



# HOSPITAL INFECTION SOCIETY

## INDIA n e w s l e t t e r

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### President's Message

Dear Colleague,

The Control of Health Care associated Infections has attained global importance. The world alliance for patient safety was launched by WHO in Oct 2004. The first challenge of the alliance was to reduce health care associated infections with hand hygiene as the cornerstone. The strategy for patient safety is based on the integration of hand hygiene, blood safety, injection safety, clinical procedures safety and water and sanitation safety. HISI extended its assistance to promote and advocate for the cause of patient safety.

With a successful 9th Conference of the HISI in February this year we saw the advent of many firsts. It was the first time that we had an entire CME devoted to Nosocomial fungal infections. There was also the first meeting of infection control nurses forum, and Dr Ganesh Mani delivered the first Brahm Prakash Oration.

The last issue of this newsletter had the guidelines on ventilation systems in hospitals, whereas the present issue has the guidelines on reuse of single use devices. These are in the draft form and need your suggestions and corrections.

Infection control activities by our members need to be highlighted and we can learn from each other's experience. Let us use this newsletter as a forum for exchange of ideas.

Do visit our website [hisindia.org](http://hisindia.org) !



**GEETA MEHTA**  
*President, HIS-I*



**ANITA ARORA**  
*Secretary, HIS-I*

### Editorial

As soon as I came to know that the IX National Conference of the Hospital Infection Society of India would be held at Chandigarh, fond memories of the city and the time spent there during my postgraduate days came to my mind. I looked forward to the conference, both as secretary of the society and the fact that I would be going back to visit a city I loved and also meet colleagues and seniors.

After lots of time and energy spent in organising the conference, the days for the conference dawned. The President, Dr. Geeta Mehta, and I travelled together by train to reach Chandigarh. What followed was a delightful stay with activity packed days during the conference and perfect weather as the backdrop, with overcast skies and some drizzle.

The preconference CME on nosocomial fungal infections was the first of its kind to be held at this conference. Right from the word go, the CME was a big success. Over the next three days the conference was a whirlwind round of sessions of talks, lectures, cases, experiences on a wide range of topics in infection control by experts from both India and abroad. I attended just about every session that the conference had to offer. The conference, like the CME, had a number of firsts - the first Prof. Brahm Prakash oration and the first meeting of the Infection Control Nurses Forum. The website of the HISI was launched at this conference.

I had a wonderful time at the conference as I really enjoyed every minute of it, not only organising but also attending and networking with my fellow colleagues, who were such a delight to be with.

Those of you who attended the conference would agree with me that the IX HISICON 2007 was a grand success. For those of you who were unable to do so, the proceedings of the conference are available on CD, which shall be posted on request.

# A need to Standardise Surveillance of Hospital Associated Infections (HAI)

## in Indian perspective through a workable approach

Dr Raman Sardana, Indraprastha Apollo Hospitals, New Delhi

### Introduction

Indian health care industry suffers from major drawbacks - the picture as of today is of scarcity amidst abundance. There is water everywhere, yet not a drop to drink. There is vast material available, there are people who are working and data is being produced, yet this is not standardised across, is non-uniform and thus cannot be put to mass use for improvement.

Though any book would give the standard definition for Surveillance of HAI (*the continuing scrutiny of all aspects of occurrence and spread of a disease that are pertinent to effective control*), yet for the sake of understanding, surveillance of Hospital Associated Infections (HAI) in a nutshell, is the process of digging out HAI through repeated observations and findings, collated as data, analysis of this data to extract out information so as to monitor the trends over a period of time. It is imperative to know the relative impact of the measures taken. We would not say that the impact can be measured exactly as there are considerable variations in medicine and is further diversified through the presence of a protean system of medical care in this country. Measures taken at one institute may not fit in the other till some form of standardisation and uniformity is available. An attempt is being made to address this issue through these write-ups.

### HAI or Hospital Associated Infections

Any defined or specified infection occurring in a patient after 48 hours of admission in the hospital (Nosocomial), as also any infection with which the patient was incubating at the time of admission or acquired before admission to a particular health care unit. This terminology is broad and justifies the concept as most of the time it is very difficult to make out whether an infection was acquired elsewhere or inside a particular health care set up or unit. This is further complicated in the Indian scenario, where there is unrestricted over-the-counter availability of antimicrobials to the masses.

### The Process

In order to standardise, we must attempt to choose parameters that are more or less universally applicable, across the institutions. Today, the health care scenario is shifting from wards to intensive care and more and more number of people are subjected to interventional procedures to sustain life. This causes breach in natural defences and as such serve as access route to micro organisms for potential infection, needing strengthening of preventive measures. Secondary and tertiary care setups can incorporate certain parameters that give adequate information on control measures implemented. What better way then to have the infection rate monitored in patients subjected to invasive medical devices?

Thus, Catheter related Blood stream infections (CR-BSI), Ventilator Associated Pneumonia (VAP) and Catheter (Indwelling-Foley's) Related UTI (CR-UTI) give an overall measurement of efficacy of an Infection control program. This is supplemented by measuring a few Surgical Site Infections e.g. Post Laparoscopic surgery, port site wound infections would be a good measure to effectively monitor the disinfection of laparoscopes, and might also give an insight into the surgical technique. Centres not doing laparoscopic surgery, may take on common procedures like inguinal hernia, thyroidectomy, etc. Single speciality units like cardiac centres may take up CABG wounds-both sternal and donor site. Trends over a period of time if monitored uniformly and under standardised formats are likely to help out even in improvement processes in surgical methodology. Comparisons of two or three different approaches to the same surgery can also be made for potential infective threats.

Surveillance activity can also dig out emergence of specific pathogens as also bring about the early detection of an impending outbreak. Therefore, the measurable parameters need to be worked out. First and foremost, is to determine common grounds, which are practical and simple to follow.

It is important that health-care professionals should recognise the difference between surveillance definitions and clinical definitions. Surveillance definitions would be a definite process based on fixed criteria with minimal subjective clinical judgment. It may over-estimate the true incidence most of the time, yet giving a powerful vision on uniformity and objective

measurement. For this, the collection of data needs to be uniform. Finally the measures need to be formulated logically and implemented, and subsequently analysed for impact by monitoring trends.

### Surveillance and HAI Indices

These are the measurable elements, which help in achieving surveillance goals. These could be indices measuring HAI like infections associated with indwelling central vascular catheters, urinary catheters, etc.

Other indices can be directly measuring some parameters like:

- Compliance with hand hygiene, pre- and post-enforcement;
- Surveillance for emerging resistance and changing microbial flora isolated pre- and post-implementation of measures, like 'restricted usage of certain antimicrobials' etc.

One can also incorporate other activities, like exposure inoculation injury surveillance programme into this.

For comparison, HAI indices can be defined unit wise (Surgical Intensive Care, Paediatric Intensive Care, etc.) and can be assigned to that unit where it has arisen i.e. where the patient was admitted prior to being shifted to another unit. This would make any vulnerable area come out glaringly and measures could be effectively installed in that area. A proforma is made and filled daily for every patient (unit wise) on central lines and/or ventilator and/or urinary catheters. It is better if a dedicated team collects the data. This helps in easy uniform flow.

### Measurement of HAI or HAI Indices

Please see the deliberations of the task force on standardisation of definitions and measurement of HAI as given in the accompanying article.

### Benefits of Surveillance

- Monitoring trends of hospital associated infections
- Monitoring preventive aspects of Hospital Infection Control Programme
- Early detection of any impending outbreak
- Rational usage of antimicrobials - reducing resistance development / costs
- Monitoring for emerging resistance and changing flora
- Controlling the emergence of naturally resistant organisms
- There is no benefit more than saving lives

### In the End

We have tried to put some salient features of HAI surveillance programme in a practical workable way but a single article cannot replace a plethora of articles on the subject or the experience of experts, and this remains a humble drop in the ocean.

Once such surveillance data is available consistently, it is advisable to compare these with other institutes. Unfortunately, due to lack of standardisation and uniformity, not much data can be compared in India. NNIS surveillance data is a good standard to work with and it categorises each unit separately e.g. teaching / non-teaching, medical / surgical / cardiovascular, etc. Once a comparison is made, it is good to know about the flora involved as also the root cause analysis of a particular occurrence. With this, certain measures need to be implemented in order to decrease the rates to minimum possible - the beginning and end of all Infection Control programmes.

A national programme on the lines of NNIS is an urgent need of the hour (We could name it as INHAIS - Indian National Hospital Associated Infection Surveillance). If we all agree to the basic programme outlined below, all can start working on it and correspond accordingly with us in the HISI. We have tried this at our institute and it has worked out very well over the years. It needs a bit of will power and some amount of responsibility. The rest is yours!

### Further Reading

1. Ayliff GAJ, Fraise AP, Geddes AM and Mitchell K (Eds.). Control of Hospital Infection, 2000 Arnold (Pub), London
2. NNIS system report, 1992-2004. Am J Infect Control 2004; 32:470-85
3. MMWR. 2002; Vol.51: no. RR-10
4. Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated, and Healthcare-associated Pneumonia. Am J Respir Crit Care Med 2005; Vol 171: 388-416

# Hospital Associated Infection Surveillance Definitions

## Deliberations of HISI Working Group on HAI Surveillance Definitions

- Dr Raman Sardana, Indraprastha Apollo Hospitals, New Delhi
- Dr Sharmila Sen Gupta, Fortis Hospital, NOIDA
- Dr Anuj Sharma, Sir Ganga Ram Hospital, New Delhi

### 1. Catheter Related Blood Stream Infections or CR-BSI

#### Definitions of Various Catheters

There is no uniformity in addressing various catheter types, hence these may be classified on the basis of time period like short and long term, on site of insertion as subclavian, femoral, umbilical, peripheral (extremities) as also peripherally inserted central catheters (PICC lines), or type of vessels - as peripheral venous, central venous and arterial; on length - as long lines and short lines, on the type of path - tunnelled or non tunnelled, etc.

Since the peripheral catheters are difficult to monitor because of too much variations in the procedures and frequent handling, the multiple sites involved within a very short period and variations of different health care personnel during that short interval, the multiple numbers a puncture is carried out and the relative paucity of true blood stream infections (phlebitis is much more commoner than BSI) in the peripheral lines, it is best to monitor the central lines which are more or less (except in emergency situations) put with total aseptic precautions and generally are single puncture procedures and are indwelling over a period of time at the same site. For determining the CR-BSI all patients in a particular unit who are on any of the following lines should be a part of surveillance activity - Midline catheters, Non-tunnelled central venous catheters, Pulmonary artery catheters, Peripherally inserted central venous catheters (PICC), Tunnelled central venous catheters, Umbilical catheters inserted into either umbilical vein or umbilical artery, peripheral catheters percutaneously inserted into central veins (subclavian, internal jugular, or femoral).

#### The following could be the Surveillance Criteria to Define CR-BSI

1. The patient has a central line in place
2. The patient has been admitted for more than 48 hours in that health care unit
3. The patient has any of the following criteria being fulfilled:
  - Recognized pathogen isolated from blood culture,

AND

- Pathogen is not related to infection from another site (other than site of an intravascular device i.e. it should not have been isolated from urinary tract / respiratory tract / wound, etc)

OR

- One of the following - fever ( $>38^{\circ}\text{C}$ ), chills, or hypotension

AND any of the following:

- (a) Common skin contaminant isolated from two blood cultures drawn on separate occasions, AND organism is not related to infection at another site.
- (b) Common skin contaminant isolated from blood culture from patient with intravascular access device AND physician institutes appropriate antimicrobial therapy.
- (c) Positive antigen test on blood AND organism is not related to infection at another site.

OR

- Patient  $\leq 12$  months of age has one of the following - fever ( $>38^{\circ}\text{C}$ ), hypothermia ( $<37^{\circ}\text{C}$ ), apnoea or bradycardia

AND one of the following:

- (a) Common skin contaminant isolated from two blood cultures drawn on separate occasions AND organism is not related to infection at another site (other than site of an intravascular device, i.e. urinary tract / respiratory tract / wound, etc).
- (b) Common skin contaminant isolated from blood culture from patient with intravascular access device AND physician institutes appropriate antimicrobial therapy i.e. a strong suspicion of sepsis.
- (c) Positive antigen test on blood AND pathogen is not related to infection at another site.

The surveillance definition for catheter-associated BSI includes all BSIs that occur in patients with central lines, when other sites of infection have been excluded. That is, the surveillance definition overestimates the true incidence of CRBSI because not all BSIs originate from a catheter. Some bacteraemia are secondary BSIs from undocumented sources (e.g. post operative surgical sites, intra-abdominal infections, and hospital-associated pneumonia or urinary tract infections).

Calculations: The denominator has been used differently in different studies India and Asia in general. However, the most practical and useful has been the CDC / JCAHO criteria of defining the CRBSI over a period of time usage of central line catheters i.e. number of catheter days

1. All the patients on central lines in a unit should be put under surveillance
2. Data should be collected for every such patient through either the Infection Control Nurse or a resident doctor (Infection Control Resident) can be assigned.
3. Above criteria should be fulfilled for classification as CRBSI
4. At the end of a month add all the catheter days, i.e. number of patients on central catheters, each day for that unit, till the end of the month. If a particular patient was on central catheter yesterday, and was counted in yesterday's figures, that patient if still on a central line today also, would be counted in today's figures too.
5. Thus by the end of the month, the total number of catheter days for a unit are added. If any patient is on two different catheters on a single day, then it should be counted as two catheter days.

No. of blood stream infections (BSI) per 1000 catheter days is then expressed as No. of Blood stream Infections / total No. of catheter days X 1000

### 2. Ventilator Associated Pneumonia (VAP)

To be classified as a case of VAP for surveillance, the following criteria, which are a simplified version from CDC and American Thoracic Society (2005) criteria, need to be fulfilled:

1. The patient should have been on mechanical ventilation (either through an endotracheal tube or through tracheostomy) in an ICU for more than 48 hours to be qualified to be a case under consideration for VAP.
2. Rales or dullness to percussion on physical examination of chest

AND any of the following:

- (a) New onset of purulent sputum or change in character of sputum.
- (b) Same Organism isolated from blood culture as from respiratory tract with no other source of infection.
- (c) Isolation of pathogen from specimen obtained by transtracheal aspirate, bronchial brushing, BAL or biopsy.

OR

3. Chest radiographic examination showing new or progressive-infiltrate/ consolidation, cavitation without carcinoma or tuberculosis or pleural effusion

AND any of the following:

- (a) New onset of purulent sputum or change in character of sputum.
- (b) Same Organism isolated from blood culture as from respiratory tract with no other obvious source of infection.
- (c) Isolation of pathogen from specimen obtained by transtracheal aspirate, bronchial brushing, BAL or biopsy.
- (d) Histopathological evidence of pneumonia

The number of ventilator days are calculated as for BSI for that unit and the number of VAP as characterised by the above criteria is also calculated over a month. The denominator is taken to be number of VAP / 1000 ventilator days i.e. number of VAP as defined by the above criteria / number of ventilator days X 1000

### 3. Catheter Related Urinary Tract Infection (CR-UTI)

To be classified for Surveillance the following needs to be fulfilled:

- The patient should have been Foley's / indwelling urinary catheter in a unit, for more than 48 hours to be qualified to be a case under consideration for CR-UTI

AND

- An indwelling urinary catheter should have been present within 7 days before the urine is cultured

AND

- Patient has history of fever (>38.3°C) urgency, frequency, dysuria or suprapubic tenderness

AND

- Patient has urine culture of  $\geq 10$  organisms /ml urine with no more than two types of organisms

The number of urinary catheter days is calculated as for BSI for that unit and the number of UTI as characterised by the above criteria is also calculated over a month. The denominator is taken to be number of UTI / 1000 urinary catheter days i.e. number of UTIs as defined by the above criteria / total number of urinary catheter days X 1000

#### Obtaining Urine Sample from Catheter (Chronic Indwelling Urethral Catheter) for Culture:

- The catheter tubing should be clamped away from the sampling area, which should be as near to the urethral meatus as is possible (to collect freshly voided sample). The soft rubber connector between catheter and collecting tubing can also be utilised for this purpose.
- The site of sampling should be prepared as for I/V line, with povidone-iodine and then 70% alcohol.
- The urine is collected by aspiration from the prepared site with a sterile needle No. 26/28 and syringes, then the sample is quickly transferred to a sterile container.
- Mention on the investigation form that sample has been collected from a catheter.

Note:

- *Routine and repeated bacteriological cultures in catheterised patients should be avoided*
- *Samples from such catheters usually do not reflect bladder pathogens.*

### 4. Surveillance of Hand Hygiene Compliance

- This can be measured directly or through indirect evidences.
- Direct observations can be made by any of the Infection Control Team members. This can usually be accomplished well through regular, especially observations during odd hours.
- Data for all categories of staff should be gathered including faculty, residents, nursing, ward boys, physiotherapists and other health care workers involved in direct patient care.
- Both pre and post-contact compliance should be observed.
- This should be followed by awareness drives and educational activity.
- Provision of accessible alcoholic hand rubs should be made, at each bed side.
- Measurement of impact of such measures implemented should again be carried out in the same unit by same team.

Calculations: Number of times a health care worker makes contact with patients, with alcohol rubbed hands / the total number of contacts made by that category of health care worker X 100 gives the percentage data.

### 5. Surveillance for Emerging Resistance and Changing Flora

This can be brought about mainly through the following:

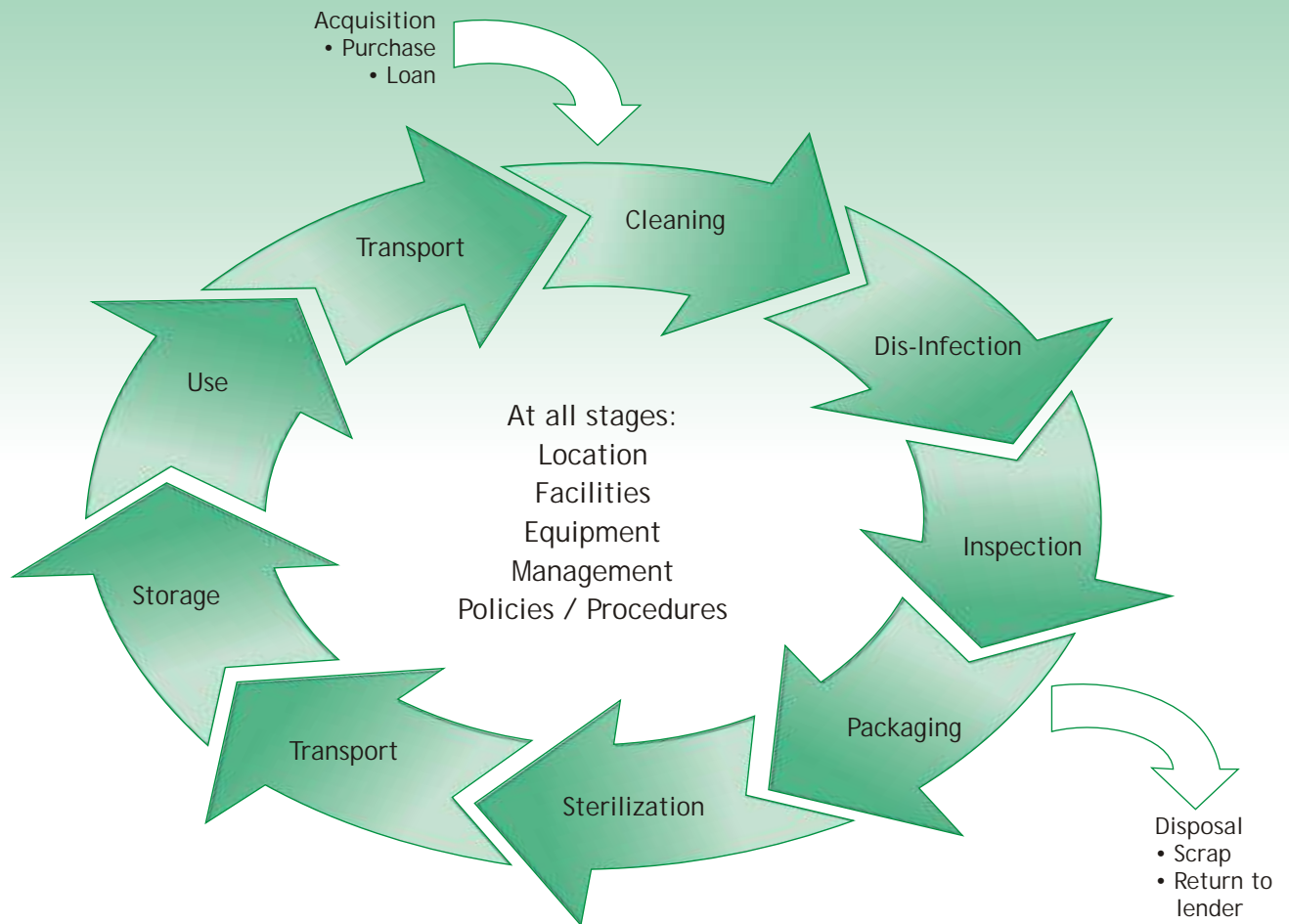
- Daily run through of microbiological records by competent personnel
- Compilation of isolated microbes and antimicrobial susceptibility, according to area or unit
- Periodic monitoring of trends through histograms or line diagrams
- A prescription audit should be carried out simultaneously by involving Pharmacy
- Analyses of factors causing a particular situation (e.g. particular practices being followed - high usage of third generation Cephalosporins in surgical prophylaxis / empirical treatment may be responsible for emergence of ESBL producers, Enterococci; inappropriate or inaccurate or sub-optimal dosage of Vancomycin may result in emergence of VRE, etc)
- A percentage isolation and resistance pattern should be worked out for totality or different units of the health care facility.
- Implementation of policy on 'Restricted Usage of Antimicrobials' - wherein certain antimicrobials are not used for empirical treatment except under dire circumstances and that too with a stringent measure to review after 48 hours of such a therapy. Written justification of continuing such a treatment by the treating team is a good deterrent.
- Calculation of DDD (Daily Defined Doses) for salient antimicrobials in a unit can be a surveillance index of over usage of certain antimicrobials.
- An increase in the DDD of an antimicrobial over a period of time, may reveal as emergence of resistant isolates or a change in the flora especially which may be inherently resistant e.g. increased usage of carbapenems in an area may result in an increased isolation of organisms like *Stenotrophomonas* or *Chryseobacterium* spp.
- An input from the inpatient pharmacy is a prerequisite for such a surveillance activity, which may have a bearing in the form of antimicrobial policy of a health care unit. Generally, prescription audits from OP Pharmacy do not divulge the true picture.

Calculating DDD: Total amount of antimicrobial used in an area in grams / adult daily dosage of that antimicrobial.

*We invite your comments and suggestions regarding hospital associated infection surveillance definitions at [hisi@HISIndia.org](mailto:hisi@HISIndia.org) before 31 December 2007*

# Reuse of Single Use Medical Devices

(Draft)



Hospital Infection Society, Mumbai Forum

This document has been prepared taking into consideration the following factors:

- The practice of reusing single use medical devices exists in many health care facilities in India.
- This practice requires standardisation.
- The practices recommended in this guideline aim to be realistic and practical without compromising on safety.

The Annexure includes the best practices for reuse of medical devices in haemodialysis units

The views expressed in this document are those of the HIS-MF members.

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# BEST PRACTICE GUIDELINES

## Reuse of Single Use Medical Devices

### Purpose

The purpose of these guidelines is to provide best practices for a health care facility for reprocessing of single use medical devices. The practices are aimed at achieving the most important parameters after reprocessing viz. sterility, integrity and functionality.

### Introduction

The practice of reprocessing single-use devices (SUDs) for reuse exists since 1970's. This has increased in recent years bringing with it concerns about the safety of such a process and the ethics involved. The problem has been compounded by the increasing number of complex devices making the process difficult. Will the reprocessed device perform as well as the original device with respect to its sterility, safety, and functionality in spite of the reprocessing?

### Rationale

Economic considerations have played a major role in catapulting reprocessing of single-use devices. In a country like India, where the cost of some of these medical devices are unaffordable to the majority and where the use of such a device is life saving, reprocessing becomes a necessity. Scientific studies from all over the world indicate the safety of reprocessing. The experience from India is also the same though evidence is lacking. The Cardiology Society of India in its paper entitled 'reuse of devices in the catheterisation laboratory' published in the Indian Heart Journal 1997; 49:329-331 has provided some direction and description of the process of reprocessing. However, in order to make the process foolproof and provide scientific evidence for its safety and efficacy, it is essential to have guidelines, which include parameters other than cleaning and sterilisation. It is also essential to address / identify a regulatory agency, which can certify / license reuse facilities.

### Single use Medical Devices

There are three categories of single-use medical devices

- Open and unused.
- Open and used
- Unopened and expired

This document considers best practice guidelines for the reuse of only the first two items viz. open and unused, open and used.

### Re-Processing

To successfully reprocess a device that has been used on a patient, institutions must be able to clean it thoroughly, sterilise it to acceptable norms, and ensure that reprocessing and reuse will not degrade its functioning. In order that a used or opened but unused SUD can be reused, a protocol has to be established which identifies the method for

- Reprocessing, repackaging, and resterilising for all items open and unused.
- Cleaning, packaging, and sterilisation for all items that are open and used.

### Definitions<sup>1</sup>

(As defined by the US FDA)

*Medical device* is an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent or other similar or related article, including a component part or accessory, which is:

- Recognised in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolised for the achievement of any of its primary intended purposes.

Single-use device means a device that is intended for one use, or on a single patient during a single procedure. The labelling identifies the device as disposable and does not provide instructions for reprocessing.

Disposable single-use device is one whose sterility has been breached or whose sterile package was opened but the device has not been used is termed as 'opened but unused single use device'.

Reprocessed, with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

Original device means a new, unused single-use device.

Critical reprocessed single-use device means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

Semi-critical reprocessed single-use device means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

Life-supporting or life-sustaining device is a device that is essential, or yields information that is essential to the restoration or continuation of a bodily function that is important to the continuation of human life. Such a device is being "used outside a device user facility" when it is used outside of a health care facility (HCF), nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. For example, a device used in a home or a doctor's office is being used outside a device user facility.

Device failure - Failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.

Distributor - Person / company who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper, or labelling of the device or device package.

Distributor, final - Person / company who distributes to the patient a tracked device intended for use by a single patient over the useful life of the device. The term includes, but is not limited to, licensed practitioners, retail pharmacies, HCFs, and other types of device user facilities.

Distributor, multiple - Device user facility, rental company, or any other entity such as a home health care agency that distributes a life-sustaining or life-supporting device intended for use by more than one patient over the useful life of the device.

Bioburden - The population of viable infectious agents contaminating a medical device.

Cleaning - A process that physically removes infectious agents and the organic matter on which they thrive, but does not necessarily destroy infectious agents. The reduction of microbial contamination depends upon many factors, including the effectiveness of the cleaning process and the initial bioburden. Cleaning is an essential prerequisite to ensure effective disinfection or sterilisation.

Contamination - The soiling or pollution of inanimate objects or living material with harmful, potentially infectious or other unwanted material. In the clinical situation, this is most likely to be organic matter and infectious agents but may also include other undesirable substances e.g. chemical residues, radioactive material, degradation products, packaging materials etc. Such contamination may have an adverse effect on the function of a medical device and may be transferred to a person during use or subsequent processing and storage.

Decontamination - A process, which removes or destroys contamination so that infectious agents or other contaminants cannot reach a susceptible site in sufficient quantities to initiate infection or any other harmful response. Differing levels of decontamination are used depending on the device and the procedure involved. The levels of decontamination are either cleaning followed

Disinfectant - A chemical agent that, under defined conditions, is capable of disinfection.

Disinfection - A process used to reduce the number of viable infectious agents but which may not necessarily inactivate some microbial agents, such as certain viruses and bacterial spores. Disinfection does not achieve the same reduction in microbial contamination levels as sterilisation.

**Sterilant** - A liquid chemical agent, which can kill bacteria, viruses and spores. *However this term is not precise and is not used. The term high level disinfectant is preferred.*

**Central Sterile Service Department (CSSD)** - A centralised department specifically designed to reprocess re-usable medical devices and equipment and to distribute pre-sterilised, commercially prepared packages for clinical use.

**Sterilisation** - A process used to render an object free from viable infectious agents including viruses and bacterial spores.

**Washer-disinfector** - An automated machine intended to clean and disinfect medical devices.

### Device classification<sup>2</sup>

Before undertaking reuse, it is necessary to classify the medical device in order to establish whether reprocessing can be safely and effectively performed. Device classification *depends on the intended use of the device and also upon indications for use.* For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialised indication is added in the device's labelling such as, "for making incisions in the cornea". Indications for use can be found in the device's labelling, but may also be conveyed orally during sale of the product. *In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned.* Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

As indicated above all classes of devices are subject to General Controls. General Controls are the baseline requirements of the Food, Drug and Cosmetic (FD&C) Act that apply to all medical devices, Class I, II, and III.

**Class I Medical Device** - a medical device where general controls provide reasonable assurance of safety and effectiveness of device OR the device is not life threatening/life sustaining OR its use is not important for preventing impairment to human health AND/OR its use does not prevent a potential unreasonable risk of illness or injury.

**Class II Medical Device** - General controls insufficient but specific controls exist for e.g. performance standards, guidelines, patient registers, post market surveillance, etc which provide reasonable assurance of safety and effectiveness of device.

**Class III Medical Device** - Neither general controls nor specific controls exist NOR is the device life supporting / life sustaining.

## BEST PRACTICE GUIDELINES

It can be appreciated from the above that every health care facility (HCF) should identify all such single use medical devices that it wishes to reuse based on available evidence and the capacity of the facility to implement the best practices for the same. HCF reprocessor becomes a secondary manufacturer and hence the practices need to be regulated to assure safety and efficacy of the reprocessed device. This regulation however needs to be provided by the local regulatory authorities. The best practice guidelines should also address issues such as registration and listing, adverse event reporting, medical device tracking, quality systems regulation, labelling, etc. Every HCF, before embarking on this activity, should refer to available regulations from local regulatory authorities and feasibility for complying with the same. The facility then can decide on the list of single use medical devices for reprocessing based on this available evidence.

- The reprocessing protocol should consider the material properties and design of the specific device.
- The protocol should ensure safety, efficacy and reproducibility.
- Essential quality assurance should be performed during reprocessing.
- Maximum number of reprocessing cycles should be specified according to devices features, use conditions, and reprocessing protocol.
- Pre-sterilisation processing conditions and techniques are critical for sterilisation success.
- Decontamination, cleaning, and washing procedures, together with sterilisation techniques could induce chemical, physical and morphological modifications on the treated surfaces and potential toxicity of the sterilised device.

## Identify SUDs to be Reused

This is essentially an activity that individual HCFs need to undertake before proceeding any further. This best practice guidelines is dictated by the following factors:

- The ability to achieve effective cleaning.
- The ability to achieve effective sterilisation.
- The compatibility of the device with the cleaning agent, process and sterilant.
- Validation of the process of sterilisation to assure safety.
- The ability to achieve safe pyrogen and endotoxin levels.
- The absorption of the sterilant by the device, which could then be transferred to the recipient (patient) i.e. toxic residues.
- The presence of a quality assurance programme demonstrating that the device has not deteriorated in either form or function during the reprocessing cycle.
- The ability to demonstrate that the original performance specifications continue to be met.
- The cost effectivity of reuse is calculated for each device based on the cost of:
  - Performing the reprocessing procedure
  - Sterilisation
  - Validation (quality assurance)
  - Maintaining relevant documentation.

The Reuse Committee shall frame the 'reuse' best practice guidelines

This best practice guidelines can be arrived at jointly in consultation with the user departments, infection control committee (microbiologists), CSSD personnel, bio-medical engineers and administrators who will form the reuse committee.

## Roles & Responsibilities of Committee Members

**User Department** - should provide the list of devices intended for reuse and the number of times that each such device can be reused based on available evidence and where evidence is not available based on experience with reusing the device without compromising safety and efficacy. Apart from cost considerations, the best practice guidelines should be based on the complexity of the device, which can hamper effective cleaning and sterilisation, and the original method of sterilisation. *Plastic SUDs that have been originally gamma irradiated cannot be resterilised by EtO nor can they be gamma irradiated a second time due to toxic residues.* The possibility and the number of times that a device can be reused should be based on available evidence and where no such evidence is available based on a document from the manufacturer and if such is not available then on consensus experience. Policies based on consensus experience should then be prospectively studied to provide scientific evidence within a reasonable period of time. The proposal for reuse including the procedure for reprocessing should then be written in consultation with members from infection control committee (ICC), microbiologists, CSSD personnel and biomedical engineers and forwarded to the infection control committee.

**CSSD / Local Reprocessing Units** - should assist clinical departments (user) in determining how to effectively clean, decontaminate and sterilise each device. A validation protocol for sterilisation should also be described.

**Bio-Medical Engineers** - should opine on the compatibility of the device with the cleaning and sterilising agents as well as the integrity of the physical and functional characteristics of the device undergoing single or multiple reuse. They should also consider the safety of disassembly of complex devices compromising with subsequent functionality on reassembly.

**Infection Control Committee** - should review the proposal that is thus received from the user departments. The committee microbiology members should assist in the microbiological evaluation of items for potential reprocessing / reuse to determine if sterilisation / disinfection can be achieved. The validation protocol should be assessed.

The 'reuse' committee thus prepares a list of single use devices that are to be reused, a cost-benefit analysis for each reusable item and a method for reprocessing and authorisation.

## Standard Operating Procedure - Reuse

### Clinical Departments / User Departments

Each user department prepares a

- list of single use devices that are to be reused.
- cost-benefit analysis for each reusable item.

User Departments, ICC, CSSD, Biomedical Engineers, Microbiologists

A method for completing each of the components/steps to support the reuse of a disposable or single-use patient-care item. Each component/step must be measurable or observable so that it may be consistently repeated. Each component/step must be accompanied by documentation to support the method for reprocessing, which includes:

1. Reprocessing area
2. Personnel
3. Cleaning and decontamination
  - Disinfection • Rinsing
  - Inspection for physical integrity and functionality • Drying
4. Packaging
5. Labelling
6. Sterilisation
7. Validation of sterilisation process
8. Storage
9. Distribution
10. Inspection
11. Informed written consent
12. Billing schedule
13. Adverse event reporting
14. Time to withdraw a device
15. Documents for completion of each task above
16. Authorisation
17. Dissemination
18. Monitoring and Review

## 1. REPROCESSING AREA

### 1.1 Buildings and Environment

#### 1.1.1 Introduction

The buildings and environment, in which components, devices, and records are received, processed, built or stored and the personnel that perform these operations will be controlled so that finished devices will consistently meet the specifications established by the manufacturer. The degree of control will allow for appropriate changes in such elements as temperature, humidity, bioburden, particles, personnel, components, devices, and records.

#### 1.1.2 Space

The CSSD / local reprocessing units shall have sufficient space and be designed to allow proper cleaning, maintenance and other necessary operations. The design should be such that there is adequate space for receiving, cleaning, packaging, labelling, storing, minimizing contaminants, assuring orderly handling procedures, and preventing mix-ups.

The parameters that need control include particulates from cardboard dust from slitting or cutting operations, microorganisms, humidity, temperature, static electricity, etc. It is recommended to have designated areas for each activity such as receiving, inspection/testing, cleaning and decontamination, drying, packing, labelling, record keeping, etc. Traffic by personnel who do not work in or manage the designated areas should be held to a minimum.

#### 1.1.3. Orderly Operations

To preclude mix ups, distinct operations or processes should be separated either physically, by walls or partitions, or spatially, by providing enough room between operations to indicated that separate activities are being performed so that no activity will spray, dust, or otherwise have an adverse effect on other adjacent activities.

#### 1.1.4. Environmental Control

Some environmental factors to be considered are lighting, ventilation, temperature, humidity, pressure, particulates, and static electricity. The degree of environmental control to be maintained should be consistent with the intended use of device and the Officer-in-Charge CSSD / local sterilisation unit will exercise this control.

#### 1.1.4.1. General Controls

General air conditioning is normally not regarded as an environmental control; however, changes in temperature and lighting can have an adverse effect on employee performance and, in turn, on assuring that the device is properly assembled, inspected, and tested. Air conditioning can control humidity, which, in turn, can affect the generation of static charges. Static charges can damage some electronic components and, in such situations, need to be controlled.

The packaging for sterile devices should be stored in a clean, dry, insect free area.

#### 1.1.4.2. Specifications

##### *Ideal Requirements:*

Particulates	Maximum of 10,000 of 0.5 micron diameter or larger per cubic foot
Humidity	45 ± 5 percent
Temperature	72 ± 2.5°F
Air Velocity	90 feet / minute ± 2 percent
Air Pressure	0.05 inches water between the clean room and other areas

Filters should be replaced as per schedule or as needed based on scheduled inspections.

##### *Minimum Requirements:*

- Adequate space and demarcated area for each activity
- No mix-up between two activities
- Good lighting
- Walls, floors and fixtures made of washable, non-corrosive, non-absorbable material
- Adequate ventilation
- Dust, insect and rodent free

### 1.2 Indicators that should be ensured in CSSD environment include

- Proper attire and dressing anteroom;
- Controlled use of, and entry into, controlled areas;
- Prohibiting eating, drinking, smoking, or gum chewing;
- Preventing use of lead pencils;
- Regulating the storage of glassware and containers;
- Preventing or controlling activities that generate dust/particulate matter viz. the cutting, tearing or storage of cardboard, debris, etc;
- Cleaning the room and production equipment per written procedure;
- The original design and cleaning of work surfaces and chairs;
- Selecting correct furniture and eliminating all non essential equipment;
- Controlling room air quality (amount of particulates, pressure, velocity, and exchange rate);
- Ensuring cleanliness of raw materials, components and tools;
- Controlling the purity, and sterility of process water
- Maintaining filters, and electrostatic precipitators.

### 1.3 Records

Records related to facilities, the environment and personnel practices need to be kept simple. The record of cleaning may be a checkmark, initial, or signature. Where a checkmark is used for repetitive work, the person's name should be on the record at least once. The schedule for cleaning may be posted or filed.

### 1.4 Personnel sanitation practices

A washroom, dressing, storage, and waste facilities should be provided, as appropriate, for personnel to maintain the needed level of cleanliness. Where necessary, such as in a clean room, special clothing and an area to don and store the garments should be provided. Clean room clothing is not to be worn into uncontrolled rooms or out side the facility.

## 1.5 Personal Practices

Eating, drinking, or smoking will be confined to specially designated areas such as a lunch room or employees lounge. Directions and containers or equipment should be provided for timely and safe disposal of rejected items, used cartridges, used gloves, EO exhaust, and other refuse.

## 2. PERSONNEL

### 2.1 Training

The person involved for each activity should be first identified and trained adequately for that activity and found to be competent. A record for the same should be in place. They should also be trained in standard infection control practices (e.g., standard precautions), including those to protect both patients and healthcare workers and should adhere to the same. Written guidelines should be prepared and periodically updated.

### 2.2 Protection

All personnel involved in the actual process of cleaning and sterilisation should receive appropriate vaccines – especially HBV. Personnel protective equipment for each activity should be provided as applicable. First aid for eye splashes and post exposure prophylaxis as applicable should also be available.

## 3. CLEANING & DECONTAMINATION

### 3.1 Prerequisite

Before sending the device for reprocessing, the user should verify that the device can still be reused and has not completed its useful life (has reached the maximum number of reuse stated for that device)

Devices, which have only one end open and are opaque are difficult to clean and should not be considered for reprocessing.

### 3.2 Introduction

Cleaning is an essential prerequisite of equipment / device decontamination to ensure effective disinfection or sterilisation. Cleaning removes soil (organic matter) and a high proportion of infectious agents by washing with a solvent (usually water and detergent), which may be heated. It is advisable to use enzymatic detergents especially for devices with a lumen or opaque items where evaluation of cleaning or visible check for cleanliness is a problem.

*All devices that have undergone cleaning and decontamination should necessarily be dried before being sent for sterilisation.*

*Cleaning can be achieved by either manual or automated methods.*

The advantage of using automated cleaning equipment is that it provides an efficient, reproducible process that can be more easily controlled than manual methods. It also provides protection for the user in reducing the exposure to aerosols, chemicals and vapours. Automated cleaning equipment include the thermal washer-disinfectors and the ultrasonic baths.

Disinfection with thermal washer-disinfectors will inactivate all microorganisms except bacterial spores, some heat-resistant viruses and cryptosporidium. This process can be used only for devices that will withstand repeated exposure to wet heat at temperatures of about 80°C. The devices must be sufficiently robust to withstand powerful water jets and be compatible with the detergents.

Exclusions:

- Excluded are hollow or porous items where the hot water will not adequately penetrate any internal lumen unless special adaptors to allow access to lumens are available.
- This process does not sterilise but items may be sterilised subsequently by an appropriate process.

The equipment has a high initial cost and requires adequately trained staff to operate and load the machine correctly. Planned preventative maintenance costs may be high and will include routine thermometric monitoring. The process may need water of a specified quality, both to disinfect and then to rinse disinfected devices.

The use of ultrasonic baths and enzyme detergent solutions for cleaning devices is recommended where the process is compatible with the

device. All lumens should be irrigated during ultrasonic cleaning to remove dislodged organic matter. Irrigation pumps are available for flushing instrument lumens and components.

### 3.3 Safety

- Care should be taken in the direct handling of intricate or sharp-edged devices to avoid injury to the handler or damage to the device.
- A waterproof protective apron or gown and robust rubber gloves should be worn.
- Eye protection may be required if splashing is likely to occur.
- The production of aerosols during the cleaning process and the provision of adequate protective equipment should be considered as part of the risk assessment. While flushing it is advisable that the activity is done with the sink filled with water.
- For devices with lumen special care should be taken while injecting the cleaning solution into the lumen so as not to cause damage.

### 3.4 Equipment Required

- A sink (not a designated hand wash basin), or a receptacle, which will hold sufficient volume of water/detergent such that the device to be cleaned can be fully immersed.
- A compatible enzymatic detergent solution at correct dilution, temperature and used for the correct contact time as available. (Follow manufacturer's instructions when available)
- Brush(es) and jet washer / handspray.
- A receptacle to contain rinse water e.g. a second sink; a drainage surface.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility e.g. drying cabinet or industrial hot air dryer.
- A chemical neutraliser, first aid kit and eye wash station in case of splashing with detergent.
- Free flowing potable water

### 3.5 Collection

- Reusable devices shall be separated from waste at the point of use itself.
- Personnel assigned to handle, collect and transport medical devices and equipment shall wear protective clothing to prevent his / her direct contact with blood or other body fluid during handling.
- Primary cleaning should be done immediately after a device has been used at the user end itself before transporting to the reprocessing area. Care should be taken to clean both the exterior surface as well as the interior lumen where applicable. At the user end, immediate on site the device is rinsed in potable cold water / tap water at room temperature and forced jet spray and flushed frequently with heparinised saline where required (especially devices which have blood or blood products in their lumen)
- The device should be inspected for physical integrity before further processing.
- All items in direct contact with patients or their body fluids should be considered to be contaminated and should be safely and securely contained. The item should be isolated in a robust, leak-proof box or plastic bag. Items should be transferred to the reprocessing area as soon as possible after pre-cleaning.
- Containers and trolleys/carts used for transporting such items should be easy to clean and disinfect, properly maintained, provide protection for the load and be designed so that items can be securely and safely held during transit.
- Items will be received into the designated dirty items section of the decontamination area. The item should be checked and the user notified if any part of the equipment is missing upon receipt.

### 3.6 Cleaning

- Cleaning of contaminated reusable medical devices shall begin as early as possible to facilitate easy cleaning and prevent drying of any left over soil / organic matter on medical devices.
- Devices composed of more than one part shall be disassembled and all jointed instruments opened.

- All devices shall be sorted according to the method of cleaning applicable.

### 3.6.1 Technique:

- The devices are again rinsed thoroughly in potable water.
- Care must be taken to remove all organic matter as appropriate to the article especially from lumens and balloons by repeated flushing action.

#### 3.6.1.1 Procedure 1

- Clean the device under reprocessing preferably with an alkaline enzymatic detergent from inside as well as outside to make it free from organic and inorganic matter. *Enzymatic detergents cannot be used at temperatures above 50°C.*
- Meticulously clean the entire surface of the device including all detachable parts, according to the manufacturer's instructions if available. Flush (at least five times) and brush to remove all organic (e. g. , blood, tissue) and other residues.
- Discard enzymatic detergents after each use because these products are not microbicidal and will not retard microbial growth
- Rinse with potable tap water / sterile distilled water.
- Dry with the help of oil, dust and moisture free compressed air using air jet having different adaptors to fit the different devices.
- Inspect the device for complete dryness, any evidence of damage and its function.
- Decontaminate used brushes after each use and discard if there are signs of wear.

#### 3.6.1.2 Procedure 2 - for narrow lumen devices

- Water spray the cannulae / lumen till clear water comes out.
- After initial cleaning, immerse the device for at least 2 hours in detergent disinfectant taking care to see that the disinfectant has reached the lumen.
- If blood clots are detected in the cannulae, immerse in 5% tri-sodium-phosphate at least for half an hour to dissolve all organic matter.
- Water spray the cannulae for at least 10 minutes to ensure all foreign matter is removed from inside the cannulae.

#### 3.6.1.3 Procedure 3 - Cleaning (manual) - non-immersion

- Non-immersion manual cleaning methods are appropriate for certain equipment where items will become compromised by soaking in aqueous solutions, e.g. electrical and electronic equipment.
- Alcohol wipes should be used to clean electrical contacts on equipment.
- Check for intactness of insulation especially on batteries as repeated sterilisation causes damage to the seals / outer covering.

#### Requirements

- Preferably an alkaline enzymatic detergent solution compatible with the device at correct dilution.
- A clean, disposable, absorbent, non-shedding cloth for application of detergent solution.
- A clean, disposable, absorbent, non-shedding cloth or mechanical drying facility (e.g. drying cabinet or industrial hot air dryer).
- An appropriate chemical neutralizer, first aid kit and eyewash station, in case of splashing with detergent.

#### Procedure

- If the item is electrical, ensure that it is disconnected from the mains supply before commencing the cleaning procedure.
- Wearing protective clothing, immerse the cleaning cloth in the detergent solution and wring thoroughly.
- Commencing with the upper surface of the item, wipe thoroughly ensuring that detergent solution does not enter electrical components.
- Periodically rinse the cloth in clean water and repeat the above steps.

- Surfaces should be carefully hand-dried using a cloth or industrial hot air dryer or placed into a drying cabinet.
- Safely dispose off cleaning materials and alcohol wipes, after use.

#### Safety Precautions (additional)

- Precautions should be taken when using alcohol, as it is flammable.
- The 'pooling' of alcohol on equipment should be avoided and alcohol evaporation ensured, if necessary by forced air drying.
- Care should also be taken to ensure that alcohol does not enter the item e.g. via ventilation slots.

### 3.7 Drying and Inspection

- For certain devices (narrow lumen/balloon) it may be necessary to test the functionality before drying.
- Ensure drying by passing, oil and moisture free, dry compressed air through it. It shall be kept for atmospheric drying if devices are delicate or not able to withstand air pressure.
- Industrial / other blowers also may be used to facilitate this process
- Alternatively, flush the channels / device with 70% to 90% ethyl or isopropyl alcohol / ether and dry with forced-air.
- The devices shall be inspected for complete dryness, damage and its function performed by user department, after the process of cleaning and decontamination.
- If found satisfactory, the device is processed further for sterilisation.
- The items will then be contained in clean preferably sterile containers and sent to CSSD / local sterilisation facility for further processing.

### 3.8 Monitoring and Control

Since there are no standard methods to monitor the process of cleaning, factors that can affect its efficiency should be controlled.

- Staff training / competence
- Water quality
- Detergent type, concentration, contact time and compatibility
- Nature of soil (organic matter)
- Method of soil removal
- Accessibility of fluid to item
- Thorough rinsing
- Thorough drying

### 3.9 Maintenance

- Regularly inspect all receptacles, sinks, surfaces including water supply and drains, for damage.
- Plan preventive maintenance for all equipment and utilities especially when using automated washers.

### 3.10 Documentation

Complete the necessary documentation. (Fill checklist, and sign)

### 3.11 Automated Cleaning & Decontamination

If automated washer/washer disinfectors are used, validate the equipment, follow manufacturer's instructions and use compatible cleaning / decontamination agents.

Have a planned preventative maintenance programme.

## 4. PACKAGING

### 4.1 Introduction

Appropriate packaging ensures the sterility of the product through its intended shelf life, as well as its efficacy at the time of use. For effective EtO sterilisation the packaging material must be breathable to allow the high-humidity EtO gas mixture to infiltrate the package. A partial vacuum is drawn before and after the cycle to facilitate the movement (in and out) of the EtO and moisture vapour. If the package does not have sufficient permeability, the process will be ineffective. As stresses in the seal area are introduced due to the pressure difference between the inside and outside of the package, a seal failure phenomenon known as steriliser creep may occur. The package must also withstand the moderately elevated process temperatures, although this is typically not a problem for most materials. *Please check with the equipment / EtO gas provider, the correct packaging material to be used.*

If the correct packaging material is not used, packages can burst from the repeated high and low pressures to which they are exposed as EtO penetrates in and evacuates. Some materials with a high affinity for EtO (polyurethane or plasticised PVC) may require several evacuation cycles to reduce EtO residuals. Large amounts of toxic ethylene chlorohydrins can form from chlorine-containing materials in the sterilised product. Excessive temperatures can distort or melt some materials.

## 4.2 Procedure

- The items are wrapped in medical grade packaging roll (one side polythene and other side medical grade paper). Double wrapping shall be ensured to avoid contamination.
- Excess air must be removed from packets before sealing, to avoid bursting. This process may not be required while using polypropylene pouches. What is important is to cheque the integrity of sealing.
- The devices shall be identified by writing cycle number and date of expiry on the packages.
- Commercially available heat sealable pouches and rolls specially made from medical grade paper and polyethylene film (thickness 1-3 mils [one thousandth of an inch] and width 7.5-30 cm) must be used. They have the advantage that the contents are readily visible after packing, to allow for easy identification. These come with printed chemical indicator hence separate chemical indicator need not be used.

## 5. LABELLING

### 5.1 Definitions - Labels and Labelling

A "label" is a "display of written, printed, or graphic matter upon the immediate container of any device." Any information required on the immediate container of a device must also appear on the outside container or wrapper, if any, of the retail package for the device, or be easily legible through the outside container or wrapper.

"Labelling" is defined as: "all labels and other written, printed, or graphic matter"

- 1) Upon any device or any of its containers or wrappers, or
- 2) Accompanying such device.

### 5.2 Requirements

If a HCF reprocesses a SUD, the HCF is responsible for ensuring that the device complies with all applicable regulatory labelling requirements. If the HCF does not ensure the device complies with FDA labelling requirements, the device is misbranded, and the HCF may be considered responsible for causing the misbranding of the device in violation of the Act.

- a. Include the name and address of the manufacturer (reprocessor), packer, or distributor.
- b. Bear the common or usual name of the device
- c. State the quantity of contents

Apart from the above. The label should clearly state the date it was packed and sterilised, the method of sterilisation, the date of expiry, the storage conditions, and its reprocessing number where applicable.

Labels may be colour coded to identify the cycle number.

## 6. STERILISATION

The device shall be sterilised by an appropriate sterilisation method for that device for e.g. ethylene oxide gas sterilisation method or vaporized hydrogen peroxide. The process of sterilisation should be strictly controlled and as per the manufacturer's instructions. The Cycle parameters must be verified, using the steriliser manufacturer's instruction manual for specific steriliser and load configuration, to be used.

### 6.1 Ethylene Oxide (EtO)

#### 6.1.1 Prerequisites

Sterilisation by EtO requires that the devices are dry.

#### 6.1.2 Parameters for EtO Sterilisation.

The critical parameters of an EtO sterilisation cycle are typically given as temperature, pressure, humidity, EtO concentration, and gas dwell time.

The cycle parameters and aeration time should be as per the manufacturer's recommendations.

#### 6.1.3 Monitoring EtO Sterilisation

- Chemical indicator (as per ISP 11140-1) shall be placed externally in the form of strips or printed on packaging material itself to differentiate processed from non-processed packages. Class 5 chemical indicators can be used in the same test pack which helps to take immediate decisions about issuing the load instead of waiting for the BI report.
- A HCF SUD reprocessor should prove during validation studies that each sterilisation process is capable of achieving sterility for each run. The sterilisation process should achieve a sterility assurance level (SAL) of 10<sup>-6</sup> for devices used in normally sterile areas of the body.
- The efficiency of EtO steriliser shall be tested by challenging a biological indicator (*Bacillus subtilis* 1264 from 3M or any other supplier) in the centre of each load. The test pack of BI should be placed at the diagonally opposite end.
- Process chart readings, particularly showing the temperature and pressure reading shall be monitored for each cycle.
- Aeration time and temperature shall be noted for each load.

### 6.2 Other methods of sterilisation used will depend on the device compatibility with that method for e.g. low temperature plasma sterilisation

#### Low Temperature Plasma Sterilisation

Is a combination of hydrogen peroxide vapour and low temperature gas plasma 50°C which can rapidly sterilise medical devices without leaving toxic residues. This process is suitable for heat and moisture sensitive devices.

The other pre-requisites for sterilisation remain the same.

If a device contains moisture, and is inadequately dried, the cycle will be rejected.

Packaging pouches are provided by Tyvek™.

Validation for each cycle should be performed with BIs.

A reference list of compatible medical devices can be obtained from the manufacturer. The materials not compatible with this system are linen, powders, liquids, wood and cellulose because these absorb hydrogen peroxide, which is therefore not available for the sterilisation process.

### 6.3 Testing for Residual Chemicals

Especially with EtO sterilisation, it is important to check the levels of residual chemicals in order to ensure that they are within acceptable limits. This activity should be carried out every time that a new instrument is installed, at the time that the equipment is recommissioned after major repairs, whenever there is a change in the cycle protocol and once every year.

### 6.4 Record Keeping

Following observations shall be recorded for each load - Date, load number, process chart for the cycle, aeration time and temperature, list of contents of the load.

A record also shall be maintained of material received and issued.

Record of Biological indicator tests shall be maintained.

### 6.5 Job Assignments

- Only trained and experienced labour staff shall carry out the cleaning and decontamination/disinfection process.
- Inspection and packing of devices shall be done by trained technicians.
- The sterilisation process shall be controlled and carried out under supervision of Section In charge / Scientific Assistance who documents all the records.

## 7. STERILISATION VALIDATION

### 7.1 Definition

The term "*Validation*" means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

*Process validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

### 7.2 Documentation

Maintain documentation to show that

- Equipment has been installed correctly and operates as intended.
- The sterilisation process has been validated as being effective in achieving sterility without adversely affecting the devices (chemical and biological indicators, physical parameters).
- For each run the specifications for sterilisation parameters have been met.

## 8. STORAGE (See section 1 above)

## 9. DISTRIBUTION

A record should be maintained for all the reprocessed devices giving details about its further distribution. Once the device is bought from the original device manufacturer, an entry should be made in the device distribution register. Apart from the device details this register should have columns to indicate the patients who have received the device. The number of columns used for each device should correspond to the number of reuse allowed. For all such times except the first, the reprocessing date should also be mentioned clearly.

## 10. INSPECTION BEFORE REUSE

On receiving a sterile reprocessed device, the sterilisation, package integrity, useful shelf-life and any damage should first be ascertained before use on a patient. One should also ascertain that there is no moisture inside the pack.

## 11. INFORMED WRITTEN CONSENT

Since the original device manufacturer does not recommend reuse, it is necessary to provide an informed choice to the patient about the use of reprocessed single use devices and any risk involved. An appropriate written informed consent should be obtained from the patient and this record should be maintained till the life of the device or patient whichever is later.

## 12. BILLING SCHEDULE

A billing schedule to describe the method for patient billing throughout the useful life of the item based on the cost of reprocessing and other related costs.

## 13. ADVERSE EVENT REPORTING

### 13.1 Introduction

A surveillance strategy to monitor patients for adverse outcomes should be established.

Individual adverse events need to be reported to the regulating authority and to the manufacturer as and when they occur so that prompt corrective measures can be instituted. The regulating authority should prepare a uniform format for the same and define the maximum time delay within which an adverse event should be reported.

As a HCF reprocessor of a device that was previously marketed as single-use, the reprocessing HCF has become the manufacturer of that device.

### 13.2 The Adverse Events to be Reported as a Reprocessor Include

- Deaths
- Serious Injuries
- Malfunctions that do not result in death or serious injury
- Remedial actions

As a SUD HCF reprocessor, the HCF should report adverse events as early as possible on becoming aware of a reportable event(s) that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health

"*Serious injury*" is defined as an injury or illness that:

- Is life-threatening;
- Results in permanent ("Permanent" means, irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage) impairment of a body function or permanent damage to body structure; or
- Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

"*Malfunction*" is defined as the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labelling for the device. The intended performance of a device refers to the intended use for which the device is labelled or marketed

## 14. WITHDRAWAL OF SUDS

The time to withdraw the medical device will be decided by the committee taking into consideration the useful life of the device and its continued functionality and integrity. The latter evidence will be maintained by CSSD.

## 15. DOCUMENTATION

### A. Supporting documentation for the written proposal

- Document attesting that an item can be effectively cleaned and reprocessed.
- Document approving the effectiveness of the cleaning and sterilisation / disinfection procedure.
- Document certifying that the item can withstand reprocessing and reuse without loss of structural mechanical or chemical integrity.
- If no scientific evidence or document exists for any of the activities listed above then based on past experience, documents can be prepared and the ongoing data collected to validate the same.

Level of Evidence	Type of Evidence
I	Evidence obtained from a systematic review of all relevant randomised controlled trials.
II	Evidence obtained from at least one properly designed randomised controlled trial.
III-1	Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method)
III-2	Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies, or interrupted time series with a control group
III-3	Evidence obtained from comparative studies with historical control, two or more single-arm studies, or interrupted time series without a parallel control group.
IV	Evidence obtained from case series, either post-test or pre-test and post-test

## B) Documents to Validate the Reprocessing Process

- Checklist to be completed at each cycle for the cleaning and decontamination process
- Process validation – sterilisation
- Equipment validation and maintenance records
- Adverse events recording
- Tracking of medical devices
- Record of toxic residue testing

## 16. AUTHORISATION

Before a facility is allowed to reprocess a SUD it should obtain license/authority to do so from a recognised body for the same. The periodicity of this licensing should be decided by the authorising body, but it is recommended that it should be at least for a period of three years. Since, for India, this would be the first time, the authorising body should prepare its own appropriate check list for the same and notify the reprocessor well in advance so that auditing can be satisfactorily completed by the reprocessor based on the requirements of the regulatory authority.

## 17. DISSEMINATION

Once the facility is authorised to carry out reprocessing, the information should be disseminated to all the concerned staff members while requesting a feedback on the effectivity and ease of the procedure.

## 18. REVIEW

The process should be reviewed at least annually and every time an adverse event is reported. Corrective action should be taken immediately and the same should be disseminated to all concerned staff members.

*We invite your comments and suggestions regarding best practice guidelines on reuse of single use medical devices at [hisi@HISIndia.org](mailto:hisi@HISIndia.org) before 31 December 2007.*

## ANNEXURE

## Reuse of Medical Devices in Haemodialysis Unit

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### Introduction

Haemodialysis is an expensive treatment, hence dialysers and blood tubings are reprocessed for reuse on the same patient. Reuse of these devices is an accepted practice worldwide. Apart from cost reduction, reprocessing of dialysers has some clinical benefit.

### Water Quality in Reprocessing

It is extremely important that water source used in reprocessing should meet or exceed AAMI (Association for the Advancement of Medical Instrumentation) standard. Water quality is essential because endotoxin or endotoxin producing bacteria may enter the reprocessed dialysers and blood tubings or when contaminated water is used to prepare germicides and can cause pyrogenic reactions during subsequent dialysis. Water used to reprocess dialysers and blood tubings must have <200 cfu/ml organisms and endotoxins <1 ng/ml. Monthly testing water for above parameters must done and the records maintained.

### Procedure of Reprocessing Dialysers

The manual method of reprocessing used in Indian centres is as follows:

1. Reprocessing is started immediately after termination of the dialysis.
2. Return blood from the circuit to the patient with 200 ml of saline using the machine's blood pump.
3. Place the end of the arterial tubing in a container of demineralised water, and the end of the venous line in a clean empty bucket. Start the blood pump at a speed of about 150 ml/minute. Pre-rinse the entire circuit, maintaining a pulsatile flow by periodic clamping of

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the venous outflow line to dislodge adherent blood products. Tap the arterial and venous headers to remove air bubbles and small clots.

4. Disconnect the arterial and venous tubings and transport the dialyser to the reprocessing area.
5. Fill the dialysate compartment with 3% hydrogen peroxide, for 2-3 minutes.
6. After closing one outlet of the dialysate compartment, connect a water source, providing treated water at 3 litres minute to the other port using a Hansen's connector. Perform reverse Ultra filtration in 3 cycles of 12 minutes each, clamping one outlet line of the blood compartment during the process. Reverse the direction of the flow with each cycle and rinse the blood compartment for 2 minutes during alteration of flow.
7. Fill the dialysate compartment with demineralised water and close both ends.
8. Inspect the dialyser for large clots in the headers or >20% of discoloured fibres, and discard, if present.
9. Perform total cell volume (TCV) estimation by displacing the water from the blood compartment into a measuring cylinder using a sphygmomanometer bulb. *Dialysers are discarded if the TCV falls to <80% of its initial value.*
10. Again rinse the blood compartment with treated water using pulsatile flow, by clamping the outflow line to remove air, and then reconnect the dialyser to the tubings. Place the arterial tubing end in a container of 4% formalin.

11. Start the blood pump; fill the blood compartment, tubings and chambers with 4% formalin using the machine's blood pump. Carefully aspirate formalin into all arterial and venous tubing side limbs with a 10 ml syringe and clamp each tubing and close with a beta cap. Finally connect the arterial and the venous tubing ends to each other with an "S" connector. Fill the dialysate compartment with the patients name and store in an individual.
12. Label the reprocessed dialyser with the patients name and store in an individual compartment at room temperature until the subsequent dialysis session.
13. During priming for subsequent dialysis, formalin is removed as described in the priming procedure.

#### Chemicals used in Reprocessing of Dialyser & Blood Tubings

*Bleach (Sodium Hypochlorite 1%)* is used as a cleaning agent. Use of bleach is associated with increase in pore size & KUF. It damages the membrane and its use is associated with protein loss.

*Hydrogen Peroxide (3%)* is used as a cleaning agent. It does not remove protein deposits and must be stored in airtight container. Deionised water should be used for dilution and it is an unstable solution.

*Peracetic acid (2%)* is used as a cleaning agent and for disinfection and it retains protein on dialyser membrane.

*Formaldehyde (40%)* is a useful agent because it does not degrade or change membrane properties. The minimum concentration required is 4% and minimum dwell time 24 hours. It is carcinogenic & an occupational irritant, leading to formation of anti-nuclear like antibody and improper removal may lead to acute reaction.

*Citric Acid* is used with heat to disinfect dialyser filled with 1.5% citric acid & heated over 95 degrees Celsius for 20 hours. Thus, this requires a temperature resistant membrane, or else the high temperature will result in membrane damage & leakage of blood.

#### Total Cell Volume:

1. Total cell volume (TCV) measurement is the most widely accepted rejection parameter, as an indirect indicator of clearance performance. TCV is not fibre bundle volume (FBV) test. The FBV is only volume of fibres. The TCV is the value of the FBV and the header cap volume. Dialyser must be discarded when this value changes by more than 20% of original value. The effect or germicide can increase or decrease the clearance cannot be detected by TCV measurement.
2. Changes in TCV directly correlate with changes in diffusive capabilities of the dialyser. When individual fibres became plugged, fibres are lost with reduction in, solute transports and there is a decrease in overall clearance. This loss in transport is non-linear because the higher velocity in the remaining fibres causes an increase in the diffusions rate inside the fibre. This explains why 20% loss in surface area only yields about ten percent loss in urea clearance.
3. 80% initial volume is the cut off point, at which the dialyser must be discarded.

Example: dialyser has an initial volume of 150ml. This dialyser must be discarded if the volume falls below 120ml.

#### Leak Test

1. Leak Test is performed to test for broken fibres or cracked potting compound. The pressure should be created 20% higher than maximum operating temperature. The rate of pressure decrease must be equal to or less than that of a new dialyser. All modern automated reprocessing units do this test automatically.
2. It is also called the pressure test. Pressure applied to blood compartment of dialyser and held. Rapid change in pressure would indicate a broken fibre, which would cause blood leak during dialysis.

Failure of this test requires that dialyser be discarded.

#### KUF Test

1. Measurement of dialyser ultra filtration rate, which changes with use and reprocessing.

2. This is not an adequate indicator of diffusive clearance changes.
3. Evidence suggests that in-vivo KUF testing could be an indicator of convective and large molecule clearances.

#### Visual Inspection

1. There should be minimal size of clotting in the filter or the header of the dialyser.
2. The dialyser should be inspected for cracks and breakage.
3. The dialyser must be properly labelled with patient and dialyser information.

#### Disinfections of Dialysers to assure that all Microbial Contamination is Eliminated

1. AAMI recommends that dialyser be filled with germicide repeatedly until the influent germicide concentration is within 10% of the original concentration and that the dialyser ports then be disinfected and sealed with new or disinfected caps.
2. Monthly test for total bacteria and endotoxin level in the water used to make up the germicide should be conducted. Testing of the germicide final used concentration should be part of centre's quality control programme, as well as verifying that each dialyser was filled with germicide.
3. The duration of storage should be appropriate for the agent used to disinfect the dialyser.
4. The presence of germicide should also be checked before the dialyser is stored for next treatment
5. Only certain dialysers can be used in this process.

#### Disinfection of External Surface:

Dialyser exterior must be cleaned and disinfected with low-level germicide, such as bleach diluted to a concentration of 1:100 of sodium hypochlorite.

#### Do's & Don't in Reuse of Medical Devices in Haemodialysis

- Ensure proper filling of dialyser with disinfectant / sterilant
- Ensure proper concentration of disinfectant / sterilant
- Ensure adequate dwell time
- Reprocessed dialyser should not be stored with new dialyser
- Storage condition should minimise deterioration, contamination or leakage
- Storage system should ensure that dialyser has enough dwell time & not so long that the disinfectant loses potency
- Dialyser is labelled properly, verify name
- No structural damage or tampering has occurred
- Dialyser ports are properly capped & there is no leakage from dialyser port of other part of dialyser
- Cosmetic appearance of dialyser is acceptable
- Test for presence of germicide
- Rinse out germicide completely
- Test for residual germicide
- Verification of label
- Ensure dialyser is reprocessed properly
- Monitoring patient during dialysis
  - Blood pressure - high/low
  - Pyrogenic reaction
  - Acute blood loss
  - Pain around vascular access site
  - Unexplained changes in blood chemistries
- If performed correctly, it's safe & effective
- 20% decrease in TBV will cause 10% decrease in clearance
- Reprocess HBsAg & HCV positive dialyser & blood tubings separately

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# IX HISICON 2007

## A brief Report by the Organising Secretary

Dr Jagdish Chander

Professor & Head, Department of Microbiology, Government Medical College Hospital, Chandigarh

The Hospital Infection Society of India held its IX National Conference (IX HISICON 2007) from 16 to 18 February 2007 at the Government Medical College Hospital (GMCH), Sector 32, Chandigarh, India. It was attended by 300 delegates, from various medical institutions all over India. These included microbiologists, surgeons, clinicians and administrators, all of whom were actively involved in policy and decision making towards the control of hospital infections. The theme of this conference was - "*Hospital Infection - The Challenge Ahead*".

### Pre-conference CME on Nosocomial Fungal Infections

A pre-conference Continuing Medical Education (CME) on "*Nosocomial Fungal Infections*" was organised on 15 February, in which 200 delegates from various medical institutions in India participated. The issue of "Nosocomial Fungal Infections" was taken up for the first time in the country. Speakers, from within the country and abroad, delivered lectures on various topics. "*Overview of Nosocomial Fungal Infections*" was delivered by Prof TD Chugh from New Delhi. Other topics were "*Epidemiology of Nosocomial Candidiasis*" by Prof A Chakrabarti from Chandigarh, and "*Nosocomial Mould Infections*" by Dr R Iyer from Hyderabad. Professor Jagdish Chander, Chandigarh spoke on "*Role of Fungi in Surgical Wound Infections*". Dr W Curtis White from Michigan, USA covered "*Fungi in Health Care Environment*". Lecture and discussions were carried out on Invasive Zygomycosis, Fungal Infections in ICUs and Transplant Recipients and Fungal Aerobiology. Current topics of interest such as "*Molecular Typing of Fungal Pathogens*" was covered by Dr A Chowdhury (VPCI, Delhi), and role of "*Antifungal Prophylaxis in High Risk Hospitalised Patients*" by Dr Vivekanand Jha, were discussed. Dr Juhi Taneja from GMCH, Chandigarh spoke on "*Hazards to Laboratory Staff Posed by Fungal Pathogens*". Lastly, there was a panel discussion on "*Guidelines for Management of Nosocomial Fungal Infections*", panelists for which were Dr KK Gombar, Dr R Iyer, Dr Anuradha Chaudhary and Dr Jaswinder Oberoi, and was moderated by Prof TD Chugh.

### Highlights of the Conference (16-18 Feb 2007)

The conference was a three days' deliberation which provided guidelines and scientific evidence to control and handle hospital acquired infections. The proceedings for the first day of the conference were eventful. After the welcome note, leading national and international experts having immense contribution in this field presented their talks and shared their experiences. The day started with lectures on '*Hospital Infection Control - International views*' by Dr Anneriet Van Duin from Netherlands and Dr Aruna Shahani from Sri Lanka. After a short tea break the sessions continued; the first one was on Drug Resistance and then on Information Technology in Hospital Infection Control. Dr Afia Zafar from Pakistan, Dr Nandini Shetty from UK and Dr Niranjan Nayak from AIIMS, New Delhi shared their experiences on the problem of drug resistance in Pakistan, London and India, respectively. Management issues of drug resistance were discussed by Dr Reba Kanungo from Pondicherry and Dr Ratna Rao from Hyderabad. Mr Michael Shemko, Dr Sanjeev Singh and Dr Anuj Sharma talked in detail about Web Based resources for infection control and also elaborated upon software development.

Post lunch session proceeded with special lectures on bench marking for patient safety and quality care by Dr Ulrika Ransjo from Sweden and on accreditation by Dr Akhil Sangal. Dr Bipin Aggarwal talked about super oxidized water which would start a new era in hospital infection control. The first Prof Brahm Prakash Memorial Oration was delivered by Dr Ganesh Mani, a renowned cardiothoracic surgeon and the oration was chaired by Prof KB Sharma, leading microbiologist and advisor.

In the evening, the inauguration ceremony of the IX HISICON 2007 was done by hon'ble Chief Minister (Haryana), Shri Bhupinder Singh Hooda. Release of the Souvenir was done by Dr Meera Sharma. Dr Geeta Mehta, President of HISI addressed the gathering on the theme of the conference '*Infection Control - The Challenge Ahead*'. Dr TS Jain, Dr Raman Sardana and Dr Anita Arora accompanied the dignitaries on the dais along with Director Principal Dr HM Swami. Dr Jagdish Chander introduced the Conference and Dr Varsha Gupta proposed the vote of thanks.

The proceedings for the second day of the conference started with lectures on '*Hospital Design and Infection Control*' by Dr Anil Gupta (MS, PGIMER, Chandigarh) and Dr V Murlidhar from Delhi. It was followed by a lecture on Nutrition and Infection Control by Dr Prabha Desikan. There was a session on Occupational Infection Hazards in which Dr TS Jain, Dr Ritu Singh Chauhan delivered lectures, Dr Pallab Ray and Dr Saurabh Datta delivered lectures on infections in NICU. Speakers from abroad, Dr Caroline Pankhurst and Dr Geoff Scott from UK, Dr Gunter Kampf from Germany, Dr Ulrika Ransjo from Sweden and Dr Charlotte Owens from USA spoke on Occupational Infection Hazards, Hand Hygiene and Surgical Site Infections, respectively. Major issue of Hospital Waste Management was taken up by Dr KS Baghotia, Dr Kamlakar Vaidya and Dr Shyamala Mani.

The last day of the Conference started with a lecture by Dr Sujata Baveja from Mumbai who spoke on '*Issues related to single use of Medical Devices*'. The day proceeded with lectures on '*Disinfectants and Disinfection, HIV Transmission in Health Care*' by Dr Neeta Patwardhan, Dr Preeti Mehta and Dr Archana B Mohan. Dr Hans Rodger from Germany cleared some facts about use of disinfectants in viral infections. Medico-legal aspects of Transmission of Infection were taken up by Dr Krishan Vij, Professor & Head, Department of Forensic Medicine, GMCH, Chandigarh. Dr Christopher Armstrong from UK talked on various aspects of *Clostridium difficile* and Atomic Force Microscopy - An Emerging Biomedical Tool was taken up by Dr DS Chitnis from Indore.

A number of free papers including oral presentations and posters were presented at the conference. The best oral paper presentation and poster presentation were won by Dr Renu Goyal from LHMC Delhi and Dr Manisha Biswas, respectively.

The Conference concluded with the Valedictory Function. Dr Jagdish Chander and Dr Geeta Mehta thanked all the delegates who attended the Conference and the Organising Committee for making the event successful. The prize distribution was done. In addition to the best paper prizes, first and second prizes were awarded for National Quiz on Hospital Infections and were won by Dr Balwinder Mohan and Dr Juhi Taneja, respectively.

### Milestones of the Conference

- The first memorial lecture instituted in the memory of Prof Brahm Prakash, a leading neurosurgeon and past president of HISI,
- Launch of the HISI website, <http://HISIndia.org>, and
- First meeting of the Infection Control Nurses Forum attended by 20 infection control nurses from India and 2 from UK.

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