ **HOUSE-KEEPING :**

Another important dept. takes care of the facilities present in the Hospital . A team of 11 Supervisors help in maintaining the cleanliness of the Hospital right from the premises , public areas and Patient areas.

➤ **ENGINEERING :**

FHM functions the way it does ie Flawlessly, thanks to this dept. the major work of this dept . is Building maintenance, Water supply , Power backup, Gas supply, Sewage treatment plant.

➤ **BIOMEDICAL :**

This dept. is again a v.important part of the hospital as it helps FHM to maintain its world class services by using world class equipments, Flawlessly. It looks after all the medical devices and Equipments .

➤ **MRD – Medical Records Dept.**

Situated at the Basement, the MRD keeps a record of all the patient files along with their details and History.

➤ **LIBRARY :**

A library is present on the Third Floor that houses various reference books, Journals, articles etc and every employee is a member.

➤ **CAFÉ JAMJAJEE :**

Situated on the 3rd Floor, the canteen of the Hospital, the unique name lies in the history and Values of Fortis and Fortis culture. A well arranged cafeteria where the staff have their meals daily.

➤ **SECURITY :**

The security although is outsourced gives a 24X& cover to the entire Hospital and especially regulates the traffic in the Parking areas

➤ **Some of the other Facilities available are :**

- Fortis inn : a paid resthouse for the attendants of Out-station patients, or the Attendants of Patients for some rest within the hospital
- Café 24 : a in house Restaurant that offers a wide variety of food for the attendants and family members of the patients.
- Bank/ATM : IDBI Bank and ATM is also present within the premises that can be very helpful to the customers in cases of need for money, and don't have to run around to get instant financial aid
- Café Coffee Day : CCD as is it well known is also present in the premises near the waiting area, again which is there to cater the needs of the people.
- Prayer Room : keeping in mind the religious and spiritual needs of the people, such a room is created where people can pray for their loved ones
- Play area : Specially for Children, this area has been designed.
- Many other Miscellaneous things like Nescafe Shop, Gift shop, etc is also present in the Hospital premises.

II . PROJECT REPORT

■ Introduction :

- Healthcare in India is prohibitively expensive for a large proportion of the population. In an effort to reduce cost, healthcare providers may resort to practices that may not match international standards and potentially compromise safety. Many hospitals in India have been resterilizing instruments and devices labelled for ‘single use’ by manufacturers. This is especially true of some of the newer devices such as those used in laparoscopic surgery. These procedures involve instruments which are expensive, e.g. harmonic shears, hernia tackers, staplers, etc. Recently, a large hospital in India decided to discontinue the use of resterilized equipment which resulted that, the cost of some operative procedures increased substantially. This generated a debate among the staff and stimulated us to look into issues related to sterilization, reprocessing and reuse of single-use devices in India as well as internationally.
- The practice of reprocessing single-use medical devices (SUDs) or reuse began in the late 1970s. Reprocessing, by definition, is the disassembling, decontamination, cleaning, inspection, testing, packing, relabelling and sterilization of SUD after they have been used on a patient for their intended purpose.
- Single-use devices in medicine were first developed in order to diminish the cost of reprocessing multi-use products. New materials have now permitted wider use of single-use products at lower cost compared with the cost for reprocessing and repackaging of multi-use devices.
- The term ‘single use’ on the packaging of medical devices means that the manufacturer intends the device to be used once and then discarded, considers the device unsuitable for use on more than one occasion.
- In other words, the designation ‘single use device’ denotes exclusively

the manufacturer's definition and not the intended purpose as per legislation.

- In general, manufacturers are not interested in the reprocessing of their single use devices and hence refuse to give any information as to whether and how their single use devices can be reprocessed and resterilized. A company for example, can decide to designate a stainless steel forceps for single use only even though it can be safely resterilized.
- SO, How are SUD's Reused here at FHM, in the CATH. LAB maintain the quality and controlling infection and successfully disinfecting it, and sterilizing it and using them on patients ?
- The Cardiology Dept. is the Heart of FHM, and it comprises of Cath Lab, NIC Lab, CCU, In-Patient Wards and OPD's

➤ CATH LAB :

- 2nd Floor, B-block, This is a patient oriented dept, which conducts Angioplasty and PTCA's.
- Patients of 2 categories are admitted here,

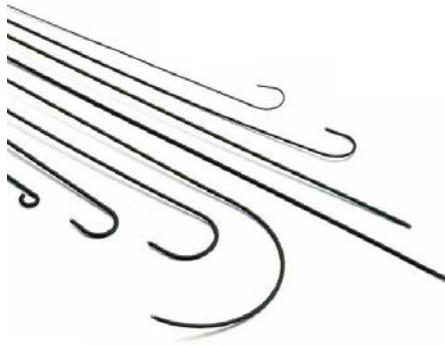
External Pts: Ext.Dr. Reference, Other Hospital Ref.

Internal Pts : Patients admitted in Emergency, ref. from OPD consultation

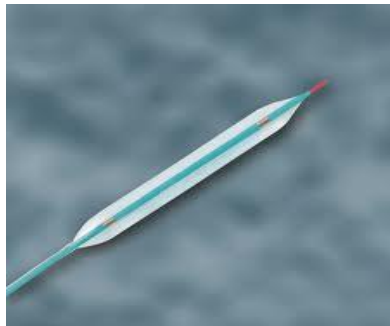
- Safety Standards : The most important reason for Safety standards to be put into place is Minimising infections to the patients, regular Fumigation of the Cath Lab, and all reusable material is properly cleaned and sterilized as per CSSD Guidelines, Provision of 1:1 patient nurse ratio to eliminate cross – infection and Isolation room for infected pts.

➤ Most commonly REUSED SUD's (Single use devices)in Cath Lab

- Guiding Wires



-Inflation Device



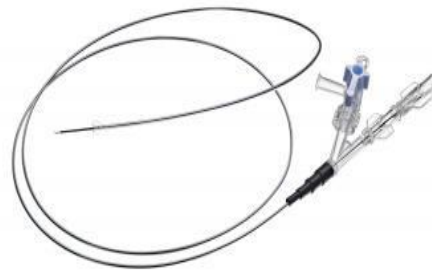
-Packed SUD



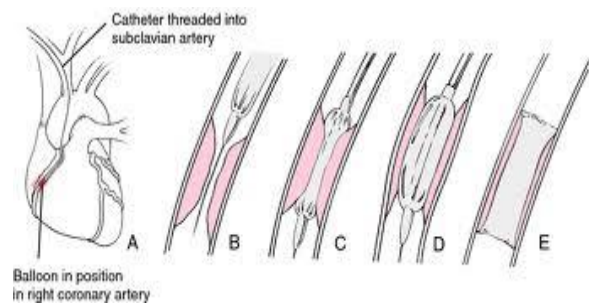
-Angio.Guiding Wires



-Catheters



- Using of Balloon (Angio)



➤ REUSE OF SUD's :

- A SUD which is to be REUSED in Patients ,must be Reprocessed to the Original Manufacturers specifications and labeled accordingly in a Good Manufacturing Practices approved facility that includes monitoring system to ensure Microbial safety and product integrity.
- In Absence of such a facility, the organization shall process the SUD in Accordance with the Infection control Guidelines in order to ensure a safe device and minimize the risk associated with the Reuse of SUD.

➤ REPROCESSING OF SUD'S:

- Catheters are v.fragile, therefore there is increased risk of damage and as they have long lumen it is difficult to evaluate whether cleaning process was properly done or not.
- **Sterilization** : Narrow lumens are best penetrated by Volatile substances, as heat cannot be used.
- **Processing Area** : it should have sufficient space and demarcated areas for every activity , and it should be insured no overlap between cleaning drying & packing, along with adequate lighting and ventilation. Temp b/w 20-24 and 10 Air changes per hour.No eating and drinking in Reprocessing areas.
- **Cleaning Process** :
 - All the Organic matter is removed from the lumens specially by repeated Flushing action
 - Devices are placed vertically inside Enzyme cleaner and kept for 2 hours and shifted to Drying area.

- **Drying**

- Clean disposable absorbent cloth used for Drying and oil free compressed gas can be used.

- **Packing**

- Once catheters cleaned, dried they are packed for sterilization, but before that documentation and checking of the instrument is done, packed in medical grade packing material compatible with ETO Sterilization. They are double packed and excess air is removed. Sealings checked and then devices sent to CSSD for ETO Sterilization

- **Sterilization :**

- Once the devices reach here, they are sterilized with the help of Ethylene Dioxide ETO and labeled accordingly, plus Colour Chaning Biomarkers are present for cross-check. After Sterilization they are labeled and either stored in a separate clean area or sent Back for Reuse

PROCESS OF DISINFECTING AND STERILIZING SUD's

- **OT** : On Trolley, SUD's after use, are wiped with Sterillium and Cleant and sent to Cath Lab Technicians for further Reprocessing

In Cath Lab

- **Disinfection** : Initially washed with saline 5 times, then dipped in enzyme cleaner (2hrs)
- **Cleaning** : After 2hrs, removed from the disinfectant and thoroughly cleaned with RO water 10 times and then dried with clean disposable lint free cloth, after that compressed oil and moisture free air is used for Complete Drying
- **Packing** : Technicians inspect the SUD and then packed using Medical grade packing material compatible with ETO sterilisation. (Double packed to prevent contamination + see through for identification + colour changing indicators + excess air removed)

CSSD

- **Sterilisation** : Process of ETO sterilization is done here and once successfully complete (indicators checked) Labelled and sent back to the Cath lab for use.)

■ Review of Literature :

"The practice of reprocessing single-use medical devices (SUDs) for reuse began in the late 1970s. Reprocessing, by definition, is the disassembling, decontamination, cleaning, inspection, testing, packing, relabelling and sterilization of SUD after they have been used on a patient for their intended purpose." [1]

"Many hospitals are routinely reusing balloon catheters, but only a few seem to follow validated and standardized reuse protocols" [2]

"The decision to adopt or reject a reuse policy has to be based on a careful risk assessment and on the individual situation at each hospital. Factors to consider include technical and personnel resources of the institution, frequency of PTCA procedures, economical and legal environment." [3]

"Different institutions and countries have adopted contradictory policies toward reuse. While Canada seems to be in the forefront of implementing a reuse policy, hospitals in the United States tend to fear legal consequences" [4]

"Ethylene oxide is the most common method of sterilizing PTCA equipment, since catheter material does not tolerate heat sterilization and the narrow lumen is penetrated best by volatile substances." [5]

"The first clinical trial comparing the use of new and reused balloon catheters was published by Plante and colleagues whose reuse protocol was based on ethylene oxide sterilization" [6]

"Reused catheters had a lower success rate than new ones. However, various authors have suggested that the detected differences may have been caused mainly by a sampling bias, since Plante compared two different centres with an obviously different patient population. In a re-analysis of the study Mak, Plante, and other co-workers demonstrated through stepwise logistic regression analysis that adverse effects were not associated with the reuse of the equipment but rather to other established risk factors of the patients "[7]

"Although the reuse of angioplasty balloon catheters is common practice in many countries, surprisingly few clinical studies on the reuse of PTCA equipment are available"[8]

■ *NEED FOR STUDY :*

- To understand the concept of Reuse of SUD's in Cath. Lab.
- To what extent Patients Health is affected when SUD's Reused?
- Reuse of SUD's- its effect on Quality Assurance & Infection Control

RESEARCH METHODOLOGY

■ RESEARCH QUESTION :-

Whether Reuse of SUD's for Procedures like Angioplasty ,PTCA in Cath. Lab is recommended or not?

■ OBJECTIVE OF THE STUDY :-

PRIMARY:

- To assess if there is an Increase in incidence of Infection in patients Post PTCA,Angioplasty when SUD's Reused in Cath Lab.

SECONDARY:

- Whether there is any predeposition of infection based on Gender
- Whether the Disinfection and Sterilization processes are according to the Quality standards.
- To know if any ill effects were encountered in Patients when Reused SUD's were used in their surgeries.

■ RESEARCH DESIGN :-

The Study Design used for this Project is Analytical study (Non-Interventional)

The Data was only very closely observed and Analysed.

■ DURATION :-

This Study was carried out from 10th May- 31st May 2014

(19th April – 9th May – Survey on Awareness about Employee Rights & Responsibilities- For NABH audit)

- STUDY POPULATION : Patients who have undergone PTCA /ANGIOPLASTY in past two months ie 1st April' 14- 20th May' 14
- SAMPLE SIZE : 100 patients
- SAMPLING TECHNIQUE : Non-Probability Convenience Sampling

DATA COLLECTION:

PRIMARY DATA :

Information about SUD's and its Reuse in Cath Lab was obtained from the staff of cath lab through interactive sessions with the Cath lab incharge, nurses, technicians.

Information on sterilization, quality maintainance and infection control was again given by the Medical coo-ordinator of Cath lab, and incharge of CSSD and the Lab technicians in Cath Lab.

SECONDARY DATA :

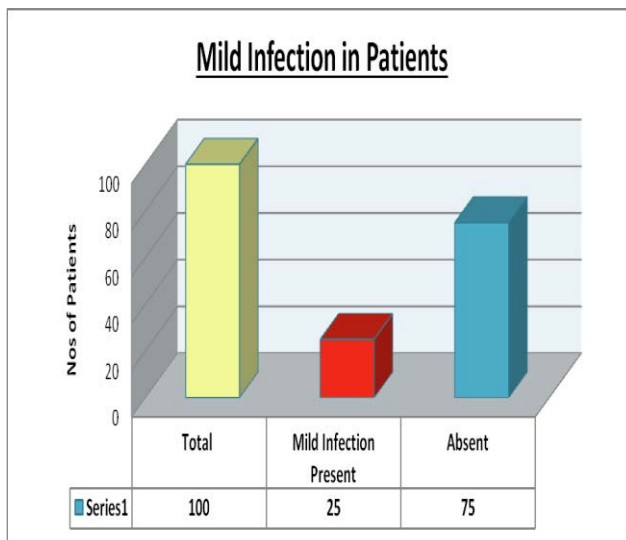
Information about SUD's and its Reuse was collected fom Internet, and also Patient Records were seen from the Cath lab Registers and the Official Intranet of Fortis,for tracking Patients Lab reports, **Medtrak** was used .(to check the CBC -Complete blood count of patients post surgery,for infection)

Plan of Execution :

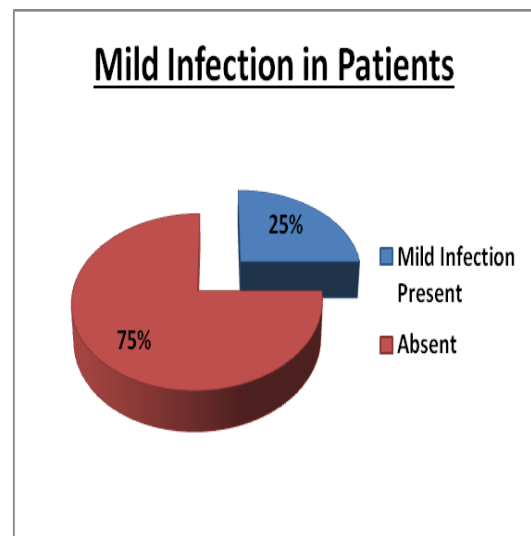
- Data about Patients who underent surgery in Cath Lab in the specified duration with and without ETO's-Reused SUD was collected first from the Cath lab Registers
- Their UHID's ,Date of Surgery ,Age,Gender was noted
- With Help of Medtrack,every patients CBC report was read and increased WBC/Seg.Neutrophils was checked.
- On basis of these , Analysis was done using MS-Excel

❖ DATA ANALYSIS

1) To know how prevalent was increase in wbc/Segmented Neutrophils (Mild Infection) amongst the Patients under Study, post PTCA/Angioplasty in Cath Lab



Graph 1

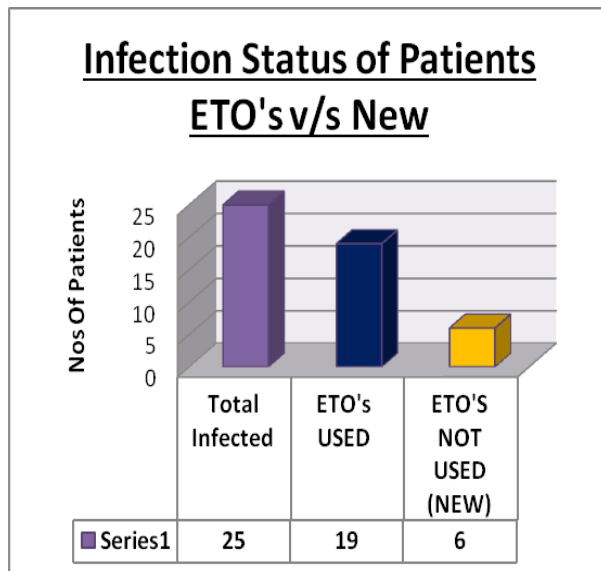


Graph 2

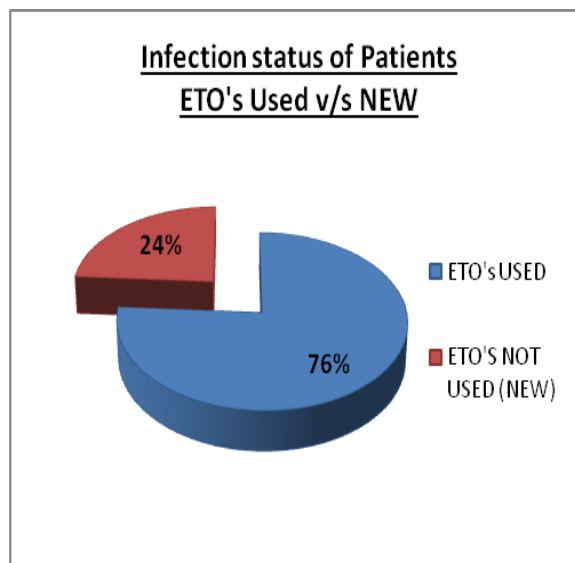
❖ **Interpretation :**

Out of the total sample size 100 Patients who underwent surgeries in the cath lab, only 25 % of the patient had Mild increase in Wbc and seg.neutrophil count, which was well within the normal range of Mild infection and which subsided in a day or two under minimum medication.

2) To know if infection in those patients in whom New devices were used for surgeries was Nil as compared to those in whom ETO's were used.



Graph 3

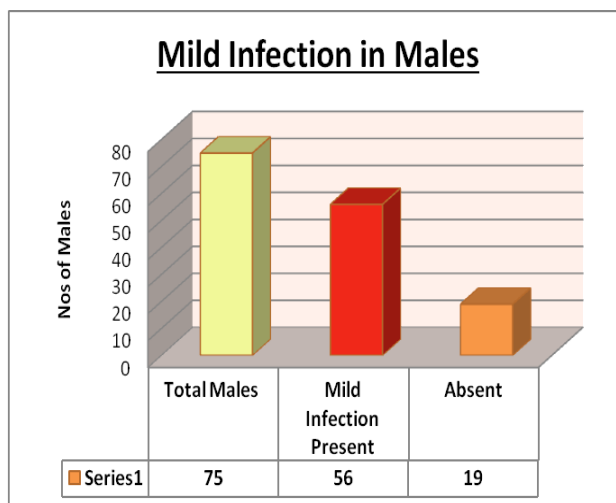


Graph 4

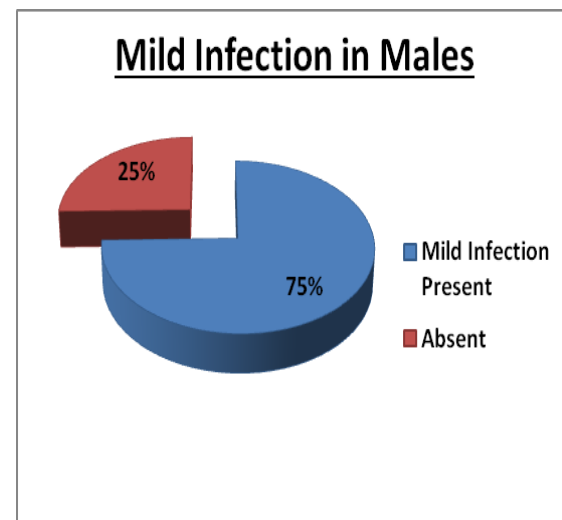
❖ Interpretation :

From the above Results we can see that even in patients in whom new devices were used there is presence of mild infection as in comparision with the patients in whom ETO's were used.

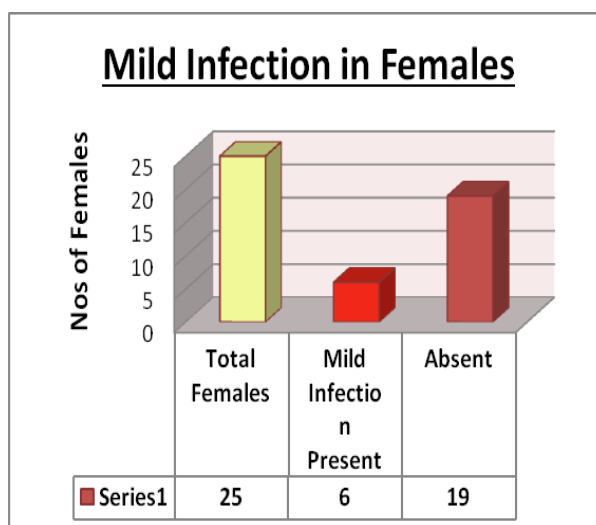
3) Post surgery in Cath Lab, who Male/Female were more susceptible for infections



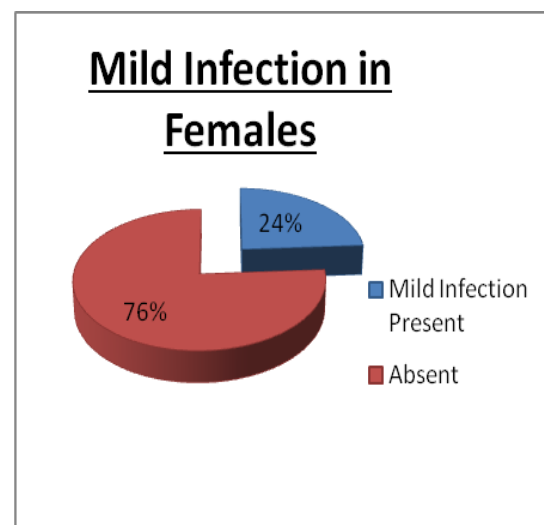
Graph 5



Graph 6



Graph 7

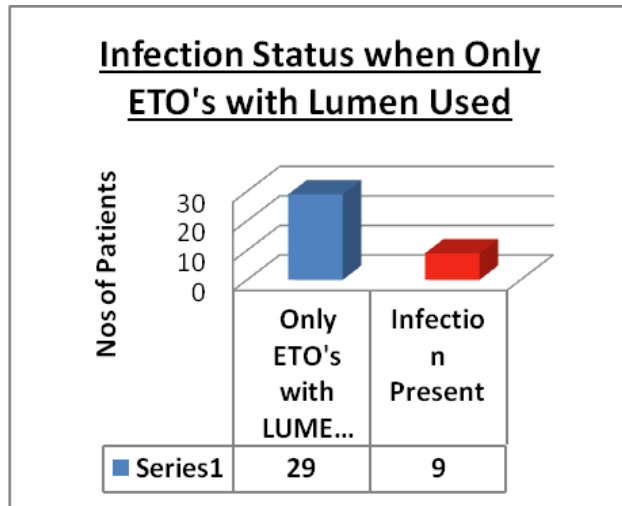


Graph 8

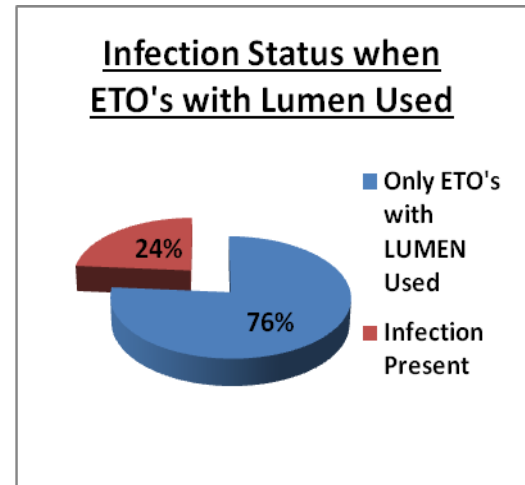
❖ Interpretation :

According to the Data, it shows that in these cases, Males were more Prone for infection than females post surgeries in Cath lab. (But this could be due to comparatively less nos. of females taken in the Sample)

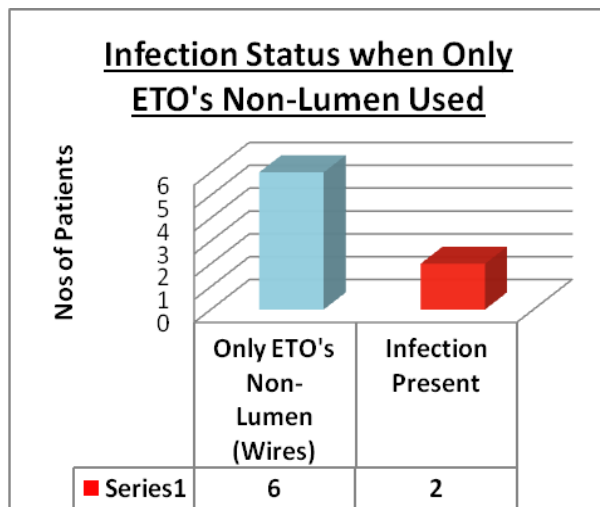
4) ETO's again are of two types, with Lumen (catheters) , without Lumen (wires), therefore are there any chances that when ETO's with Lumen were used as compared to when ETO's Non-Lumen were used, was there any significant increase in Infection.



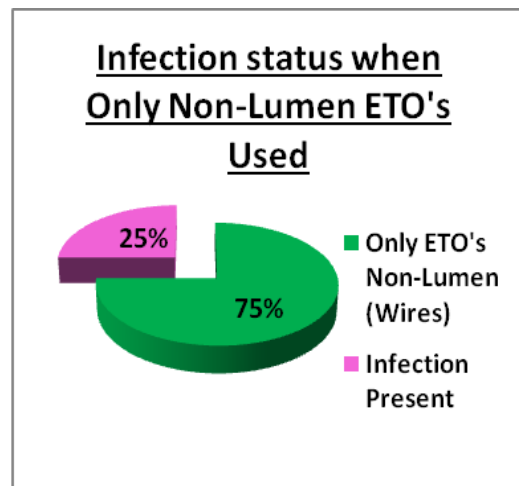
Graph 9



Graph 10



Graph 11

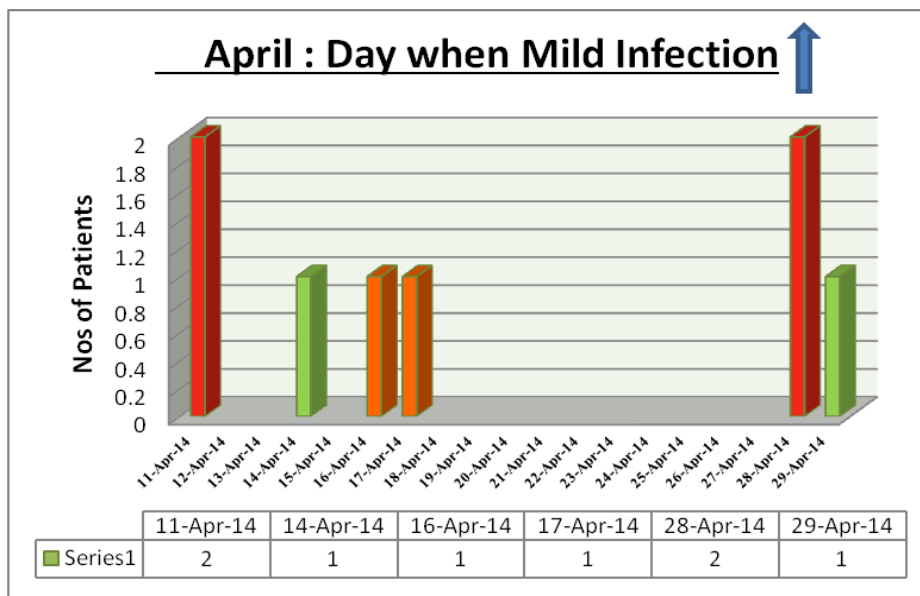


Garph12

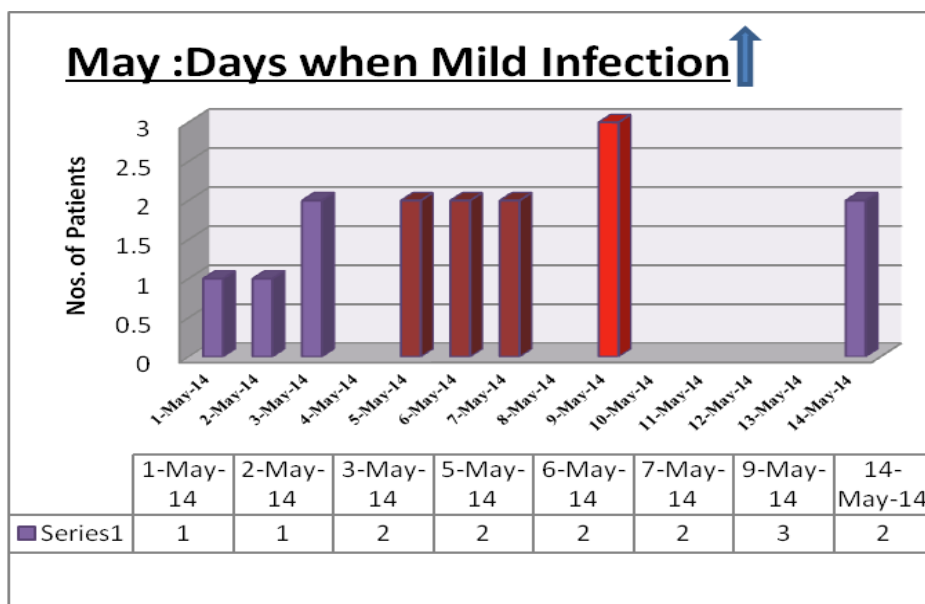
❖ Interpretation:

According to the results, there isn't a considerable difference in infection status of the patients in between ETO- with Lumen and ETO –without Lumen

5) According to the Monthly records, what was the infection status of the patients



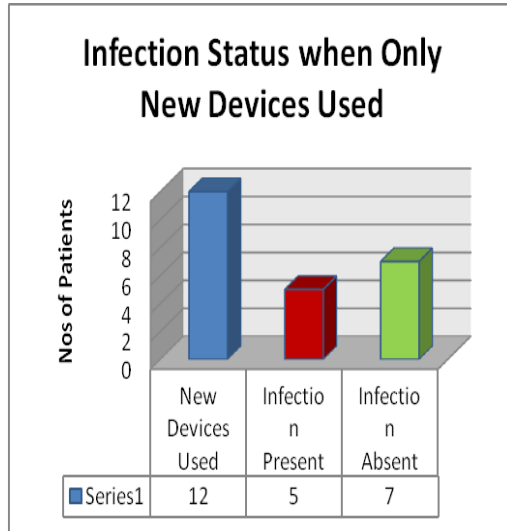
Graph 13



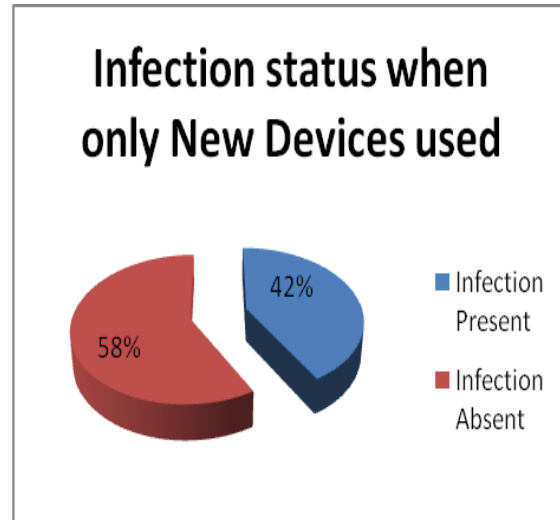
Graph 14

- ❖ **Inference** : There were some days in both the months, when there was a slight increase in Mild Infection amongst the patients, namely 5th-9th May and 11th and 28th April

6) Is there any evidence that the cause of infection is ETO's only and if New devices used and SUD's disposed there isn't any chance of infection?



Graph 15



Graph 16

- ❖ **Inference :** Thus we can say that Mild infection could be due to many other reasons and not only reuse of SUD's as, even when New devices used, there were incidences of Mild infection amongst Patients.

FINDINGS :

- From the above data, we can say that , Reuse of SUD's in Cath Lab is Advisable IF all the necessary precautions and proper Reprocessing and sterilisation done.
- We can see that Reused SUD's are not the Only cause of Mild infection, it could be due to many other reasons, thus only Reused SUD's not the source of infection.
- Mild infection was Also found in patients in whom, Absolutely New devices were used.
- It was observed certain days in APRIL -11TH 12TH , and 28TH , and in MAY 5TH 9TH there were more cases of infection as compared to the other days, and there could be a possibility that maybe the sterilisation procedures may have not been up to the Mark o those days. A Retrospective study could be done.
- Male were seen to be more prone for infection, according to my study, but there could be a bias , as the Nos of females taken in the study were less as compared to males.

SUGESSTIONS :

- 1 .Every product whether disposable or reusable has a functional life which cannot be determined precisely. If a product can be economically reprocessed with validated protocols and deemed to be functional, there is no reason to discard it after one use, and be considered for Reuse.
2. If safe sterilization and reprocessing can be achieved, according to the Quality standards, it will be of use to both the patient and the environment..This practice could be adopted by hospitals that are interested in controlling costs of expensive medical instruments and reducing environmental waste.
3. In addition to the Biomedical waste of the hospital, large amount of toxic non-biodegradable waste generated by disposing medical devices. This could be decreased if the devices are reused after being adequately sterilized.
- 4 And also, Most importantly, the financial burden of using single-use devices only once will need to be borne by the patient alone while reuse will reduce the financial burden substantially for the patients.
5. Only Precaution to be kept in mind is , the disposal of Ethylene dioxide. The major disadvantages of ethylene oxide sterilizationare its toxicity, its ozone depleting effect, and the fact that residual fluid in the balloon could reduce the sterilizing effect.
6. Some risks pertaining to improper reprocessing of medical devices include cross-contamination and hospital-acquired infections, inadequate decontamination and cleaning, and residues created from chemical agents during sterilization that could be unsafe and cause Infections or allergies. Therefore a Strict Protocol should be followed and checked regularly and the staff to be trained and explained about PROPER REPROCESSING TECHNIQUES.

REFERENCES :

- 1] Human Services, Food and Drug Administration,
Center for Devices and Radiological Health. *Guidance for industry and for FDA staff: Enforcement priorities for single-use devices reprocessed by third parties and hospitals*. 2000 Feb 8. Available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/000053g2.pdf>

- [2] Comis J. Reuse of single-use cardiac catheters. 7-1991.Canadian Coordinating Office for Health Technology Assessment

- [3] *European Heart Journal* (2000) **21**, 185–189 Article No. euhj.1999.1691, available online at <http://www.idealibrary.com> on

- [4] Browne KF, Maldonado R, Telatnik M, Vlietstra RE,Brenner AS. Initial experience with reuse of coronary angioplasty catheters in the United States. *J Am Coll Cardiol*1997; 30: 1735–40.
[Vaitkus PT. Patient acceptance of reused angioplasty equipment.*Am Heart J* 1997; 134: 127–30.]

- [5] Bentolila P. Experiments conducted on cardiac catheters.10-1994. Reuse of disposable medical devices, Fourth CCOHTA Regional Symposium, October 6–7, 1994,Montreal, Canada
Mak KH, Eisenberg MJ, Eccleston DS, Cornhill JF, Topol EJ. Reuse of coronary angioplasty equipment: technical and clinical issues.*Am Heart J* 1996; 131: 624–30.
Plante S, Strauss BH, Goulet G, Watson RK, Chisholm RJ.Reuse of balloon catheters for coronary angioplasty: a potential cost-saving strategy? *J Am Coll Cardiol* 1994; 24: 1475–81

[6] Mak KH, Eisenberg MJ, Plante S, Strauss BH, Arheart KL, Topol EJ.

Absence of increased in-hospital complications with reused balloon catheters. Am J Cardiol 1996; 78: 717–19.

[7] Reuse of single-use devices: Looking back, looking forward M. HUSSAIN, K.P.

BALSARA, S. NAGRAL THE NATIONAL MEDICAL JOURNAL OF INDIA VOL. 25,
NO. 3, 2012

