

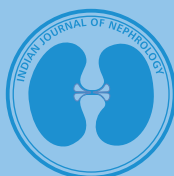
ISSN 0971-4065



Vol 22, Supplement, December 2012

INDIAN JOURNAL OF NEPHROLOGY

Indian Society of Nephrology
Guidelines for
Hemodialysis Units

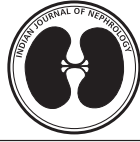


Official Publication of the Indian Society of Nephrology

Free full text at
www.indianjnephrol.org



Medknow



Editor

V Sakhuja

Deputy Editors

V Jha, HS Kohli

Associate Editors

SK Agarwal, GT John, V Kher, AS Narula, R Pisharody

Editorial Board

A Almeida, CK Jacob, AL Kirpalani, KK Malhotra, SC Tiwari

Emeritus Editors

KS Chugh, RK Sharma

Advisory Board

National

G Abraham (Chennai)
Anuradha (Hyderabad)
AK Bhalla (New Delhi)
N Choudhury (Guwahati)
KV Dakshinamurthy (Hyderabad)
SC Dash (Bhubaneshwar)
AR Datta (Calcutta)
KL Gupta (Chandigarh)
M Jayakumar (Chennai)
K Joshi (Chandigarh)
OP Kalra (New Delhi)
A Gopal Kishan (Hyderabad)
MA Muthusethupathi (Chennai)
G Narayen (Hyderabad)
DK Pahari (Calcutta)
SK Pareek (Jaipur)
KC Prakash (Chennai)
MM Rajapurkar (Nadiad)
DS Rana (New Delhi)
BV Shah (Mumbai)
PP Varma (New Delhi)
R Kasi Visweswaran (Trivandrum)

International

A Agarwal (USA)
VK Bansal (USA)
JM Bargman (Canada)
CR Blagg (USA)
J Chapman (Australia)
M DeBroe (Belgium)
J Feehally (UK)
R Khanna (USA)
N Lameire (Belgium)
R Mehrotra (USA)
RL Mehta (USA)
BVR Murthy (USA)
S Naicker (S Africa)
D Pugsley (Australia)
K Venkateswara Rao (USA)
TKS Rao (USA)
M Sayegh (USA)
A Singh (USA)
PC Singhal (USA)
K Sud (Australia)
M Suthanthiran (USA)
JJ Weening (Amsterdam)



Indian Journal of Nephrology

Official Publication of the Indian Society of Nephrology

General Information

The journal

Indian Journal of Nephrology (ISSN: Print -0971-4065, Online -1998-3662) is peer-reviewed journal published on behalf of the Indian Society of Nephrology. The journal publishes information relating to nephrology. The Journal is published bimonthly in January, March, May, July, September and November.

Abstracting and indexing information

The journal is indexed/listed with Abstracts on Hygiene and Communicable Diseases, CAB Abstracts, Caspur, DOAJ, EBSCO Publishing's Electronic Databases, Excerpta Medica / EMBASE, Expanded Academic ASAP, Genamics JournalSeek, Global Health, Google Scholar, Health & Wellness Research Center, Health Reference Center Academic, Hinari, Index Copernicus, Indian Science Abstracts, IndMed, MedInd, OpenJGate, PrimoCentral, ProQuest, PubMed, Pubmed Central, Scimago Journal Ranking, SCOLAR, SCOPUS, SIIC databases, Summon by Serial Solutions, Tropical Diseases Bulletin and Ulrich's International Periodical Directory.

Information for Authors

There are no page charges for IJN submissions. Please check <http://www.indianjnephrol.org/contributors.asp> for details.

All manuscripts must be submitted online at www.journalonweb.com/ijn.

Subscription Information

Copies are sent to the members of ISN free of cost. A subscription to Indian Journal of Nephrology comprises 6 issues. Prices include postage. Annual Subscription Rate for non-members-

- Institutional: INR 3000.00 for India
USD 150.00 for outside India
- Personal: INR 2000.00 for India
USD 100.00 for outside India

For mode of payment and other details, please visit www.medknow.com/subscribe.asp.

Claims for missing issues will be serviced at no charge if received within 60 days of the cover date for domestic subscribers, and 3 months for subscribers outside India. Duplicate copies cannot be sent to replace issues not delivered because of failure to notify publisher of change of address.

The journal is published and distributed by Medknow Publications and Media Pvt. Ltd. Copies are sent to subscribers directly from the publisher's address. It is illegal to acquire copies from any other source. If a copy is received for personal use as a member of the association/society, one cannot resale or give-away the copy for commercial or library use.

Change of Address

ISN Members:

Vivekanand Jha, MD, DM
Secretary, Indian Society of Nephrology,
Postgraduate Institute of Medical Education
and Research, Chandigarh 160 012, India.
Email: vjha@pginephro.org
Ph: 91-172-275 6733 (office) 275 5123 (lab)
Fax: 91-172-274 0282

The copies of the journal to the members of the association are sent by ordinary post. The editorial board, association or publisher will not be responsible for non receipt of copies. If any member/subscriber wishes to receive the copies by registered post or courier, kindly contact the publisher's office. If a copy returns due to incomplete, incorrect or changed address of a member/subscriber on two consecutive occasions, the names of such members will be deleted from the mailing list of the journal. Providing complete, correct and up-to-date address is the responsibility of the member/subscriber.

Nonmembers: Please send change of address information to subscriptions@medknow.com.

Advertising policies

The journal accepts display and classified advertising. Frequency discounts and special positions are available. Inquiries about advertising should be sent to Medknow Publications, media@medknow.com.

The journal reserves the right to reject any advertisement considered unsuitable according to the set policies of the journal.

The appearance of advertising or product information in the various sections in the journal does not constitute an endorsement or approval by the journal and/or its publisher of the quality or value of the said product or of claims made for it by its manufacturer.

Copyright

The entire contents of the Indian Journal of Nephrology are protected under Indian and international copyrights. The Journal, however, grants to all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, perform and display the work publicly and to make and distribute derivative works in any digital medium for any reasonable non-commercial purpose, subject to proper attribution of authorship and ownership of the rights. The journal also grants the right to make small numbers of printed copies for their personal non-commercial use.

Permissions

For information on how to request permissions to reproduce articles/information from this journal, please visit www.indianjnephrol.org/.

Disclaimer

The information and opinions presented in the Journal reflect the views of the authors and not of the Journal or its Editorial Board or the Publisher. Publication does not constitute endorsement by the journal. Neither the Indian Journal of Nephrology nor its publishers nor anyone else involved in creating, producing or delivering the Indian Journal of Nephrology or the materials contained therein, assumes any liability or responsibility for the accuracy, completeness, or usefulness of any information provided in the Indian Journal of Nephrology, nor shall they be liable for any direct, indirect, incidental, special, consequential or punitive damages arising out of the use of the Indian Journal of Nephrology. The Indian Journal of Nephrology, nor its publishers, nor any other party involved in the preparation of material contained in the Indian Journal of Nephrology represents or warrants that the information contained herein is in every respect accurate or complete, and they are not responsible for any errors or omissions or for the results obtained from the use of such material. Readers are encouraged to confirm the information contained herein with other sources.

Addresses

Editorial Office

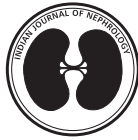
Prof. Vinay Sakhuja,
Editor, Indian Journal of Nephrology,
Department of Nephrology,
Postgraduate Institute of Medical Education and Research,
Chandigarh-160012, India.
Ph: (+91) 0172-2756731
Fax: (+91) 0172-2744401
Email: vsakhuja2009@gmail.com; editor@indianjnephrol.org
Website: www.indianjnephrol.org

Published by

Medknow Publications and Media Pvt. Ltd.
B5-12, Kanara Business Centre,
Off Link Road, Ghatkopar (E),
Mumbai – 400075, India.
Phone: 91-22-66491818
Website: www.medknow.com

Printed at

Nikeda Art Printers Pvt Ltd,
Bhandup, Mumbai, India.



Indian Society of Nephrology Guidelines for Hemodialysis Units

Table of Contents

Introduction	S1-S2
Setting up of HD Unit	S3-S4
Personnel	S5-S6
Machine and Dialyzer	S7-S11
Dialysate	S12-S12
Water Treatment	S13-S15
Vascular Access	S16-S19
Priming, Connecting and Disconnecting	S20-S21
Anticoagulation	S22-S23
Dialyzer Reuse	S24-S27
Dialysis Dose	S28-S28
Prevention of Infection	S29-S34
Emergency Services	S35-S35
Laboratory Support	S36-S36
Nutrition	S37-S38
Cardiovascular Disease Monitoring and Therapy	S39-S39
Mineral and Bone Disorder Monitoring and Therapy	S40-S41
Hypertension	S42-S42
Diabetes	S43-S43
Dialysis in Intensive Care Unit	S44-S45



ISN Guidelines for Hemodialysis Units

WORK GROUP

CHAIR

Mohan Rajapurkar

Director, Postgraduate Studies and Research
Consultant Nephrologist
Muljibhai Patel Urological Hospital, Nadiad

MEMBERS

Rajeev A Annigeri

Consultant Nephrologist,
Apollo Hospitals,
Chennai

Amit Gupta

Professor of Nephrology
Sanjay Gandhi Postgraduate Institute of Medical
Sciences,
Lucknow

Vivekanand Jha

Professor,
Department of Nephrology
Postgraduate Institute of Medical Education and
Research, Chandigarh

Vijay Kher

Chairman,
Division of Nephrology and Transplant Medicine
Medanta Kidney and Urology Institute,
Medanta - the Medicity,
Gurgaon

Valentine Lobo

Consultant Nephrologist,
Department of Nephrology,
King Edward Memorial Hospital,
Pune

Dhananjay S Ookalkar

Ashwini Kidney and Dialysis Centre,
Nagpur

T Ravi Raju

Former Principal and Head Department of Nephrology
Andhra Medical College, Vishakhapatnam
Former Director of Medical Education,
Andhra Pradesh

Anita Saxena

Associate Professor of Nephrology,
Sanjay Gandhi Postgraduate Institute of Medical
Sciences, Lucknow

Abhijit Taraphder

Consultant Nephrologist,
Apollo Hospital,
Ex-Professor and Head of Nephrology,
Institute of Postgraduate Medical Education and
Research,
Kolkata

Address correspondence to: Vivekanand Jha, Secretary, Indian Society of Nephrology, Department of Nephrology, Postgraduate Institute of Medical Education and Research, Chandigarh 160012, India. E-mail: vjha@pginephro.org

Introduction

The burden of chronic kidney disease (CKD) is increasing all over the world including in India. The best-known adverse consequence of CKD is end-stage kidney disease (ESRD). The incidence of ESRD in India has been estimated at 165–225 per million population.

By replacing some of the lost functions of the kidney, dialysis has permitted hundreds of thousands of patients to live and function. Of the two modalities of dialysis, hemodialysis (HD) and peritoneal dialysis (PD), the former is by far more popular.

HD started in India in 1961. The growth was slow in the initial years, but has exploded in the past 5 years. Growth in the number of standalone dialysis units is especially remarkable. Most dialysis units are privately run. The majority of renal replacement therapy (RRT) patients in India are on in-center HD. It is estimated that currently there are about 1500 HD units in India, about 90% in the private sector. Non-nephrologists and technicians manage a significant proportion of these units.

A number of factors determine the survival and quality of life of patients on HD. Central to this is delivery of adequate dialysis. This requires adherence to the minimum quality standards. Anecdotal evidence suggests that the quality of dialysis delivered to patients in India varies from center to center. Part of the reason is the lack of minimum defined standards of care for HD units.

Discussions amongst members of the Indian Society of Nephrology (ISN) made it clear that those wishing to set up new dialysis units had no guidance to help them with this process. When asked whether availability of such a resource would be useful, there was an enthusiastic support from the membership.

The ISN set up an independent Work group to fill this gap. The Executive Committee identified a set of experienced nephrologists who represented the entire spectrum of nephrology practice in India: small and large units, public sector and private sector, and representation of all geographic regions. The bottom line was absence of any conflict of interest, experience and record of leadership in providing high-quality dialysis.

This group was charged with the responsibility to develop a set of guidelines that would define the minimum standard that should be satisfied by dialysis units so as to improve the general quality of dialysis delivered to our patients. The advice to this group was not to conduct an exhaustive literature

review but to gather documents or guidelines that existed elsewhere, synthesize what they have learned from years of experience and then put them together in a form that would be useful both for setting up a new unit or for modification of an existing unit. Additionally, sections pertinent to management of dialysis patients such as investigations, cardiovascular assessment, nutritional management, and evaluation and management of chronic kidney disease-mineral and bone disorder (CKD-MBD) have been included. Finally, we have included a short section on RRT in intensive care units (ICUs).

The proposed guidelines described a level of practice that should be achievable in almost all situations. It does not propose to advise those willing to establish the most state of the art dialysis unit with all modern gadgetry. Rather, the focus is on providing adequate quality of dialysis so as to improve patient outcome and quality of life. Special emphasis has been laid on measures that will ensure patient safety.

The group met twice, but was in constant touch through information technology tools. In the initial meeting, the scope of the document was decided and work was divided between workgroup members. Workgroup members were expected not only to bring lessons from personal experience, but also conduct wide-ranging consultations with others who could make significant contributions. As the document took shape, chapters were exchanged between workgroup members. Another physical meeting then took place to finalize the basic structure of the document. Once the rough draft had been finalized, it was uploaded on the (ISN) website for public review. Comments received were then discussed between the workgroup members and the document modified accordingly.

The group followed a language used by major guideline development organizations such as the Kidney Disease: Improving Global Outcomes (KDIGO). We use the word “recommended” where it is felt that the statement represented a well-established practice standard, might be followed by most reasonable practitioners, most patients in this situation would want the recommended course of action because deviation might compromise dialysis quality or patient safety. We use the word “suggested” to indicate a measure that is optional and can be used to further improve the quality. This decision will be made on availability of resources, and consistent with the values and preferences of the patient.

The work group has tried to harmonize this document with guidelines and standards recommended by other major professional organizations or statutory bodies in other countries. Since independent technical expertise is difficult

to obtain for an individual, we have tried to include details of technical aspects including architectural plan and design for a proposed HD unit or a water treatment system.

A special feature of this document is the suggested steps for monitoring, auditing, and quality control measures for each component. We hope that such a system would permit us to document improvement in the quality and outcomes in a longitudinal fashion.

We hope that this document will be the first step in standardizing the practice of HD in our country and developing performance measures. Finally, we believe that this document would be the

basis for eventual development of policy by statutory bodies.

This has been a rewarding and enriching process for the workgroup members. We look forward to feedback on this document. Progress is inevitable, and some of the statements made in this document may need to be rewritten as new information becomes available. Though unlikely, there is this possibility that some important aspect has been overlooked. The plan is to review this document on a periodic basis.

We therefore request you to send in your comments and suggestions both regarding the content of the document and its presentation. All communication should be sent to the ISN Secretary (admin@isn-india.org).

Use of the Guidelines

This document is intended to provide guidance and assist in decision-making for those health-care personnel intending to set up or running a hemodialysis unit. These guidelines are not designed to define a "standard of care" or suggest an exclusive way of practicing hemodialysis. We understand that variations in practice will be required after taking into account needs of individual patients, available resources and local limitations. Everyone using these recommendations is responsible for evaluation of the need and appropriateness of applying these guidelines in a given setting. Lay persons reading this document should consult medical professionals for understanding how to best apply these guidelines.

Author Help: Online submission of the manuscripts

Articles can be submitted online from <http://www.journalonweb.com>. For online submission, the articles should be prepared in two files (first page file and article file). Images should be submitted separately.

1) **First Page File:**

Prepare the title page, covering letter, acknowledgement etc. using a word processor program. All information related to your identity should be included here. Use text/rtf/doc/pdf files. Do not zip the files.

2) **Article File:**

The main text of the article, beginning with the Abstract to References (including tables) should be in this file. Do not include any information (such as acknowledgement, your names in page headers etc.) in this file. Use text/rtf/doc/pdf files. Do not zip the files. Limit the file size to 1 MB. Do not incorporate images in the file. If file size is large, graphs can be submitted separately as images, without their being incorporated in the article file. This will reduce the size of the file.

3) **Images:**

Submit good quality color images. Each image should be less than **4 MB** in size. The size of the image can be reduced by decreasing the actual height and width of the images (keep up to about 6 inches and up to about 1800 x 1200 pixels). JPEG is the most suitable file format. The image quality should be good enough to judge the scientific value of the image. For the purpose of printing, always retain a good quality, high resolution image. This high resolution image should be sent to the editorial office at the time of sending a revised article.

4) **Legends:**

Legends for the figures/images should be included at the end of the article file.

Setting up of HD Unit

Setting up of maintenance HD (MHD) unit is a major challenge for an uninitiated nephrologist. The purpose of this guideline is to help design a new unit.

HD Area

We recommend that the HD area should have the following features:

1. The dialysis area should be air-conditioned so as to achieve 70–72°F temperatures and 55–60% humidity.
2. Each machine should be in the center of at least 11 × 10 feet. (110 sq feet) area [Figure 1] to allow easy movement of personnel and resuscitation equipment on all four sides of the patient.
3. Each machine area should be easily observed from the nursing station.
4. Nursing station should have enough space for nurses/ technicians, a computer terminal, and working desk/bench.
5. Head end of each bed should have stable electrical supply with at least three outlet of 5/15 amps, oxygen and vacuum outlet, treated water inlet, and drainage.
6. There should be separate areas for dialyzing patients with conditions that require isolation. This area should have independent water supply and drainage facilities.
7. Facilities for hand washing and alcohol-based hand rub/sterilant dispensers should be available in all patient areas.

Dialyzer Reprocessing Area

1. We recommend an independent area for reprocessing the dialyzers. This should have a workbench and sink with side-board and drainage. The workbench should have separately marked treated as well as untreated water supplies at water line pressure of 1.3 kg/cm² (20 psi). There should be two sinks (one for initial cleaning and the other for filling sterilant, packing, and labeling) for the workbench.
2. We suggest that the space should be sufficient for two persons working simultaneously.
3. We suggest that reprocessing area should be equipped with a hood and an exhaust fan.
4. We recommend the use of sinks with a depth of at least 45 cm with a drainage mesh at a depth of around 20 cm to prevent the dialyzer and tubing resting in the effluent.
5. We recommend that washing area be equipped with two outlets or a “T” connection. Two different fittings should be provided on the water line at each reprocessing area, a standard tubing to clean the blood compartment and a Hansen connector for backwashing the dialysate compartment.
6. We recommend the use of 316 SS, or medical grade polyvinyl chloride (PVC) for fittings.

7. We recommend a physically separate reprocessing area for processing dialyzers of patients with hepatitis B virus (HBV) and hepatitis C virus (HCV) infection.
8. We suggest that space should also be provided for dialyzer reprocessing machine(s).
9. We recommend stable electrical supply and drainage for the work bench.

Storage Areas

1. We recommend two separate storage areas, one for new supplies (dry storage) and another for reprocessed dialyzers (wet storage).
2. We recommend a separate area with a workbench for preparation of sterile trays for dialysis startup kit, and preparation of injections.
3. We suggest that there should be designated places for storage of emergency equipment, keeping wheelchairs/trolleys and weighing scale.
4. We suggest that there should be an area for dirty utility. The area should be designed in such a way that once personnel and material enter this area, they do not have to come back to the clean dialysis area.

Other Areas

1. We suggest that there should be a separate area for examining patients.
2. We suggest that there should be office area for nurses and technicians.
3. We recommend provision of sufficient designated area for the stay and relaxation of attendants accompanying the patients. Patients waiting to go on dialysis and those who have recently completed dialysis could also utilize the same area.
4. We suggest that all activities not directly related to a HD procedure including creation (not puncture) of vascular access be done in a separate procedure room.

The following equipments are suggested for the procedure room:

- Operating table
- Operating lights
- Ultrasound: preferably with a vascular probe for localizing and puncturing central veins
- C-Arm imaging system
- Instrument storage facility
- Clean and dirty utility.

In case such a facility is available in any other area of the hospital, the HD unit can share it.

The dry storage area should have sufficient space to store adequate supply of dialyzers, tubings, HD concentrate solutions, IV fluids, and other consumables. It should also have space for stationery, linen and records.

The wet storage is for reprocessed dialyzers and tubings

- We suggest that there should be separate change rooms for male and female staff.
- We recommend that if the MHD unit is a part of a general hospital set-up then the areas for reception, waiting, records, consulting room, and storage could be shared.
- We recommend that there should be adequate number of toilets for staff, patients and accompanying persons, preferably separate for males and females.

Power supply and Plumbing

- We recommend stable voltage continuous supply. The supply should be stable and uninterrupted, pure sine wave both voltage and frequency regulated. The use of electrical surge protectors is recommended to protect dialysis machine's electronics.
- Online uninterrupted power supply (UPS) with at least 30-min backup is suggested. The power capacity of the UPS should be able to support all functions of the dialysis machine.
- We recommend a generator of adequate capacity where power supply is erratic.
- We recommend use of SS grade 316 or medical grade PVC for treated water pipelines

Stainless steel does not corrode, rust, or stain with water as ordinary steel does, but despite the name it is not fully stain-proof. It is also called corrosion-resistant steel (CRES) when the alloy type and grade are not detailed, particularly in the aviation industry. There are different grades and surface finishes of stainless steel to suit the environment the alloy must endure. Stainless steel is used where both the properties of steel and resistance to corrosion are required. 300 series, stainless steels have an austenitic crystalline structure, which is a face-centered cubic crystal structure. Austenite steels make up over 70% of total stainless steel production. They contain a maximum of 0.15% carbon, a minimum of 16% chromium and sufficient nickel and/or manganese to retain an austenitic structure at all temperatures from the cryogenic region to the melting point of the alloy. The most widely used austenite steel is the 304 grade or A2 stainless steel (not to be confused with A2 grade steel, also named Tool steel, a steel). The second most common austenite steel is the 316 grade, also called marine grade stainless, used primarily for its increased resistance to corrosion.

- We recommend that the number of bends in pipelines be kept to a minimum and blind loops be avoided.
- We recommend that all drainage should be connected directly to the main drainage line in a straight line without bends or blind loops.

We recommend that the area should be brightly lit to facilitate performance of procedures. If possible, provision should be made for dimming the lighting.

Others

We recommend that there should be an established system for record keeping. We suggest use of an electronic system for patient as well as unit records. The records system should have adequate security to ensure protection of privacy of the patients.

We recommend that all statutory precautions are taken against fire. Fire escapes should be clearly visible.

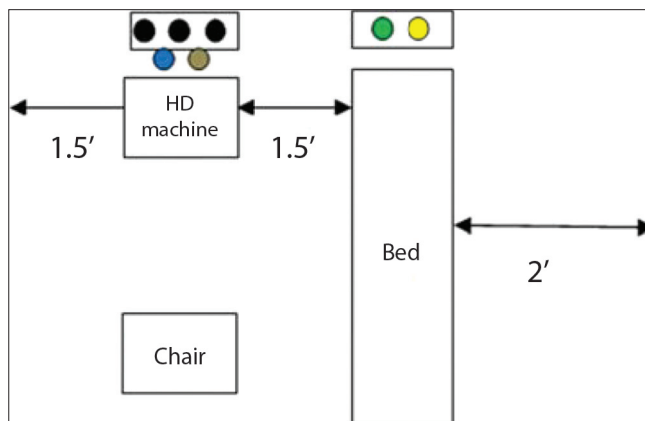


Figure 1: Showing typical HD machine area, Black dots Electricity outlets, Green dot: Oxygen outlet, Yellow dot: Vacuum outlet, Blue dot: treated water inlet, Ash dot: drainage outlet

Acknowledgements

We are grateful to Mr. Manish Shah and Mr. Bhavin Suthar.

Personnel

We recommend that the HD facility should have sufficient specialist and support staff.

We recommend that dialysis unit should have the following categories of regular staff:

- a) Nephrologist
- b) Dialysis doctors (nephrologist can also be a dialysis doctor)
- c) Dialysis technicians/ nurses
- d) Dialysis attendants/ sanitation personnel

We suggest access to the following:

- a) Medical social worker
- b) Dietician

We recommend the following qualifications, job descriptions, and appraisal/updating schedules for different categories of staff working in HD unit.

NEPHROLOGIST

Training

1. DM/DNB in Nephrology or
2. MD with 2 year training in nephrology from a recognized center.

Job description

1. Responsible for overall functioning of the unit.
2. Assess all patients, frame dialysis prescriptions, evaluate co-morbid illnesses, advice concomitant therapies, and make/ approve specific recommendations.
3. Perform regular review of all patient charts.
4. Carry out periodic review of water quality and infection control measures.
5. Periodically evaluate the performance of dialysis doctors, technicians, and nurses.
6. Provide 24×7 hour consultation cover.
7. Be responsible for enforcement of patient care and safety rules and regulations.
8. Act as liaison between the hospital management, statutory bodies, dialysis staff, and patients.
9. Protect patient rights.
10. Supervise in-house teaching program.
11. Be in charge of periodic performance audit.
She/he should sit with the team and discuss all issues of concern. The unit should maintain a record of performance parameters, including but not limited to: proportion of patients with arteriovenous fistula (AV) fistula, treatment compliance rates, infection rates categorized by site, organism and sensitivity, nutrition, rehabilitation status, co-morbidity management, clinically important events, drop-outs, and outcomes.

We recommend that the nephrologist should regularly

participate in national/zonal chapter meetings of ISN and other recognized continuing medical education (CME) programs at least once a year.

DIALYSIS DOCTORS

Training

1. M.B.B.S. with a valid registration.
2. One-year house job.
3. Certified in advanced cardiac life support (ACLS).
4. Experience in central line placement.
5. Experience in critical care management.

Job description

1. To be involved in day to day patient management.
2. Before starting dialysis: Assess hemodynamic status, indication of dialysis, vascular access, and any co-morbid illness.
3. During dialysis: Overall direct monitoring including dialysis prescription, care of vascular access, adequacy of flow, complications, and maintain liaison with and follow instruction of the nephrologist.
4. At the time of closure: Check access site, hemodynamic status, any complication, and give specific instruction if needed.
5. For in-patients: assess the patient at least once in the ward after dialysis.
6. Accompany the patient to the ward, if critically ill.
7. Handle/supervise/guide supporting staff in cardiopulmonary resuscitation.
8. Have working knowledge of the dialysis machine, water treatment plant, ventilator, defibrillator, and other gadgets in the dialysis unit.
9. Act as the team leader during the day to day functioning of the unit.
10. Ensure implementation of all guidelines.
11. Look after the safety and security of the supporting staff.
12. Take regular teaching sessions for the dialysis staff.

We recommend that the dialysis doctor should participate in recognized CME programs of Indian Society of Nephrology or Indian Society of Hemodialysis at least once in 2 years.

DIALYSIS TECHNICIANS

Training

One year or longer certificate course in dialysis technology (after high school) certified by a government authority or have sufficient verifiable hands-on experience.

Job description

1. Performing all aspects of the dialysis procedure as per prescription.

2. Conducting discharge assessment.
3. Following instructions of the dialysis doctors.
4. Conveying to the dialysis doctor any new event/change in patient status and recommending changes in the treatment based on the current needs of the patient.
5. Facilitating communication between the patient and patient's family on one side and the treating team on the other.
6. Keeping an inventory of items in the unit.
7. Providing oversight and direction to the trainee technicians/nurses.
8. Participating in continuous quality improvement activities.
9. Entry and maintenance of records of all patients and produce them for medical auditing.

We recommend that technician should attend update sessions meant for dialysis technicians at least once a year.

Contents of training program for a dialysis technician

Fundamentals of renal anatomy and physiology.

Principle of dialysis.

Water quality, water treatment, and water distribution.

The dialysis machine: connectology and upkeep of machines.

Basics of vascular access.

Dialyzers and tubings including cleaning and preservation.

Anticoagulation.

Dialysate: composition and ingredients.

Common complications of dialysis: How to manage them at bedside.

Basic evaluation of a patient before, during and after dialysis.

Infection control and safety.

Dialyzer reprocessing.

Cannulation (vascular access): the broad principles.

Critical care dialysis (continuous renal replacement therapy (CRRT)/sustained low-efficiency dialysis (SLED)) and pediatric patient management.

Universal precautions for prevention of transmission of infections.

Basics of peritoneal dialysis.

DIALYSIS NURSES

Training

Auxiliary nurse midwife (ANM) + 6 month experience in a dialysis unit. Should be registered with the local Nursing Council.

Job Description, Auditing, and updating

As for dialysis technicians.

ATTENDANTS / SWEEPERS

We recommend at least one attendant for every ten dialysis beds.

DIETICIAN

Should be involved in development of nutritional care plan, documentation, ongoing nutrition assessment and remedial

steps, patient education, research, and participate in medical review audit.

MEDICAL SOCIAL WORKER

Should be involved in psychosocial evaluation, case work counseling of patients and families, group work, evaluate and facilitate rehabilitation, team care planning and collaboration, facilitating community agency referral, improve communication with treating team

All health care personnel should be licensed or certified by appropriate authority. The credentials of medical professionals and other staff should be verified and evaluated.

The facility should comply with all local, state and central regulations regarding employment.

All staff should be at least 18 years old.

We recommend that the organization have a well-defined organizational chart, which should be prominently displayed.

We recommend that personnel records shall be maintained for all employees.

We recommend that the number of personnel be sufficient to ensure patient care and safety.

We recommend a patient:technician/nurse ratio of 3:1.

We recommend that a formal system of staff evaluation and monitoring be established with annual performance evaluation.

We recommend that the organization have a well-documented disciplinary procedure and grievance handling mechanism.

We recommend that the organization should address the health needs of the employees.

We recommend that all staff should be screened for transmissible infections including blood-borne viruses.

We recommend that the staff must receive all recommended vaccinations.

Personnel records should contain

Application for employment and a record of any disciplinary action taken.

Wage and salary information, time records, authorization, and record of leave.

Job responsibilities.

Verification of the respective employment requirements for the staff position held, including annual verification of basic skills, and annual evaluation of personnel performance. This evaluation shall be in writing. There shall be documentation to verify that the employee has reviewed the evaluation and has had an opportunity to comment on it.

Documentation of training and development activities for the staff.

Documentation of health and vaccination records for all employees, including volunteers.

Machine and Dialyzer

The dialysis machine and the dialyzer (or artificial kidney) is central to the delivery of HD. With a wide range of machines, dialyzers and treatment variations, the caregiver is spoilt for choice. A rational decision has to be made between offering optimum and flexible treatment with adequate safety on one hand, and cost on the other.

We recommend the following for a HD machine

1. We recommend that all equipment used in the delivery and monitoring of HD should be certified and approved by an appropriate statutory authority to ensure compliance with relevant safety standards for electrical equipment in clinical use.
2. We recommend use of a single patient, single pass system, or central delivery system.
3. We recommend that all new or refurbished HD machines will have the following components, which should be properly functioning at all times:
 - a) Presistaltic blood pump to achieve a unidirectional flow of up to 400 ml/min.
 - b) Heparin pump.
 - c) Arterial and venous line pressure monitors.
 - d) Air bubble detector.
 - e) Mixing proportion unit with bicarbonate dialysis facility, rate of dialysate delivery from 300 to 500 ml/min or more.
 - f) Conductivity meter.
 - g) Blood leak detector.
 - h) Dialysate temperature regulator with a range of 35–39°C.
 - i) Volumetric adjustable ultrafiltration (UF) control.
 - j) Safety devices: alarms, venous blood clamp.
4. We suggest the following optional items depending on the available resources:
 - a) On-line blood volume monitor.
 - b) On-line urea clearance.
 - c) Sodium and ultrafiltration profiling.
 - d) Single needle dialysis.
 - e) Optical detector (online monitoring of dialysis adequacy).
5. We recommend that patient safety should not be compromised.
6. We recommend the following features regarding alarms built into the HD system:
 - a) The range and sensitivity of the alarms should be set internally as default and the operator should only be able to operate within the set range without being able to alter these settings, especially while HD is in progress.
 - b) Alarms should be visible from at least 2 meters and easily audible (70 dB).
 - c) All blood alarms (air detector, arterial, venous, blood leak, transmembrane pressure, blood pump torque) should automatically shut off the blood pump, clamp the venous return line, and stop UF, thus isolating the patient.
 - d) Equipment should be programmed to automatically switch to “safe mode,” thus isolating the patient from the HD machine.
7. We recommend regular preventive servicing of the machines by qualified engineers or technicians. These designated technicians may be located in-house or may be from an external agency.
8. We recommend that records of routine servicing should be maintained.
9. We recommend provision for emergency electric power supply for life-saving equipment in case of power failure. An UPS backup of up to 30 min is suggested for each machine.
10. We suggest that machines should be replaced after 5–10 years of service or after 15,000–40,000 hours of use, depending upon assessment of machine condition and specifications provided by the manufacturer.
11. We recommend the following evaluation and monitoring steps every day:
 - a) Automatic “self-test” prior to each HD treatment to confirm proper performance of operative and protective functions of the machine. This step should never be bypassed.
 - b) Check conductivity of the final dialysate being delivered to the dialyzer in each shift. This must be within the manufacturer’s stated specifics. The conductivity should be checked with an independent properly calibrated reference meter.
 - c) Confirmation of the pH of bicarbonate dialysate with a pH meter in each shift. Dialysis should not be started if the pH is below 6.5 or above 7.5, even when conductivity is within acceptable limits.
 - d) Dialysate temperature should be within the manufacturer’s specifications. Temperature may be checked with a reference thermometer.
 - e) Verification of absence of residual germicide (with an assay known to detect the minimum acceptable level) before starting dialysis.
 - f) Perform a test of proper functioning of the air/foam

detector. This test should be a direct test of function of the alarm, causing interruption of the blood pump and actuation of the blood line clamp, either by introducing air into the venous level detector or by removing the tubing so that air is sensed by the detector as recommended by the device manufacturer.

- g) Check the blood leak detector for armed status according to the method recommended by the manufacturer.
- h) Perform applicable tests of the UF control system as prescribed by the manufacturer.
- i) All other alarms should be tested according to the manufacturer's instructions.
- j) Observation of dialysate flow should be made while the machine is in a "dialyzing" mode. Absence of flow should be confirmed when the machine is in "bypass" mode actuated by both manual setting of the machine to bypass or via any of the alarm functions that will cause the machine to enter a bypass mode.

If the particular delivery system is equipped with a "self-alarm check" mode, it is important that the user understand that, most often, it is a check of the electronic circuitry, and not a confirmation of all vital functions of specific alarms

12. We recommend the following evaluation steps once a month:

- a) Microbiological monitoring of water for production of dialysate, and actual dialysate entering and exiting the dialyzer for bacterial levels.
- b) Sampling should be done at the termination of dialysis at the point where dialysate exits the dialyzer. Total microbial counts should not exceed 2000 colony forming units per milliliter.
- c) Trend assessment: All information, that is, bacterial levels, conductivity and pH readings, etc., should be logged on a chart across a page so that readings can be examined and compared over a period of time. This tool makes it possible to compare current readings to those taken during the past several days/weeks/months.

13. We recommend that the actual numerical result of a test should be recorded and verified by the operator after each test.

All electrical and other equipment used in the facility should be maintained free of defects to prevent potential hazard to patients or personnel.

Directions pertaining to preventative maintenance requirements for the entire dialysis delivery system as provided by the manufacturer should be followed.

A master schedule of all preventative maintenance should be developed. Such a master schedule will list every machine by serial number (or other identifier) and identify when preventative maintenance is required.

Dialysis units should have an established and agreed upon plan of action for repair and troubleshooting of HD machines

Dialyzer

We recommend that the dialyzer should meet the following specifications:

- a) *Made of biocompatible, synthetic (e.g., polysulfone, polyacrylonitrile, polymethylmethacrylate) or modified cellulose membrane (e.g., cellulose acetate).*
- b) *Cuprophane membranes should be used only when other membranes are not available or patient is intolerant to all others.*
- c) *We recommend that either low flux or high flux biocompatible membrane may be used for regular HD.*
- d) *We recommend that use of high flux dialyzers be restricted to units that can ensure European standard of quality of water.*
- e) *In case an allergic reaction to a specific dialyzer is encountered, we recommend that the particular dialyzer should not be used and this should be specifically written in bold letters on the dialysis folder of the patient to prevent its inadvertent use.*

Surface area of the dialyzers should be chosen based on the required dialysis dose and the body size of the patient. Large surface area dialyzers should be avoided in pediatric patients and adult patients with small body size.

A large array of dialyzers based on biocompatibility, flux and surface area is available for clinical use. Most often a single type of dialyzer may be sufficient in most patients in a dialysis unit. However, some patients may have specific needs and may require change in the dialyzer specifications. Hence, dialyzers with specifications other than that generally used in the dialysis unit may also be stocked or should be accessible at a short notice.

Alarms

Inflow (prepump) pressure monitor: Inflow pressure is 80 to -200 mmHg. If there is poor blood flow from the vascular access the alarm will beep and the blood pump will stop. Once the pump stops, the suction is relieved and the alarm is deactivated.

Common causes for excessive suction are a thrombus or fibrin plug at catheter tip (venous catheter), improperly placed arterial needle, clotting of arterial needle (AV fistula), drop in patient's BP, kinking of arterial line, or use of a too small needle.

Outflow (venous) pressure monitor: It is usually +50 to +250 mmHg. Causes for alarm could be clotting of the venous blood line filter or venous line/needle, high blood flow rate when using a small venous needle, kinked venous line, stenosis at the venous limb, or improperly placed venous needle.

Air detector: Important alarm to prevent air embolism, which can be fatal. Common sites for air entry include the region around the arterial needle, leaky tubing connections, broken blood tubings, or an open saline infusion tubing or port.

Conductivity: Most common causes of reduced conductivity are empty concentrate container or defect in the proportioning pump.

Temperature is automatically limited between 35°C and 39°C for most machines in the dialysis mode. Low temperature alarms could be as a result of a loose heater cable, tripping of the safety switch or a faulty sensor in some machines.

Blood leak: A blood leak alarm should be confirmed by testing the effluent dialysate with a test strip used for detecting hemoglobin in the urine. If leak is confirmed, the dialysate compartment pressure should be set to -50 mmHg or lower to minimize entry of bacteria from the dialysis solution into the blood side of the extracorporeal circuit. The blood should be returned and dialysis should be discontinued. The defective dialyzer should be discarded and a new dialyzer should be used to restart dialysis.

Annexure

HD Machine

Blood pump consists of two or more spring-loaded rollers and a stator supporting the blood tubing. One of the rollers should occlude the tube at all times to prevent uncontrolled flow in the circuit as well as back leak.

1. Volumetric dialysis machines use flow sensor systems (inflow and outflow) that measure the pre- and postdialyzer flow rates (the difference is the UF rate) or by matching the dialysate inflow and outflow rates (a separate pump is available for UF). By keeping the pumps out of sequence, the dialysate flows continuously.
2. Dialysate is produced by mixing two solutions, : an acid concentrate and bicarbonate concentrate in proportion suitable for dialysis. This is done by two methods:
 - a) Fixed-ratio proportioning systems: Cylinders of known volumes are used to proportion the dialysate concentrate and treated water in exact amounts, and a series of valves control the cyclic filling and emptying of each cylinder.
 - b) Servo-controlled (variable-rate) systems: A control sensor monitors the dialysate conductivity and regulates the flow of the dialysate concentrate within the specified conductivity limits. Flow can be regulated using variable-speed pumps, variable-orifice valves, or other mechanisms. Servo systems also employ a second conductivity sensor to monitor the mixture and to initiate action (e.g., bypass, alarms) if conductivity is outside specified limits.
3. The heparin pump is mostly a syringe pump, although a roller pump may be used. Heparin is infused downstream into the positive-pressure segment of the blood circuit (postblood pump, predialyzer). If heparin pump is located at prepump in the negative-pressure segment, the risk of air embolism is enhanced.
4. Air bubble detector: Infusion of more than 50 ml of air is often lethal, unless rescue measures are applied immediately. The air leak detector is placed distally in the venous blood line. In case of a leak, air enters the extra-corporeal circuit on the negative pressure side and presents as foam with micro-bubbles. Ultrasound-based sensors are preferred to optical detectors, since they have a higher sensitivity in detecting air foam, typically detecting air bubbles of 50–100 μ l. Detection of air foam triggers an audible and visual alarm, clamps the venous line, and stops the blood pump.
5. Arterial pressure monitor: It measures the pressure between the access needle and the blood pump. The normal pressure reading in this segment of the blood circuit is negative (sub-atmospheric). The pressure transducer signal is amplified and converted to an electrical signal. Alarms may indicate patient disconnection, separation of blood tubing, inadequate access, or obstruction/kink in the blood circuit. Actual achieved blood flow is sometimes calculated by the machine software using the arterial pressure, pump segment length, and diameter using Poiseulles equation.
6. Venous pressure monitor: The venous pressure may build up owing to resistance to venous return anywhere between the venous drip chamber and the venous needle (together with the access pressure). Venous pressure monitors normally read positive pressures. Out-of-range pressures trigger clamping of the blood line, stopping of the blood pump, and activation of appropriate alarms, with shutting of the venous return.

7. Conductivity meter: The ionic constituents of the dialysate determine its conductivity. Conductivity monitoring ensures proper water to concentrate ratio of the dialysate. The units of conductivity are milliSiemens per centimeter. The normal range is 12–16 mS/cm; high and low alarm settings should be within $\pm 5\%$ of the sensitivity settings. The conductivity sensor must be made of high-quality corrosion resistant, temperature compensated material. Conductivity can be affected by temperature or acetate:chloride or chloride:bicarbonate ratios. External readjustment of the alarm settings by machine operators can lead to dangerous situations and must never be attempted.
8. The blood leak monitor allows detection of blood leaks and dialysate contamination downstream of the dialyzer. Red blood cells present in the dialysate scatter light. The monitor looks for loss of transparency when light is passed through the dialysate column (postdialyzer). The monitor (infrared or photo detector) has a “flow-through” configuration (sensor is at the bottom, and therefore, air bubbles do not interfere). The sensitivity is 0.25–0.35 ml of blood per liter of dialysate. Loss of sensitivity may occur owing to biofilm, deposits, or clots. Monitor triggers visual and audible alarms, immediately deactivating blood pump.

DIALYSATE DELIVERY SYSTEM

The dialysate delivery system delivers dialysate to the dialyzer at proper concentration, temperature, pressures, and flow. The system also monitors dialysate and blood compartments such as dialysate pressure, UF rate, blood leak into the dialysate, changes in the pressure of the blood circuit, air or air foam in the blood and other parameters.

Single patient, single pass systems discharge dialysate to drain after one passage through the dialyzer and are used to deliver dialysate to one patient at a time. Single patient systems, also called “negative pressure systems,” maintain a sub atmospheric (negative) dialysate pressure in order to accomplish fluid removal. In contrast, the central delivery system maintains a single “central dialysate proportioner” which prepares dialysate for a number of bedside consoles or bedside stations. Spent (discarded) dialysate is discarded to the drain after it has made a single pass through the dialyzer.

Disinfection prevents transmission of infections between patients. The disinfection may be performed using bleach, citrosteril, or heat. Disinfection with bleach is recommended at least once a week and after any blood leak in to the dialysate. Disinfection with citrosteril may be performed daily. All steps for sterilization recommended by the manufacturer must be followed. With standard disinfectant fitted to the rear of the machine, bleach must be administered via the pickup stick (concentrate connectors) at the front of the machine. Gloves and protective glasses must be worn during the procedure by the operator.

Maintenance

The schedules and procedures established by the manufacturer for preventive maintenance should be followed. Such schedule should specify the maximum time intervals either in number of hours of operation of the system or in calendar days between preventative maintenance procedures.

Maintenance log

A history record of all repairs and maintenance for each piece of equipment should be maintained. This record describes all technical operations performed on the equipment, parts used, actions taken, tests performed to assure proper functioning before and after maintenance/repair. The dates and the personnel performing maintenance/repair should be documented. A summary of all maintenance and repair work containing a very brief description of the maintenance/repair (e.g., “300 hour maintenance” or “adjusted conductivity” or “repaired inoperable blood pump,” etc.), date, and person performing action should be kept at the front of the “history file.” Such a log provides a trend analysis of any problems related to the delivery system, as well as a quick confirmation of maintenance being performed according to schedule. *Repair and Troubleshooting*

Dialysis units should have an established and agreed upon plan of action in case of failure of entire machine or a component to ensure that patients are not put to risk. This plan should be approved by the Nephrologist and communicated to all facility staff. Repair and maintenance on a delivery system should only be performed by qualified personnel as defined by the nephrologist.

Quality assurance

It consists of several components such as policies and procedures, staff training and continuing education, and monitoring and evaluation.

Each dialysis units should have “policies and procedures” for dialysis delivery, which should be developed as per the need, implemented and evaluated periodically.

Staff training and education should include operation and proper use and monitoring of dialysis delivery system.

POLICIES AND PROCEDURES

An essential step in designing the facility’s quality assurance program is the development, implementation, and evaluation of policies and procedures for dialysis delivery systems. All standards previously described must be incorporated into these policies and procedures. Specifically, the policies and procedures must address the scope of care and therapeutic choices to be made within the unit and equipment, disposables, and supplies used in the dialysis facility. Comprehensive policies and procedures must also address the interrelationships of each component.

The unit should have a policy about the type of patient that can

be accepted in the unit. For example, a freestanding dialysis unit should not accept unstable patients with problems related to other organ systems that might require multidisciplinary care. Policies and procedures must also address safe and effective operation of the delivery system.

STAFF TRAINING AND CONTINUING EDUCATION

Responsibilities for operation and use of the delivery system

including preventative maintenance, troubleshooting and repairs, daily or per-treatment safety and other system checks and recordkeeping should be clearly defined and understood by the personnel. Each responsibility should stem from a specific policy or procedure. Staff training should be through a well-defined and organized program, with clearly defined content based on behavioral objectives for the learner.

Author Help: Reference checking facility

The manuscript system (www.journalonweb.com) allows the authors to check and verify the accuracy and style of references. The tool checks the references with PubMed as per a predefined style. Authors are encouraged to use this facility, before submitting articles to the journal.

- The style as well as bibliographic elements should be 100% accurate, to help get the references verified from the system. Even a single spelling error or addition of issue number/month of publication will lead to an error when verifying the reference.
- Example of a correct style
Sheahan P, O'leary G, Lee G, Fitzgibbon J. Cystic cervical metastases: Incidence and diagnosis using fine needle aspiration biopsy. *Otolaryngol Head Neck Surg* 2002;127:294-8.
- Only the references from journals indexed in PubMed will be checked.
- Enter each reference in new line, without a serial number.
- Add up to a maximum of 15 references at a time.
- If the reference is correct for its bibliographic elements and punctuations, it will be shown as CORRECT and a link to the correct article in PubMed will be given.
- If any of the bibliographic elements are missing, incorrect or extra (such as issue number), it will be shown as INCORRECT and link to possible articles in PubMed will be given.

Dialysate

We recommend the following specifications for the dialysate

- 1) Only those commercially produced concentrates that have been approved for clinical use by appropriate authority should be used.
- 2) Water used to prepare the dialysate must have been treated to achieve Association for the Advancement of Medical Instrumentation (AAMI) standard.
- 3) If dialysate with a composition different from standard (potassium, calcium) is used, it should be prominently labeled.
- 4) Concentrates should be stored according to type, composition, and proportioning ratios to reduce the risk of mismatching concentrates. Access to storage areas should be restricted. Only authorized, trained personnel should mix and dispense concentrates.
- 5) Concentrates from large containers should be dispensed into smaller ones with a “keyed” dispensing system. Concentrates should preferably be purchased in single-treatment (2½-gallon) containers.
- 6) Dispose of concentrates left over from the previous treatment. Do not pour remaining concentrate into another container or use in the next treatment. Replace empty or partially full containers with full ones.
- 7) The final diluted dialysate should be analyzed every 6 months, with every new batch of dialysate and after each major servicing/repair of dialysis machine.

We recommend the use of bicarbonate rather than acetate as a buffer.

We recommend that the concentration of HD solutions should be such that after dilution to the stated volume the final concentrations of the ions expressed as mmol/l are in the following ranges: sodium 135–145, potassium 0–4, calcium 1.0–2.0, magnesium 0.25–1.0, bicarbonate (acetate equivalent of bicarbonate) 32–40, chloride 95–110.

We suggest that sodium concentration may be adjusted to levels outside the range of 135–140 mmol/L by HD machines with variable sodium capabilities only when prescribed by physician in charge.

We recommend maintaining the potassium concentration at 2 mmol/l for routine HD to keep predialysis serum potassium below 6 mmol/l. However, dialysate potassium concentration varying from 0 to 4 may be used depending on patient need.

When dialysis fluid potassium is other than standard, a label indicating the concentration should be displayed.

We suggest using dialysate containing glucose at 100–200 mg/dl concentration, which is preferable to glucose free solution.

Bicarbonate dialysis requires mixing two concentrates: acid and bicarbonate with treated water. Bicarbonate concentrate is typically supplied in powder form, to be mixed with treated water immediately preceding dialysis. Acid concentrate, containing an electrolyte composition similar to that of acetate concentrates but at a lower pH, is supplied in liquid form. The availability of acid/bicarbonate concentrates with varying ionic contents and proportioning ratios increases the probability of an inappropriate dialysate. The problem is further compounded by the availability of two types of HD machines with different proportioning systems: fixed-ratio and servo-controlled (variable-rate).

Risks and hazards related to dialysate: Approximately half of patient complications related to dialysis concentrate are related to the quality of water used for preparing dialysate or the concentrate. The remaining 50% are related to user errors or machine malfunctions

Briefly, problems related to manufacturers include the following:

- a) *Bacterial growth in liquid bicarbonate concentrate.*
- b) *Actual electrolyte content of the concentrate was different than described on the label.*
- c) *Foreign matter in liquid bicarbonate concentrate.*
- d) *High levels of aluminum contaminating acetate concentrate*

Incidents related to user error, or machine malfunction include:

- a) *Improper sodium concentrations due to mis-calibration of or improper proportioning by the dialysis delivery systems.*
- b) *Use of wrong concentrates or improper mixing of concentrates due to staff misreading labels.*
- c) *Bacterial problems related to improper disinfection of storage containers or use of water containing excess bacteria.*

Water Treatment

The average HD patient is exposed to approximately 25 times the amount of water normally ingested by an individual in a day. Exposure is without the protective barrier of the gastrointestinal tract and the detoxification function of the kidneys, increasing the risk of toxicity caused by the numerous chemical and microbiological contaminants in the water. The final quality of the water is dependent on the configuration of the treatment system and the quality of the feed water. High flux dialyzers and hemodiafiltration demands the use of ultrapure water. Dialysis units should design a system capable of generating appropriate quality water.

We recommend that all HD units should have water treatment systems designed to achieve the water quality of AAMI standards [Table 1].

We suggest that the HD units should aim to achieve European Standards of purity of water [Table 2].

We recommend that treated water should meet with the following three standards of water quality:

- a) Chemical purity.
- b) Microbiological purity.
- c) Endotoxin purity.

We recommend that a water treatment system should consist of the following:

- a) Pretreatment of the source water.

- b) Reverse osmosis (RO).
- c) Storage facilities.
- d) Distribution of treated water.

We recommend that an assessment be made of the following before designing a water treatment unit:

- a) The quality and possible contaminants of the source water. These should be calculated at maximum contamination during the year.
- b) The amount of water needed. Assuming each HD machine would work three shifts of 4 hours each every day, 480 liters of water/day will be needed per machine.

We recommend that incoming water should be treated for the following (pretreatment):

- a) Filtration to remove suspended impurities.
- b) Activated carbon filtration to remove chloramine.
- c) Softener or deionizers.

We recommend that a stainless steel (grade 316) or medical grade PVC water tank be used for water storage. The tank must have de-aeration valve and drain facility at the bottom, so that complete water could be drained out. It should have an airtight lid.

We recommend that all pipelines, valves joints and connectors after RO system should be stainless steel (grade 316) or medical grade PVC.

Table 1: Comparison of maximum permissible water contaminant levels and methods of analysis recommended by the European Pharmacopoeia and the AAMI

Contaminant	Methods of analysis	AAMI	European Pharmacopoeia
Aluminum	Atomic absorption spectrometry	0.0100	0.0100
Antimony	Atomic absorption spectrometry	0.0060	0.0060
Arsenic	Atomic absorption spectrometry	0.0050	0.0050
Barium	Atomic absorption spectrometry	0.1000	0.1000
Beryllium	Atomic absorption spectrometry	0.0004	0.0004
Cadmium	Atomic absorption spectrometry	0.0010	0.0010
Calcium	Atomic absorption spectrometry	2 (0.05mmol/l)	2 (0.05mmol/l)
Chloramines	Colorimetry	0.1000	0.1000
Chromium	Atomic absorption spectrometry	0.0140	0.0140
Copper	Atomic absorption spectrometry	0.1000	0.1000
Cyanide	Spectrophotometric	0.0200	0.0200
Fluoride	Molecular photoluminescence	0.2000	0.2000
Free chlorine	Colorimetry	0.5000	0.5000
Lead	Atomic absorption spectrometry	0.0050	0.0050
Magnesium	Atomic absorption spectrometry	4 (0.16mmol/l)	2 (0.08mmol/l)
Mercury	Atomic absorption spectrometry	0.0002	0.0010
Nitrate	Colorimetry	2.0000	2.0000
Potassium	Flame photometry 8	(0.2mmol/l)	2 (0.08mmol/l)
Selenium	Atomic absorption spectrometry	0.0900	0.0900
Silver	Atomic absorption spectrometry	0.0050	0.0050
Sodium	Flame photometry	70 (3.0mmol/l)	50 (2.2mmol/l)
Sulfate	Turbidimetric method	100	100
Thallium	Atomic absorption spectrometry	0.0020	0.0020
Zinc	Atomic absorption spectrometry	0.1000	0.1000

We recommend that bends and blind loops should be kept to a minimum.

We suggest online 0.22µ membrane filter and ultraviolet light after RO. Ultraviolet light is also suggested after activated carbon filter and before RO.

For monitoring, we recommend the following:

- a) **Chemical purity:** Online conductivity meters after deionizers and RO. There should be visible and audible alarm for improper conductivity in the dialysis technician's station. The alarm should lead to stoppage of water beyond RO. The water should re-start only after adequate conductivity is achieved. Treated water sample should be sent for detailed chemical analysis to an independent laboratory having adequate instrumentation for testing at least once in 3 months. The results should be mandatory part of the record system.

Table 2: Maximum levels of the different water purity grades

Maximum levels	AAMI Water	European pharmacopoeia		
		Regular water	Ultrapure water	Sterile water
Microbial contamination (CFU/ml)	200	<100	<0.1	<0.000001
Bacterial endotoxins (IU/ml)	< 2	<0.25	<0.03	<0.03

Table 3: Maintenance of water treatment system

Component	Monitoring Parameter	Maintenance required	When
Depth Filter	Pressure drop across filter	Backwashing and Rinsing	Twice a week and daily during the monsoon or when water contains extra suspended particles/impurities.
Activated Carbon Filter	Pressure drop across filter	Backwashing and Rinsing	Twice a week
Activated Carbon Filter	Chlorine in product water	Changing of charcoal	If > 0.1 µg/ml.
Softener	Hardness	Regeneration	Failure to achieve 10 folds decreases.
Membrane filters	Pressure drop across filter	Change of filter	Drop > 25%
Reverse Osmosis membranes	Inlet, Reject and Permeate pressures and flows	Increase in inlet pressure > 25%, or decrease in permeate flow by 25%	At the time of offline cleaning of membranes
Reverse Osmosis membranes	Conductivity	Increase by 50% from baseline	Offline leaning or replacement of membranes
Deioniser	Conductivity or resistivity	< 1megaohm or > 0.5 micromhos	Regeneration with acid and alkali
Storage tank and Pipeline	Bacterial counts	>50% increase over baseline.	Cleaning and Disinfection

- b) **Microbiological purity:** This should be checked once every 30 days to achieve the standards as per Table 2. It is recommended that pour plate method on nutrient poor medium should be used. Incubation should be at room temperature (20–24°C) for 7 days.
- c) **Endotoxin levels:** Should be checked once in every 30 days to achieve the standard as per Table 2.

We recommend that each component of the water treatment system must be thoroughly cleaned and sterilized as per the manufacturer's recommendation. After sterilization, it is essential that the sterilent is completely removed before the treated water is used for dialysis.

We recommend the following for cleaning of RO membranes:

- a) Membranes should be taken offline and the system shut down during the process. The flow of reject should gradually increase if the process is successful.
- b) Membranes should be backwashed at low pressure using an external pump and flow in the same direction as normal operation. Each membrane should be cleaned individually. The following cleaning solutions are required.
- c) Sodium tripolyphosphate and sodium edetate at a pH adjusted to > 10 to remove calcium scales and low-level organic foulants.

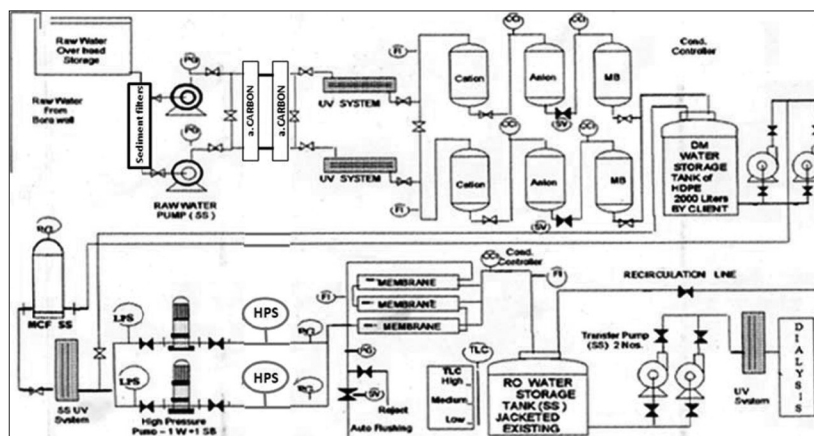


Figure 1: Suggested architect plans for water treatment system in a stand- alone MHD facility. (SS - Stainless steel, UV - Ultraviolet, MB - Mixed bed, DM - Demineralised (Deionised), PG - Pressure gauge, RO - Reverse osmosis, LPS - Low pressure switch, HPS - High pressure switch, MCF SS - Micro clean filter stainless steel)

- d) 2% citric acid (no pH adjustment required) to remove calcium carbonate, metal oxides and inorganic colloidal compounds. This also provides disinfection.
- e) A water wash is recommended between the cleaning solutions.
- f) A final disinfection using 1% peracetic acid or 2% formalin (to be treated for at least 6 hours) is recommended.
- g) We recommend discarding the first 200–250 liters of water or permeate over 1 hour after a cleaning and disinfection cycle. The pH of permeate should be confirmed before using.

The following steps are recommended for cleaning and disinfection of the distribution system.

- a) The storage tank should be filled with 50–100 liters of 1% sodium hypochlorite.
- b) After allowing a contact time of 30 min the solution is circulated in the loop for 20 min and drained followed by a complete rinsing with water that is discarded until a negative test with a starch iodide paper or a conductivity equal to that of the feed water is obtained. Inline steam or ozone can be used in place of sodium hypochlorite.

We recommend a log should be documenting the performance of the water treatment system components and indicating the maintenance done on each component. A suggested schema is shown in Table 3. Figure 1 shows the planning of a water treatment plant for a standalone unit.

Annexure

Limulus amoebocyte lysate (LAL) Assay for endotoxins

1. Add 0.1 ml of reconstituted (as instructed in package insert) pyrotell (C.No.G2003/G2125) (0.03/0.125 EU/ml).
2. Add 0.1 ml test specimen or control (C.No.E0005 - Positive control or C. No. W0504 LRW - LAL Reagent Water - Negative control).
3. Mixed vigorously (vortex) for 20–30 seconds.
4. Place the reaction tubes at 37+1°C water bath for 60 min.
5. Remove reaction tubes and invert the tubes in one smooth motion.
6. A positive test is indicated by the formation of a gel which does not collapse when the tube is inverted by 180°.

Vendors

1. Nexus, Division of Span Diagnostics, 173-B New Industrial Estate, Udna, Surat – 394 210. Cell: 9825831746 Fax: +91 261 28679319,
2. Lonza India Private Limited, 2nd Floor, Krishnama House, 8-2-418, Road No. 7, Banjara Hills, Hyderabad - 500034 Tel: +91 40 4123 4000 Fax: +91 40 4123 4090 Cell: +91 87 9099 6211

Microbial culture

1. One hundred milliliter of treated water is collected in sterile and pyrogen free container.
2. Pour 1 ml sample of water on Soya triptone agar (nutrient deficient), McConkey agar and Nutrient Agar plates. Suggested source: Himedia Labs (<http://www.himedialabs.com/HML/Pages/default.aspx>).
 - Place in an incubator at 37°C, and check for the bacterial colony formation after 48 hours and 7 days.

- Colonies are counted in the plates with positive growth and expressed as the colony forming unit (cfu) per ml.

Test for microelements in RO water

1. One hundred milliliter of treated water is collected in a glass stoppered bottle (BOROSIL) previously washed in the following way for proper decontamination from microelements.
2. Bottle is washed twice with mild detergent solution followed by repeated washing with treated/pyrogen free water.
3. Washed bottle is oven dried.
4. Bottle with hydrochloric acid (HCl) diluted in treated/pyrogen free water and then keep overnight under 0.1N HCl.
5. Repeatedly wash with treated/pyrogen free water.
6. Wash the bottle with the sample RO water 10 times with vigorous shaking.
7. Drain out the washing water.
8. Collect the sample of treated water (100 ml) in bottle for analysis. Close the stopper immediately.
9. Estimation is done for the following analytes: Aluminum (Al), Arsenic (As), Barium (Ba), Beryllium (Be), Bismuth (Bi), Calcium (Ca), Cadmium (Cd), Cobalt (Co), Chromium (Cr), Copper (Cu), Iron (Fe), Mercury (Hg), Potassium (K), Lithium (Li), Magnesium (Mg), Manganese (Mn), Nickel (Ni), Phosphorus (P), Lead (Pb), Sodium (Na), Palladium (Pd), Rubidium (Rb), Antimony (Sb), Tin (Sn), Titanium (Ti), Vanadium (V), Zinc (Z), Chloride, Thallium (Tl), Nitrate, Fluoride and Sulfate.

Vascular Access

Vascular access has been described as the “Achilles heel” of HD. A permanent vascular access, preferably an arteriovenous (AV) fistula should be constructed prior to first dialysis. However, a large number of patients first for HD without any access in place. These patients start and even continue dialysis with catheters.

Regular monitoring of an AV fistula and early intervention for malfunction can prolong the life of these accesses. Comprehensive care of a vascular access involves a team approach involving the patient and several caregivers in order to obtain the best possible results.

We recommend creation of a permanent vascular access for every patient on HD in the following order of preference:

- a) Radiocephalic AV fistula.
- b) Brachiocephalic AV fistula.
- c) Saphenous vein forearm grafts.
- d) Brachiocephalic fistula with transposed vein.
- e) Upper arm autologous saphenous vein grafts.
- f) Polytetrafluoroethylene (PTFE) grafts (straight or U) at any site.

We recommend access creation in the nondominant arm.

In patients who do not have a fistula, we recommend dialysis with a double lumen uncuffed nontunneled soft catheters inserted in the internal jugular vein. An AV fistula should be created as soon as possible.

Autologous Saphenous vein grafts are preferred over PTFE grafts because of lower costs and thrombogenicity.

We recommend that the subclavian vein should not be used for gaining temporary access unless the internal jugular is unusable and no permanent access is possible on that side. Even a single subclavian cannulation is associated with a 35% risk of stenosis.

We suggest that the femoral vein on the left side may be used as a temporary vascular access with rigid single lumen cannula in an emergency situation only.

Cannulae in the femoral vein should not be retained for longer than 7 days and should never be used in the outpatient setting.

We suggest avoiding right sided femoral vein cannulation in prospective transplant recipients.

All HD units should aim to have AV Fistula in at least 65% of new patients and in 90% or more of prevalent patients at all times.

We suggest that cuffed tunneled biluminal soft catheters inserted in the internal jugular vein with an exit site on the anterior chest wall may be utilized as semi-permanent access. The cuff should be placed subcutaneously above the clavicle and at a distance of 3–4 cm from the exit site. This approach should be used only when a permanent access cannot be created in the foreseeable future.

We suggest that venous grafts, both autologous and PTFE may be used within 3 weeks of construction.

Patient preparation and evaluation for access preparation

A history should be obtained regarding past central or peripheral or venous or arterial cannulation, previous attempted AV fistulae, time and possible cause of access failure (if applicable), presence of cardiac disorders, malignancy and prothrombotic tendency or anticoagulation.

Physical examination of both upper extremities should include:

- a) Examination of peripheral pulses.
- b) Bilateral upper extremity blood pressure measurement.
- c) Presence of edema.
- d) Presence of collateral veins.
- e) Collapsibility.
- f) Allens test and Modified Allens Test.

Allen's test assesses collateral circulation in the hand, in two steps.

- a) Step 1 occludes the radial artery for several minutes and compares the hand color to the other hand. The hand is said to have sufficient collateral circulation through the ulnar artery if there is no change in color.

Preservation of peripheral and central veins

Patients with CKD IV or V should not have venipunctures or peripheral cannulae in the forearm or above the wrist once a decision to create an AV fistula for dialysis has been taken.

Patients admitted in hospital should be provided with bracelets labeled “No Venipuncture” to be worn during admission.

Patients should be educated about preservation of forearm veins.

Design and performance of temporary accesses

The diameter of the cannula and the length determine the blood flow.

Single lumen femoral cannulae should be at least 19 cm long to reach the IVC. Flows of > 200 ml/min are not obtained with standard femoral single lumen cannulae.

The length of a cannula in the right internal jugular vein should be 13.5 cm for an adult, while that of a left internal jugular cannula should be around 16 cm, that of a right sub-clavian cannula should be 15 cm and a left subclavian vein cannula 16 cm.

The cannulae should be at least 12 F to obtain flows of 300 ml/min and 14 F if higher flows are desired For children, 8 and 10 F cannula can be used.

Cuffed tunneled cannulae should have a total length of at least 35 cm for right internal jugular and a length of 44 cm for left internal jugular.

- b) Step 2 occludes the ulnar artery. A change in hand color means the potential for radial artery occlusion is high. That is a positive Allen's test, which contraindicates radial-artery use for an AV fistula

The modified Allen's test may be carried out as follows:

- a) Instruct the patient to clench his/her fist, or if the patient is unable, close the hand tightly.
- b) Apply occlusive pressure with the fingers to both the ulnar and radial arteries. This maneuver obstructs blood flow to the hand.
- c) While applying occlusive pressure to both the arteries, have the patient relax his/her hand. Blanching of the palm and fingers should occur. If it does not, you have not completely occluded the arteries with your finger.
- d) Release the occlusive pressure on the ulnar artery. Flushing of the hand should occur within 5–15 seconds. This denotes that the ulnar artery has good blood flow. This normal flushing of the hand is considered to be a positive modified Allen's test. A negative modified Allen's test is one in which the hand does not flush within the specified time period. This indicates that ulnar circulation is inadequate or nonexistent. In this case, the radial artery supplying arterial blood to that hand should not be used for an AV fistula.

Preoperative imaging/mapping

Ultrasonographic mapping of venous drainage of the extremity is suggested in difficult cases. A tourniquet should be applied to the upper arm and the vein diameter measured. The vein diameter should be between 2 and 2.5 mm. This assessment should be done when patient has achieved near ideal volume status.

In cases of previous fistula failure and history of central vein cannulation venography should be done for patency and adequacy of peripheral and central veins.

Patients with fistulae lost due to early unexplained thrombosis should have a thrombotic screen.

We recommend the following steps for preparing the access for cannulation:

1. Access should be examined at each session prior to starting dialysis.
 - a) Fistulae should be examined to confirm a low pitched continuous bruit and a thrill, absence of edema, normal limb temperature, absence of ischemia, steal, and large collateral veins.
 - b) Fistulae should not have a water hammer pulse on examination.
 - c) Veins should collapse upon raising the arm above the level of the heart.
2. Wash (or ask the patient to wash) the access site with antimicrobial or plain soap and water.
3. Wash hands.
4. Cleanse the skin by applying any one of the following:

- a) 0.5–2% chlorhexidine gluconate in 70% ethyl or isopropyl alcohol.
- b) alcoholic chlorhexidine (0.5–2% chlorhexidine gluconate in 70% ethyl or isopropyl alcohol).
- c) 70% isopropyl alcohol using sterile swabs.

5. Cleanse in a circular, rubbing motion from the center outwards, for 1 min immediately prior to cannulation. Do not use a backward and forward movement.
6. Wear sterile gloves for cannulation if the skin needs to be re-palpated.
7. Gloves should be changed if contaminated.
8. The skin at the site of puncture should be infiltrated with 2% xylocaine using a 26G needle. Alternatively, Lignocaine-Prilocaine gel should be applied over the region 30 min prior to puncture.
9. Initial cannulation of the AV fistula should be with 17G needles equipped with a “back eye”. Flows of up to 200 ml/min can be obtained with a 17G needle. Subsequent cannulation should be with a 16G needle to obtain flows of 300 ml/min and with a 15G needle to obtain flows of > 300 ml/min.
10. We recommend railroading technique rather than a buttonhole technique should be followed for cannulation.
 - a) Railroading – At each dialysis session, puncture of the fistula should be done 1–2 mm away from the previous point and a return to the original site should occur after 6–7 sessions.
 - b) Buttonhole – Every puncture is done through an identical point. This eventually leads to decreased pain sensation at the site but also to weakening of the vein wall and aneurysmal dilatation.
11. The “arterial needle” should point toward the anastomosis and the “venous needle” should point away from the anastomosis.

We recommend the following for care of a catheter

1. Dressings of a vascular access should be transparent, occlusive, and strong enough to resist the weight of the dialysis cannulae. Micropore or Tegaderm is a useful dressing.
2. The skin around the exit site of the access site should be clipped of hair, and tincture benzoin should be applied to the area prior to application of the dressing.
3. Mupirocin ointment should be applied to the exit site of both cuffed and uncuffed cannulae.
4. Centers that experience outbreaks of catheter-related sepsis should carry out surveillance cultures using nasal swabs of all patients and dialysis personnel once a year and treat all and staphylococcal carriers.
5. Mupirocin ointment may be applied to the external nares, axilla, and groin in patients using cuffed tunneled cannulae as a vascular access who have been found to be staphylococcal carriers.

6. Patients and attendants should wear a disposable surgical mask during any manipulation of access needle/catheter, dressing changes, and connection and disconnection to the dialysis machine.
7. Dressings should be changed weekly and whenever wet, visibly soiled or stained with blood or other material. Cannulae should not be unnecessarily manipulated.
8. The hubs of the cannulae should be cleaned with sterile swabs soaked in 2% alcoholic chlorhexidine, the connection to blood tubings done without touching the hubs or connectors, and the joint wrapped with a swab soaked in 2% alcoholic chlorhexidine or 10% povidone iodine for 10 min.
9. The cannulae should be flushed with sterile saline till free of blood prior to anticoagulant instillation after each dialysis.

We recommend the following steps for monitoring and detection of complications:

1. The maximum blood flow obtained from the access should be documented at each dialysis.
2. A progressive drop in the flow obtained with properly positioned needles of the same gauge should prompt further investigation of the access for stenosis.
3. Venous pressure should not be used to monitor stenosis in an AV fistula vein but may be used to monitor stenosis in an A V graft.
4. The venous pressure should be measured using 17G needles within the first 5 min of dialysis at a blood flow of 200 ml/min. Serial readings are more useful than a single one. An increase of more than 20% or an absolute value persistently > 120 mm of Hg is indicative of a graft outflow stenosis.
5. Fistula and graft stenosis should be investigated by fistulograms. Ultrasonography is an alternative but is highly operator dependant and can give fallacious readings due to deep collateral veins.
6. A fistulogram or CT fistulogram should evaluate the AV anastomosis, the draining veins, and the central veins (subclavian and superior vena cava).
7. Fever or rigors during HD in patients with indwelling cannulae should prompt evaluation of the vascular access as a source of infection.

Following "Rule of 6" should be followed for an AV fistula

- A vein of at least 6 mm in diameter with clearly distinguishable margins.
- A cannulation length of at least 6 cm from the anastomosis.
- Flow of at least 600 ml/min and a depth of not more than 6 mm from the skin.
- Use 6 weeks after the time of creation.
- Numerous collateral veins should not be visible and there should be no evidence of venous hypertension.

We suggest the following measures to prevent access dysfunction

1. Antibiotic locks may be used in patients with cuffed tunneled cannulae. Citrate (4%) has antibacterial properties and may be used alone as an alternative to heparin as a locking solution.
2. Prophylactic antibiotic lock solutions should never include drugs like Vancomycin, which are to be retained for therapeutic use.

Preparation of antibiotic cannulae locks

Trisodium citrate is commercially available as a 46% solution. This may be diluted 10 times with sterile water for injection to produce a 4.5% solution.

Gentamicin – citrate Lock solution: 46% trisodium citrate is diluted with sterile water 1:5 to produce a 9.2% solution. One milliliter of this solution is mixed with 0.5 ml of 10 mg/ml gentamicin injection and the resulting 1.5 ml is injected into each limb of the cannulae. The final solution containing 6.1% citrate and 3.3 mg/ml of gentamicin can be used as either a prophylactic or therapeutic lock solution.

Gentamicin – heparin solution: One milliliter of gentamicin injection containing 10 mg is mixed with 4 ml of heparin containing 1000 units/ml. Up to 1.5 ml of the solution should be instilled into each limb of the cannulae. The final solution contains 800 units/ml of heparin and 2 mg/ml of gentamicin. Stronger concentrations should not be used and care should be taken not to exceed the volume of the cannulae to avoid systemic toxicity.

Treatment of complications in permanent Access

Surgical revision or percutaneous intervention should be attempted to salvage a stenosed AV fistula or graft before attempting to construct a new access.

Thrombolysis or surgical thrombectomy should be attempted in case of an early acute access thrombus.

Surgical thrombectomy is rarely successful in cases of late thrombus formation, which are usually due to an underlying stenosis.

Treatment of complications in temporary access

- *Temporary cannulae in the femoral vein should always be removed if suspected to be infected.*
- *Temporary cannulae in the internal jugular vein may be retained for a 24–48 hour period while systemic antibiotics are administered, but should be removed if fever persists and subsequently replaced at a fresh site.*
- *Cuffed tunneled cannulae may be retained for 72 hours or longer while antibiotic therapy according to culture reports is administered. Systemic antibiotics should be accompanied by local antibiotic lock solutions, the concentration of which can be several times higher than that of the minimal inhibitory concentration (MIC) reported for blood cultures.*
- *Cannulae may be changed over a guide wire if fever persists for > 48 hours.*
- *Cannulae should be removed and a fresh cannulae inserted if bloodstream infection is accompanied by exit site and tunnel infection or abscess. (fat necrosis should be distinguished from pus) or if culture grows, Staphylococcus aureus, Candida species or Gram negative bacilli or if infection is accompanied by diminished cannulae performance.*
- *Decreased flows or high venous pressures should be investigated with a catheterogram, which should include visualization of the SVC for intraluminal thrombosis, migration or formation of a fibrin sheath.*
- *Local thrombolysis may be attempted for cannulae thrombus or luminal thrombus.*
- *Catheter change over a guide wire may be required for fibrin sheath formation.*

Announcement

“QUICK RESPONSE CODE” LINK FOR FULL TEXT ARTICLES

The journal issue has a unique new feature for reaching to the journal’s website without typing a single letter. Each article on its first page has a “Quick Response Code”. Using any mobile or other hand-held device with camera and GPRS/other internet source, one can reach to the full text of that particular article on the journal’s website. Start a QR-code reading software (see list of free applications from <http://tinyurl.com/yzlh2tc>) and point the camera to the QR-code printed in the journal. It will automatically take you to the HTML full text of that article. One can also use a desktop or laptop with web camera for similar functionality. See <http://tinyurl.com/2bw7fn3> or <http://tinyurl.com/3ysr3me> for the free applications.

Priming, Connecting, and Disconnecting

Complications can develop as a result of incorrect connection and disconnection of a patient from the extracorporeal circuit. This is the period when both patients and unit staff are under pressure to speed up the entire procedure, increasing the risk of mistakes, strict adherence to a protocol and the use of checklists is necessary to prevent complications.

We recommend that during catheter connect and disconnect procedures, both dialysis staff and patient should wear surgical masks. Face shield should not be used without surgical mask.

We recommend that a label mentioning the name and hospital registration number of the patient should be put on the new dialyzer.

In case a dialyzer is being reused, we recommend that the name and registration number of the patient should be checked by two persons and the patient's records be documented in the records.

We recommend thorough rinsing of dialyzer in order to ensure removal of leachable allergens.

We recommend 1 L normal saline for rinsing the blood compartment of a new dialyzer and 2 L for a dialyzer that is being reused. This is done to eliminate all the air and residual sterilant from the dialyzer, blood lines, and for priming of the circuit. The last 500 ml of normal saline is heparinized with 1000 units of heparin.

We recommend rinsing the dialysate compartment of dialyzer with dialysate for at least 5 min before initiating dialysis.

We recommend that all alarms should be checked at the start.

We recommend the following points for patient assessment before dialysis:

1. Record weight.
2. Measure BP in lying and standing position.
3. Ask for any new symptoms.
4. Assess dry weight and plan target UF.

We recommend the following procedure for handling percutaneous venous cannulae:

1. Apply mupirocin or povidone iodine at exit site.
2. Aspirate residual heparin or clot from each catheter lumen.
3. Check patency of catheter lumina by irrigating with heparinized saline (100 units/ml).
4. The lumen and catheter tips should never remain open to air. A cap or syringe should always be placed on or in the catheter lumen while maintaining a clean field under the catheter connectors.
5. Caps should be soaked in povidone-iodine and kept wrapped in gauze soaked in povidone-iodine for the entire length of the dialysis. Alternatively the caps can be sterilized with ethylene oxide autoclaving during the

dialysis and can be reused after the dialysis is completed.

6. Catheter lumens must be kept sterile. Interdialytic infusions through the catheter are forbidden.
7. Inspect the exit site for evidence of infection (redness or purulent discharge).
8. If any evidence of exit site infection is seen a swab should be sent to the laboratory for culture.
9. Clean exit site with povidone-iodine and dry before dressing.
10. Apply local antiseptic ointment such as mupirocin.
11. Exit site should never be immersed in bath water. Showering is best avoided but if the patient showers it should be done prior to coming for dialysis where a new dressing and antibacterial ointment can be promptly applied.

We recommend the following procedure for handling Arteriovenous fistula or/graft:

1. Check the fistula for patency and function after applying tourniquet.
2. Place both needles in the vein downstream to the anastomosis.
3. Arterial needle is placed distally as compared to the venous needle.
4. If the patient has a poorly distended venous limb, briefly apply a tourniquet to define the location.
5. A 16 or 15 gauge needle should be used in adults.
6. Prepare the needle insertion site with povidone-iodine.
7. Arterial needle is inserted first 3 cm from the anastomosis site. The needle is inserted bevel up at a 45° angle pointing either upstream or downstream.
8. The venous needle is inserted at a 45° angle pointing downstream (usually toward the heart).
9. The insertion point of the venous needle should be at least 3–5 cm downstream to the arterial needle to minimize recirculation.

We recommend the following procedure for initial heparin administration

1. Administer heparin loading dose into the venous port and flush with saline.
2. Start blood flow after 3 min of administration.
3. Alternatively, heparin can be injected into the arterial line leading to the dialyzer and blood pump started immediately.

We recommend the following procedure for initiating dialysis:

1. Keep blood flow rate initially at 50 ml/min and increase to 100 ml/min until the entire blood circuit fills with blood.

2. The priming fluid in the dialyzer can either be given to the patient in case the BP is low or disposed off in the drain.
3. Ensure proper level in the venous drip chamber.
4. Promptly increase blood flow rate to target (250–300 ml/min).
5. Record the pressure levels at inflow and outflow monitor.
6. Set the pressure limits slightly above and below (10–20 mmHg) the operating pressure to ensure that the blood pump will stop in case of any change of operating pressure beyond the set limits.
7. Initiate dialysis solution flow.
8. Enter the UF volume desired in the machine.

We recommend regular monitoring of the patient during dialysis

1. The BP should be monitored and recorded as often as necessary.
2. We recommend checking the blood pressure every 15 min in an unstable patient. In a stable patient BP this should be done every 30–60 min.
3. In symptomatic diabetic patients, we suggest measuring the capillary blood glucose to detect any episode of hypoglycemia.

We recommend the following steps for termination of dialysis

1. Return blood in the extracorporeal circuit using saline or air.
2. Air should not be used if the dialyzer is to be reprocessed.
3. If saline is used, patient receives 100–200 ml of this fluid during the rinse back procedure.
4. If air is used,
 - a) Switch off blood pump first.
 - b) The arterial blood line is clamped close to the patient.
 - c) The arterial blood line is disconnected just distal to the clamp, opening it to air.
 - d) Blood pump is restarted at a rate of 20–50 ml/min and

the air is allowed to displace the blood in the dialyzer.

- e) When the air reaches the venous air trap or when the air bubbles are first seen in the venous blood line, the venous line is clamped.
- f) The blood pump is stopped and the return procedure terminated.

We recommend the following for closure of vascular access

AV fistula

1. Remove the needles from the AV fistula and apply gauze.
2. Tie tourniquets firmly over the gauze pieces with just enough pressure to stop bleeding; but without occluding the flow.
3. Patient is advised to loosen the tourniquet straps after 4–6 hours and remove the tourniquets if no oozing is noted from the puncture sites. Patients should be advised to report if it takes longer than 4–6 hours for bleeding to stop and then confirm a functioning fistula.

Venous catheters

1. Fill the dead space of each lumen with 1000 u/ml heparin through the injection ports. Do not use higher concentration of heparin as it may result in significant anticoagulation.
2. Soak catheter hubs or blood line connectors in povidone-iodine for 3–5 min, then dry prior to application.
3. Cover catheter with a sterile dry dressing.
4. We suggest not using nonbreathable or nonporous transparent film dressings since they pose a greater threat of exit site colonization than dry dressings.

We recommend postdialysis monitoring of the patient as follows:

1. Ask for any symptoms.
2. Measure blood pressure both standing and lying positions.
3. Record the UF (predialysis weight minus postdialysis weight).
4. Measure postdialysis weight.

Anticoagulation

The HD circuit has a large extracorporeal surface area and the passage of blood through the circuit results in activation of coagulation cascade. The consequences of clotting are blood loss and loss of dialyzer surface area leading to reduced solute clearance. Anticoagulation is required to prevent clotting during a session and also to prolong the life of the dialyzer for reuse. Unfractionated heparin is traditionally used for anticoagulation. Low molecular weight heparin, trisodium citrate, fondaparinux, and prostacyclin (all of which are expensive) may be used in specific situations. The long-term safety of these agents has not been completely established in dialysis.

Factors favoring clotting of extracorporeal circuit

- Low blood flow
- High hematocrit
- High UF rate
- Dialysis access recirculation
- Intra dialytic blood and blood product transfusion
- Intra dialytic lipid infusion
- Use of drip chambers (air exposure, foam formation, turbulence)

We recommend the following precautions to prevent dialyzer clotting

Priming

1. Follow the correct priming technique to prevent retained air in dialyzer. (Refer guideline on priming technique).
2. Ensuring adequate priming of heparin infusion line.

Heparin administration

1. Use correct loading dose (see below).
2. Use correct heparin pump setting for constant infusion.
3. Starting of heparin pump in timely manner.
4. Ensuring timely release of heparin line clamp.
5. Allow time after loading dose for systemic heparinization to occur.

Vascular access

1. Ensure adequate blood flow by correct needle and catheter position.
2. Correct needle position to prevent recirculation.
3. Adequate uninterrupted blood flow by preventing repeated machine alarm situation.

We recommend that

1. The heparinization schedule should be decided taking into consideration the risk of bleeding and other co-morbidities.
2. Low risk patients and those without co-morbidities like central nervous system (CNS) bleed, GI hemorrhage, or pericarditis are routinely treated with full dose heparinization.

3. Patient at slightly increased risk of bleeding and those in whom heparin free dialysis is unsuccessful due to frequent clotting should receive tight heparinization.
4. Heparin free dialysis should be considered for those with pericarditis, recent surgery with bleeding complications or risks (vascular and cardiac surgery, eye surgery, renal transplant, and intracranial surgery), coagulopathy, thrombocytopenia, intracerebral hemorrhage, and active bleeding from any other site.
5. We recommend that in situations where the use of heparin is contraindicated (e.g., heparin induced thrombocytopenia (HIT) and heparin free dialysis is not advisable, the operator may choose alternative anticoagulants.

We recommend the following heparinization protocols

1. Routine anticoagulation with unfractionated heparin:

Either intermittent or continuous delivery techniques should be used.

- a) Intermittent bolus: Bolus loading dose 35–55 units/kg followed by intermittent maintenance dose of 10–20 IU/kg boluses every hour. No heparin to be given after last half hour of dialysis.
- b) Constant infusion: Bolus loading dose of 35–55 units/kg followed by constant infusion.

Dose

Body weight between 50 and 90 kg: no change in dose.

Body weight outside these limits: bolus dose 75–100 units/kg; Infusion dose 750–1000 units/hour.

Termination of heparin infusion

AV fistula – 1 hour before end of dialysis.

Venous catheters – at the end of dialysis.

Reversal of over heparinization.

Injection protamine 1 mg for every 100 units heparin.

2. Tight heparinisation

Delivery technique: Bolus dose followed by constant infusion.

Do not try intermittent boluses as it will lead to rising and falling clotting times.

Dose

Initial bolus dose: 750 units.

Heparin infusion rate: 600 units/hour.

Termination of heparin infusion: Continue till end of dialysis.

Target clotting times

ACT test baseline value 120–150 seconds.

Routine heparinization: During dialysis desired range +80% (200–250 seconds); at the end of dialysis +40 % (170–190 seconds)

Tight heparinization: During dialysis desired range +40% (170–190 seconds); at the end of dialysis +40% (170–190 seconds)

3. Heparin free dialysis

Rinse with saline containing 3000 units heparin/L

Drain out heparin containing saline by filling extracorporeal circuit with patient blood or unheparinized saline

Keep blood flow to 400 ml/min. In case high blood flow is not possible (small patient size, very high predialysis plasma urea level), use small surface area dialyzer, reduce dialysate flow or shorten treatment session.

Periodic saline rinse is recommended. One schedule is 250 ml every 30 min.

Inspect dialyzer for evidence of clotting during rinse.

In case clotting detected, consider changing dialyzer or terminating dialysis.

Remove amount of saline infused by increasing the ultra filtration accordingly.

Bicarbonate dialysis solution with low concentration citrate.

Use dialysis solution containing 0.8 mmol/L citrate.

4. Regional citrate (high concentration anti coagulation).

Infuse tri sodium citrate in arterial blood line.

Use dialysate containing no calcium.

Infuse calcium chloride in venous blood line.

Assessing coagulation during dialysis

Extremely dark blood.

Shadows or black streaks in the dialyzer.

Foaming with subsequent clot formation in the drip chambers and venous trap.

Rapid filling of transducer monitors with blood.

Tethering (blood in the postdialyzer venous line segment that is unable to continue in the venous chamber but falls back into the line segment). Presence of clot at the arterial side header.

Extra corporal circuit pressures exceeding preset limits.

Reduction in residual dialyzer volume.

Staying in touch with the journal**1) Table of Contents (TOC) email alert**

Receive an email alert containing the TOC when a new complete issue of the journal is made available online. To register for TOC alerts go to www.indianjephrol.org/signup.asp.

2) RSS feeds

Really Simple Syndication (RSS) helps you to get alerts on new publication right on your desktop without going to the journal's website. You need a software (e.g. RSSReader, Feed Demon, FeedReader, My Yahoo!, NewsGator and NewzCrawler) to get advantage of this tool. RSS feeds can also be read through FireFox or Microsoft Outlook 2007. Once any of these small (and mostly free) software is installed, add www.indianjephrol.org/rssfeed.asp as one of the feeds.

Dialyzer Reuse

Reuse of dialyzers, tubings, and end caps is banned by law in many countries, but is widely practiced in India to reduce cost. An analysis of reuse practices adjusted for covariates, concluded that dialyzer reuse per se was not associated with increased mortality.

There are variations in the practice of reuse in terms of the method of reprocessing (manual vs automated), the use of chemicals and disinfectants and tests of performance.

Although the main objective of reprocessing dialyzers is lowering cost, this should not compromise the quality of dialysis and safety of patients. Another concern is the relative environmental load of reprocessing chemicals vs that of discarded dialyzers.

1. We suggest that hollow fiber dialyzers may be reprocessed in order to reduce the cost of the HD procedure.
2. We recommend that units that practice reuse should have an adequate protocol of reprocessing and a reliable system of monitoring.
3. We recommend that only dialyzers that have been validated and are approved for reuse by the manufacturers [Table 1] should be reused. This information can be found on the label.
4. We suggest manual reprocessing when the reuse machine is not available.

Automated techniques eliminate human error, making the process more reproducible; provides an accurate estimation of fiber bundle volume, leak testing and in vitro measurement of the ultrafiltration coefficient. The number of reuses obtained by automated reprocessing may be consistently higher than by manual reprocessing, however, studies with the manual method have also shown similar reuse numbers where a protocol was rigidly adhered to and monitored.

6. We recommend chemical disinfectant reprocessing.
7. We recommend heat reprocessing only for polysulfone dialyzers.
8. We recommend that dialyzers from patients with hepatitis B and C virus infections should be reprocessed in a separate reprocessing area.
9. We recommend performance testing for all reused dialyzers.
10. We recommend not using visual impressions as the sole criteria for continuing to reuse a dialyzer. Studies have demonstrated that dialyzers which appeared normal on

inspection delivered an inadequate dose of dialysis.

11. We suggest that tubings, end caps, O rings, and dialyzer headers may be reused.
12. We suggest that venous or arterial transducer protectors should not be reused.
13. We recommend that operators should wear appropriate protective gear for all reprocessing procedures.
14. We recommend that the process of reusing dialyzers should be monitored for efficacy and safety.
15. We recommend that the process including the results of performance tests should be documented by the operator and verified by the dialysis doctor.
16. We recommend that the decision to discard a dialyzer should be taken by the dialysis technician/nurse as per protocol. The dialysis doctor should make the decision in case of any protocol deviation.

Reuse procedure involves a high risk of mucosal splash with contaminated material/effluent. The risk of transmission of hepatitis B is approximately 30% after a mucosal exposure, around 3% for hepatitis C and 0.3% for human immunodeficiency virus (HIV).

We recommend the following for automated reprocessing

1. The automated reprocessing machine should be capable of
 - a) performing the three tests of performance, namely, estimation of fiber bundle volume, UF coefficient, and pressure leak testing. These should be recorded.
 - b) carrying out a disinfection cycle of its hydraulics.
2. Automated reprocessing techniques usually follow the same sequence of steps or a slightly modified cycle as described below for manual reprocessing. These are specified by the manufacturer and should be carried out as advised.
3. The chemicals required for cleaning and disinfection cycles should be connected to the machines as specified by the manufacturer.
4. Periodic changing of the chemicals should be carried out with checks for exhaustion.

For manual reprocessing, we recommend the following procedure:

1. Return the blood using the machine's blood pump and 0.9% normal saline. Air should not be allowed to enter the blood tubings or the dialyzer. It is advisable to then add around 1000 units of heparin to the saline bottle and further fill the circuit after disconnecting it completely from the patient. Following this step the arterial and venous tubings are joined with a universal connector and heparinized saline is circulated in the extracorporeal

circuit for about 5 min. The pressure leak test described below may be performed at this time.

2. Remove dialyzer and tubings from the machine and take to the reprocessing area in a covered tray to avoid blood spills. The tubings are disconnected and the blood compartment of the dialyzer is connected to the water source. The blood compartment is rinsed with water till the effluent is clear.
3. Clean by instilling 1% hypochlorite into the blood compartment till it is completely filled and allowed to stay for not more than 2 min. Immediate rinse out of the cleaning agent from the blood compartment is recommended. If hydrogen peroxide is used, it should be instilled in the dialysate compartment and backwashing or reverse UF started after 1–2 min. Peracetic acid based agents usually also contain hydrogen peroxide and should therefore also be instilled in the dialysate compartment.
4. Inspect the dialyzer for a large number (> 20%) of discolored fibers, large clots in the header, generalized blackening, change in color, or aesthetically displeasing appearance. If the clots in the headers appear small and friable the header may be removed from the dialyzer to be cleaned separately.
5. Rinse out the cleaning agents with water.
6. Backwashing or reverse UF – one end of the blood compartment is connected to the water supply, which is turned off, while the other end is left open. One end of the dialysate compartment is capped, while the other is connected to a water supply with a pressure of 1–1.3 bar through a Hansen's connector. The water should enter the dialysate compartment and exit through the blood compartment. This step is the most critical and is carried out for at least 15 min with periodic 1–2 min rinsing of the blood compartment. The direction of flow should be reversed at 5 min intervals.

Requirements for manual reprocessing

Cleaning and disinfecting agents

These should be available online in the reprocessing areas. Overhead tanks containing the chemicals maybe of 25–50 liters capacity, and should be refilled with fresh solutions every week, after cleaning. All tanks and piping for sodium hypochlorite should be composed of medical grade PVC, and those for formaldehyde, glutaraldehyde, and peracetic acid should be composed of 316SS.

Sodium hypochlorite

1–2%. Commercially available cans (10%) should be diluted.

Hydrogen peroxide

This is meant for instillation only in the dialysate compartment.

Formaldehyde 4%

Commercially available as 40%, this can be diluted with the water used for reprocessing to give a final strength of 4%.

Glutaraldehyde 2%

This has to be freshly prepared and activated. The chemical potency of the solution may be tested with Schiff's reagent, which produces a magenta color similar to that seen with formaldehyde. Glutaraldehyde should be used for preserving the end caps, universal connectors, O rings and dialyzer caps when not in use. The solution should be replaced at intervals of not less than 10 days. Small containers containing Glutaraldehyde should be available both at the dialysis stations and at the reprocessing areas.

Peracetic acid (renalin/hemoclean)

The undiluted solution should be diluted to prepare two solutions of 2% (200 ml in 10 liters of water) as a cleaning agent and 3.5% (350 ml in 10 liters of water) as a disinfectant.

Measuring cylinder

Scientific laboratory grade with a capacity of 100, 200, and 1000 ml should have a least graduation of 2 ml (preferably 1 ml).

Covered tray for transferring dialyzer and tubings to the reprocessing areas.

Carrying out tests of performance

The blood and dialysate compartment are filled with water and both openings of the dialysate compartment are capped. The dialyzer is placed over a scientific measuring cylinder and the water from the blood compartment expelled into the cylinder with a sphygmomanometer bulb or a large syringe. This is the total cell volume (TCV), or the fiber bundle volume (FBV) of the dialyzer. The dialyzer should be discarded if the TCV is < 80% of its initial value.

A better examination of the fibers is possible when the headers are removed. The headers and the O rings should be placed in glutaraldehyde while the dialyzer is being reprocessed. If the dialyzer or the header cannot be made free of clots or too many fibers appear blackened it should be discarded.

If the header is removed special care should be taken to check the O ring and replace it properly. Improper placement of the O ring or failure to replace it will result in a blood leak when the dialyzer is next used.

We suggest that all dialyzers should be tested before the first use and over reliance not placed on the stated values.

Pressure leak testing can be performed at the time of priming the dialyzer using the dialysis monitor or by using a vacuum gauge. The venous bubble trap is filled with saline up to 2/3 of its volume and connected to the venous pressure transducer. The venous outflow line is clamped and the blood pump run at a speed of 100–150 ml/min, until the venous pressure rises to 400 mm of Hg. The blood pump is then turned off. The pressure should decrease slowly by around 1 mm/second. If the pressure drops abruptly, there is likely to be a leak due to rupture of

some of the fibers and the dialyzer should be discarded.

Filling with disinfectant

Air from the blood compartment is once again rinsed out with water, and the dialyzer filled with the disinfectant from the other direction, allowing the disinfectant to displace water. Both the blood and the dialysate compartment should be completely filled with disinfectant.

Labeling and storage

Patients name, hospital number, the TCV, the reuse number and the date should be marked in indelible ink and affixed to the dialyzer. The dialyzer should be placed in a sealed polyethylene bag and stored in a rack with separate compartments for each dialyzer. The minimum period of storage at ambient temperature should be 24 hours, for complete action of the disinfectant. If the dialyzer is not used for 7 days, should be refilled with disinfectant at this point in time.

Priming and checking for residual disinfectant

The dialyzer should be primed with at least 2000 ml of 0.9% normal saline using the dialysis machine blood pump at a speed of 150 ml/min. The dialysate lines should be connected and the dialysate compartment filled with dialysate flowing at 500 ml/min prior to starting the priming procedure. Failure to "dialyze" the disinfectant out may result in inadequate removal and reactions after starting dialysis. The pressure leak test may also be performed at this time.

After 2000 ml of saline priming, effluent from the venous line should be checked for the presence of residual disinfectant. This should be done using a commercial (Formacure) test strip or Schiffs reagent, which gives a magenta color if the concentration of formalin is > 5 ppm. Residual peracetic acid and sodium hypochlorite should be tested with starch iodide paper. Absence of citric acid should be documented by absence of color change with litmus or pH papers. A pH of 6–8 confirms the absence of citric acid.

We recommend the following procedure for heated citric acid reprocessing. (This method has only been validated for polysulfone dialyzers.)

- Preparation of the citric acid solution. – 1.5% citric acid solution is prepared by dissolving 150 g of anhydrous citric acid in 10 liters of water of AAMI or purer standard. The concentration of the citric acid solution can be verified by testing its conductivity (f 2875 micro Siemens/cm) at 21°C.
- The steps of prerinsing, cleaning, inspection, backwashing, and performance testing are carried out as described earlier. The dialyzer is wiped dry with a sterile gauze pad and the blood compartment filled with citric acid. The dialysate compartment is filled 4/5 with citric acid and capped. The dialyzer is labeled as above and also with a heat sensitive strip, which changes color on exposure to heat, and placed in a sealed polythene bag.
- The dialyzer is placed in a hot air oven at 95°C continuously

for 20 hours. The dialyzer is removed from the oven, checked for any leak, and exposure to heat by confirming change in color of the heat sensitive paper. The presence of citric acid in the dialyzer is confirmed by a pH of 2.2 on a pH meter or pH paper strips.

- Performing a pressure leak test is mandatory for dialyzer reprocessed by heat.
- Although there is no evidence to support the reuse of blood tubings, this practice is widespread.

We recommend the following steps for reprocessing tubings

- The tubings are washed free of blood by treated water of AAMI or EU standard, and then with a 1.6% solution of sodium hypochlorite.
- The arterial and venous bubble chambers should be gently tapped to release clots.
- The side tubings are all cleared by clamping the outlets to dislodge any adherent material.
- Tubings are again rinsed with water and then connected to a supply of 4% formaldehyde, which is allowed to completely displace water and air from the tubings.
- Tests of performance: No objective tests of performance are available for blood tubings.
- The tubings should be discarded if:
 - the normal elasticity appears to be lost,
 - there are visible cracks,
 - change from the normal transparent appearance,
 - damage to any of the hubs.

A test sometimes useful is to compare the elasticity of the pump segment with that of new tubing on a blood pump. Failure to give 90% of the flow obtained with a new tubing segment, or "slipping" of the tubing or a "slapping sound" from the rollers may indicate a malfunction of the pump segment of the tubing and require it to be discarded.

Reuse of Dialyzers and Tubings of Patients with AKI

No separate procedure is required to be followed for reprocessing dialyzers or tubings in patients with AKI. We suggest single use of dialyzers in AKI.

A lower rate of reuse is expected in patients undergoing slow extended daily dialysis, extended sessions and anticoagulant free dialysis sessions.

Monitoring of Outcomes and Quality control of Dialyzer Reprocessing

We recommend that efficacy and safety of reused dialyzers be monitored regularly

- The spKt/V with new and reused dialyzers should be monitored at least once a month.
- Rigors, fever, and hypotension on dialysis suggest

the possibility of infection caused by failure of the reprocessing technique, and hemolysis caused by the chemical disinfectants.

3. In case of rigors, fever, and hypotension or a visible change in the color of the blood in the tubing, the dialysis should be stopped. Blood should not be returned to the patient.
4. Samples should be sent for culture, LDH, and smear examination.
5. The dialyzer should be rinsed with sterile normal saline and the effluent tested for:
 - a) Residual disinfectants as described above.
 - b) Cultured on TSA and R2A at 25°C and 37°C.
 - c) Endotoxin by Gel clot LAL assay.

Table 1: Dialyzers validated and approved for reuse⁶

Manufacturer	Models approved for multiple use
Asahi medical Co Ltd	AM-R series, APS series
Baxter Healthcare Corp	CA 90, CA 110, CA 130, CA 150, CA 170, CA 190, CA 210 CAHP 110, CAHP 130, CAHP 150, CAHP 170, CAHP 210 CT 190, CT 210 PSN 130, PSn 150, PSn 170, PSN 210
Althin Fresenius Medical Care	Althin Altraflux 200/Altra Nova 200 F4, F5, F6, F7, F8 F60M, F70M, F80M F60A, F70A, F80A F60B, F70B, F80B Optiflux 200A
Gambro Healthcare	Polyflux 17R, Polyflux 21R
Minntech Corp	Primus 100, Primus 1350, Primus 2000
Terumo Medical Corp	CLIRANS T-series

New features on the journal's website

Optimized content for mobile and hand-held devices

HTML pages have been optimized for mobile and other hand-held devices (such as iPad, Kindle, iPod) for faster browsing speed.

Click on **[Mobile Full text]** from Table of Contents page.

This is simple HTML version for faster download on mobiles (if viewed on desktop, it will be automatically redirected to full HTML version)

E-Pub for hand-held devices

EPUB is an open e-book standard recommended by The International Digital Publishing Forum which is designed for reflowable content i.e. the text display can be optimized for a particular display device.

Click on **[EPub]** from Table of Contents page.

There are various e-Pub readers such as for Windows: Digital Editions, OS X: Calibre/Bookworm, iPhone/iPod Touch/iPad: Stanza, and Linux: Calibre/Bookworm.

E-Book for desktop

One can also see the entire issue as printed here in a 'flip book' version on desktops.

Links are available from Current Issue as well as Archives pages.

Click on  View as eBook

Dialysis Dose

HD replaces only some of the functions performed by the native kidneys. Inadequate dialysis adversely affects survival, increases frequency of other complications and decreases quality of life. There is no single clinical or laboratory parameter to assess adequacy of dialysis

1. We recommend that all ESRD patients receive thrice weekly 4-hour HD sessions.
2. We suggest that patients choosing to receive twice a week dialysis should receive 6-hour sessions.
3. We recommend not less than twice a week (less than 8 hours in two sessions) dialysis.
4. We recommend that all incident patients should be informed about the possibility, advantages and disadvantages of daily as well as chronic peritoneal dialysis.
5. We recommend blood flows of at least 300 ml/min and dialysate flows of 500 ml/min.
6. We recommend monitoring residual renal function once in 6 months by an average of 24 hours urea and creatinine clearances.
7. We recommend use of Kt/V or urea reduction ratio (URR) as a measure of dialysis prescription.
8. We recommend the target weekly Kt/V of 4.2–4.8.
9. We suggest to target the urea reduction ratio (URR) to > 65%. Postdialysis sample should be taken 2 min after dialysis or 15 seconds after slowing pump speed to 100 ml/min.
10. We suggest that the minimally adequate dose of dialysis can be reduced among patients with residual kidney function of greater than 2 ml/min/1.73 m², but the minimum single-pool Kt/V should be no lower than 60% of the minimum target for those without residual renal function.
11. We suggest assessment of the dialysis dose in stable HD patients once per month. More frequent measurements may be required in patients not doing well on dialysis.
12. We recommend a search for the cause of low Kt/V or URR.

Once identified, we recommend taking corrective steps to improve effective HD treatment times, blood flows, correct errors in blood sampling, or improve dialyzer clearance.

We recommend that clinical examination and laboratory testing be used to assess adequacy. Enquiry should be made about well-being and rehabilitation status of the patient. Physical examination should include looking for evidence of fluid accumulation, unexplained reduction in dry weight, increasing erythropoietin (EPO) requirement, or unexplained decrease in albumin, phosphate or creatinine values. We do not recommend routine use of the online Kt/V monitors. This facility is available as an option in modern dialysis machines. It offers the advantage of being possible on each and every dialysis session, does not require a lag time, and no blood collection is required. As the machine software uses the Watson formula to calculate V, it is often overestimated and consequently Kt/V measured by online sodium or conductivity monitoring underestimates urea based measurements by around 0.03.

Assessment of adequacy of HD is important. Patient's symptoms are important but alone are poor indicator of overall uremic status.

Similarly, blood urea nitrogen (BUN) and creatinine are misleading

because a low BUN and creatinine may reflect malnutrition and poor muscle mass rather than sufficient dialytic removal.

For those on twice a week (8 hour/wk) dialysis, we recommend the following:

1. Residual renal function (RRF), measured by an average of 24 hr urea and creatinine clearance, should be > 2 ml/min
2. Residual renal function should be monitored more frequently.
3. Patients should be monitored closely for appearance or worsening of symptoms related to under-dialysis and/or malnutrition by subjective and objective clinical criteria.
4. In case of deterioration of nutritional status or if RRF falls to < 2ml/min, patient should be advised increase in HD duration and/or frequency.

Urea clearance has been used mechanistically in a formula Kt/V and shown to reflect the amount of dialysis prescribed and delivered. Kt/V is defined as dialyzer clearance of urea (K obtained from manufacturer of dialyzer and is available as ml/min), multiplied by duration of dialysis and divided by volume of distribution of urea in the body (v in ml), which is approximately equal to total body water. There is no universally accepted target value for the Kt/V. It is recommended that target single-pool Kt/V of approximately 1.4–1.6 be achieved. These levels are consistent with the 2006 Kidney Disease Outcome Quality Initiative (K/DOQI) guidelines for HD patients with minimal residual renal function (less than 2 ml/min/1.73 m²).

Residual renal function facilitates the regulation of fluid and electrolyte balance, and may enhance survival. It is recommended that the minimally adequate dose of dialysis can be reduced among patients with residual kidney function of greater than 2 ml/min/1.73 m², although the minimum single-pool Kt/V should be no lower than 60% of the minimum target for those without residual renal function.

Hemo study established that the risk of death (primary outcome) and secondary outcomes of combined hospitalization and death were not different between high dose vs standard dose or high flux vs low flux dialysis. In India, a large number receive twice a week or less dialysis. Dialysis dose received by patients is mostly not measured and we do not have studies to provide any specific guidelines based on Indian data. However, such patients should have more frequent measurements of residual renal function and if it is less than 2 ml/min/1.73 m² then thrice a week dialysis should be recommended.

Issues to be looked for in case of low Kt/V or URR

An assessment of fistula integrity

- Suboptimal treatment duration.
- Possible technical errors in the method of obtaining BUN samples.
- Dialysis machine and patient specific variables:
 - Inadequate machine calibration.
 - Low blood flow rates.
 - Hypotensive episodes that require changes in treatment.
 - Overestimation of dialyzer clearance.
- We recommend online calculators for calculation of kT/V.
- We suggest: www.hdcn.com/calcf/dzer.htm

Prevention of Infection

The HD patient is susceptible to infections. Bacterial infections carry a higher short-term mortality and increase the risk of long-term cardiovascular complications in dialysis patients. Viral infections like hepatitis B and C progress to liver cirrhosis and increase the morbidity and mortality.

The staff members of a dialysis unit are uniquely at risk of contracting these viral infections from contaminated blood and dialysate.

Preventing the transmission of infections involves several links in the chain involving patients, the dialysis procedure and ancillary care, the staff of the unit and various administrative and waste disposal protocols. A comprehensive infection preventive protocol includes hygiene measures, vaccination, dialyzer reprocessing, and disposal of biohazardous materials.

The suggested guidelines have been prepared by combining essential features from several documents, and are meant to guide infection control implementation and surveillance in HD units.

HD facility is conducive for transmission of infection since multiple patients receive dialysis concurrently. Transmission can occur directly or indirectly via contaminated devices, equipment and supplies, environmental surfaces, or hands of personnel.

The important infections that develop in these patients include viral infections such as hepatitis B and C, HIV and bacterial infections, especially those involving vascular access. The prevalence of antimicrobial-resistant bacteria has increased rapidly in health-care settings, including HD units in recent years. Multi-resistant organisms (MRO) are defined as bacteria that are resistant to one or more classes of antimicrobial agents. These include Methicillin Resistant Staphylococcus aureus (MRSA), Vancomycin Resistant Enterococci (VRE), Extended Spectrum β -lactamase (ESBL)-producing Klebsiella pneumonia, Carbapenem-resistant Acinetobacter baumannii (CRAB), and Clostridium difficile (antibiotic associated diarrhoea). Antimicrobial use and direct contact transmission of resistant strains are the two main factors that have contributed to this significant increase.

We recommend that HD units should establish written protocols for all procedures including cleaning and disinfecting surfaces and equipment in the dialysis unit based on the following guidelines:

Hand hygiene

1. Unwashed hands of healthcare workers are the major route of transmission of microorganisms in healthcare settings.

2. Staff should cover any cuts and abrasions with waterproof dressings. Staff who has extensive untreated cuts or chronic skin disease, such as eczema, should not work in dialysis units when their skin lesions are active.
3. Hand hygiene includes hand washing with soap and water, and/or applying an alcohol-based hand rub (e.g., sterilium)
4. Hands should be washed with soap and water when visibly dirty or contaminated with proteinaceous material (e.g., blood or other body fluids).
5. If hands are not visibly soiled, an alcohol-based hand rub can be used.
6. Hand hygiene should be performed:
 - a) before and after patient contact.
 - b) after contact with a source of microorganisms (body fluids and substances, mucous membranes, nonintact skin, or inanimate objects that are likely to be contaminated).
 - c) after removing gloves.
7. Hand hygiene facilities should be located as close as possible to the point of contact with patients and dialysis equipment.
8. One hand wash basin should be provided for every 2–3 dialysis stations in the main dialysis area and a minimum of one in an isolation room.
9. Soap solution must be provided in dispensers with disposable cartridges or single-use bottles, to prevent bacterial contamination of the product.
10. Alcohol-based hand rubs should be placed at the point of contact, for example:
 - a) Next to or attached to the frame of dialysis bed or chair.
 - b) At points of entry and exit of dialysis room.
 - c) At staff stations or chart and medication trolleys.

Use of gloves

1. Clean, nonsterile gloves should be worn when contact with blood or body fluids is anticipated; this includes contact with patients and dialysis equipment.
2. Gloves must be changed and hands cleaned between patients and/or stations. •
3. Gloves must also be changed and hands cleaned between different activities on the same patient (e.g., moving from a contaminated to a clean body site).
4. Gloves should be worn for any cleaning activities.
5. Hands should be decontaminated or washed after removing gloves.
6. Gloves should not be washed or reused.

Personal protection

1. Face protection (eyewear/goggles, masks) is required to

protect the mucous membranes of the eyes, nose, and mouth when performing procedures that may generate splashes or sprays of blood or body fluids (e.g., during initiation and termination of dialysis).

2. Personal eyeglasses and contact lenses are not considered adequate eye protection.
3. Plastic aprons are indicated to prevent contamination of clothing with blood, body fluids, and other potentially infectious material.
4. A long-sleeved, fluid-barrier (impervious) gown should be worn if exposed areas of the body, for example, arms, body front, are likely to be contaminated by blood or body fluids.
5. All personal protection equipment (with the exception of eyewear/goggles unless soiled) must be changed and hands cleaned:
 - a) Between attending different patients.
 - b) If it becomes splashed with blood or body fluids.
 - c) On leaving the work area.

Environmental Issues including Equipment and Consumables

1. Storage of equipment close to dialysis machines and patients should be minimized.
2. **We recommend that regularly used equipment such as adhesive tapes, tourniquets, blood pressure cuffs, and clamps should be designated to each patient.**
3. Consumables taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.
4. Cleaning of dialysis machines and chairs/beds.
5. Dialysis machines should be internally disinfected, externally cleaned (and disinfected if indicated), and dried after each patient.
6. The exterior of the machine should be effectively cleaned using manufacturer's protocols.
7. Special attention should be given to cleaning control panels on the dialysis machines and other surfaces that are frequently touched and potentially contaminated with patients' blood.
8. Cleaning of noncritical surfaces (e.g., dialysis bed or chair, countertops, external surfaces of dialysis machines and equipment) should be done with neutral detergent and warm water.
9. The following procedure should be adopted for any surface/item that is visibly contaminated with blood or following dialysis of a patient infected with blood borne virus:
 - a) Clean with neutral detergent and water, and then
 - b) Disinfect with sodium hypochlorite 1% (1000 ppm available chlorine; 1:10 dilution).
 - c) Remove chlorine residues from metallic surfaces with water as sodium hypochlorite in high concentrations (>500 ppm) is corrosive to metals.
10. The machine should be decommissioned if spillage occurs at inaccessible locations, such as behind the blood pump until proper cleaning and disinfection are done.
11. The following practices should not be used:
 - a) Blood tubing draped or clipped to waste containers.
 - b) Use of attached waste containers during priming of dialyzers.
 - c) Placing items on tops of machines for convenience (e.g., dialyzer caps and medication vials).
 - d) We recommend that due to the instability of chlorine compounds all diluted solutions should be discarded at the end of the day.

Disinfection of HD machines

1. **We recommend that dialysis units follow the manufacturer's recommendations.**
2. Disinfection should include the following:
 - a) Heat disinfection (80–90°C) after each dialysis.
 - b) Citric acid and heat disinfection at the end of the day.
 - c) Bleaching (5% chlorine) once a month.
6. We do not recommend frequent bleaching because of possible damage to the machine.
7. Manufacturers producing dialysis machines each recommend a different procedure for decontamination, but they concentrate only on bacterial kill. It is recommended that efficacy of decontamination procedure should additionally take into account level of biofilm and endotoxin removal.

The development of bacterial biofilms in the hydraulic circuit of hemodialysis machines can be prevented by frequent use of chemical and heat disinfection strategies.

Dialysate

1. **We recommend not using liquid bicarbonate dialysate concentrate more than 24 hours after opening since it supports rapid bacterial proliferation.**
2. Bottles containing unused dialysate should be immediately capped and the exterior of the bottle wiped over with detergent and water as part of the overall procedure of cleaning the hemodialysis machine.
3. The date and time of opening should be recorded on the bottle using an indelible pen.
4. Opened bottles containing unused fluid should be discarded after 24 hours.
5. Unfinished bottles used for infected patients must be discarded immediately after the dialysis session.

Medications

1. **We recommend that medications (including multiple dose vials) or supplies (syringes, swabs, etc.) taken to the patient's station should be used only for that patient and should not be returned to a common clean area or used on other patients.**

2. We suggest that multiple dose vials should be used for the same patient.
3. **We recommend that bags or bottles of intravenous solution should not be used as a common source of supply for multiple patients.**
4. **We recommend that when multiple dose medication vials (e.g., heparin, vials containing diluents) or solution bags are used for multiple patients, individual patient doses should be prepared in a clean, centralized area away from dialysis stations and delivered separately to each patient.**

External transducer protectors

Should be fitted to the pressure lines of extracorporeal circuit.

Should be replaced if the filter becomes wet.

Using a syringe to clear the flooded line may damage the filter and increase the possibility of blood passing into the dialysis machine and is not recommended.

5. **We recommend that medication vials should not be carried from station to station.**
6. **We recommend not carrying vials, syringes, swabs, or other supplies in pockets.**
7. If trays are used to deliver medications to individual patients, they must be cleaned between patients.
8. Do not handle and store medications or clean supplies in the same or an adjacent area to the place where used equipment or blood samples are handled.

Needle and sharps

1. **We recommend that all needles and sharps must be disposed of into an approved closed, unbreakable container according to the biomedical waste management rules.**
2. Needles should not be manually recapped.
3. No-touch technique should be used to drop the needle into the container, as it is likely to have a contaminated surface.
4. These containers should be located as close as possible to the point of generation either attached to a trolley or on a mobile stand.
5. Containers should be large enough to accommodate the types of devices being used in the area.
6. They should be closed and sealed when 2/3 full and disposed off in approved manner.

Blood spills

1. For minor spills on surfaces (e.g., benches, counter tops) we recommend
wiping up with paper towel soaked in undiluted 1% sodium hypochlorite and then wash with neutral detergent and hot water and allow it to dry.
2. For major blood spills we recommend the following:
 - a) Cover with chlorine powder (10,000 ppm available

chlorine) and leave for 2 min or limit spread using paper towels and slowly flood contaminated area with undiluted sodium hypochlorite 1% (5000–10,000 ppm); leave for 2 min before cleaning up.

- b) This should be followed by washing with neutral detergent.
3. Common equipment including weighing scales should be cleaned after use with detergent and water at least daily and when they become visibly soiled or come in contact with body fluids.

Blood borne virus screening and management

1. **We recommend that all patients should be tested for HBV, HCV, and HIV on admission to the dialysis unit including after transfer from another unit.**
2. **We recommend testing for HBV and HCV infection using a nucleic acid-based method.**
3. All maintenance dialysis patients should be retested every 6 months for HBV, HCV, and HIV infection.
4. All HBsAg-negative patients must be vaccinated against hepatitis B using approved protocol.
5. Anti-HBs titers should be checked 4 weeks after the last dose and at 6 monthly intervals thereafter.
6. Nonresponders (anti-HBs titers < 10 IU/ml) should receive three more doses of the vaccine.
7. All staff members should be vaccinated against hepatitis B, have their anti-HBs titer tested and be aware of their serostatus, that is, whether or not they have titers > 10 U/ml.
8. Testing of staff and carers for HCV or HIV is only recommended following a needlestick injury or body fluid exposure.
9. Patients with different blood borne virus infections should be managed separately.
10. HBsAg, HBeAg, and HBV DNA positive patients should be dialysed in a separate room.
11. Units with high (>10%) prevalence of HCV infection should strongly consider dialyzing anti-HCV positive patients in a separate room.
12. Where there are no isolation facilities, positive patients should be separated from susceptible patients (negative for HBsAg, anti-HBs, anti-HBc, anti-HCV, or anti-HIV), and undergo dialysis on dedicated machines.
13. Patients with anti-HBs \geq 10 mIU/mL may undergo dialysis in the same area as HBsAg-positive patients. In case HBV patients are not dialyzed in a separate area, these patients should be placed as buffer between HBsAg-positive and negative patients.
14. When a room/area/machine has been used for dialyzing infected patients, it should be used for uninfected patients only after cleaning and disinfection.
15. Dialysis staff members caring for positive patients should not care for susceptible patients at the same time (e.g.,

during the same shift or during patient change-over), but may change in different shifts.

16. If staff members must care for both positive and negative patients during the same shift, they must change their gown and gloves, and clean their hands in between patients.
17. Close contacts of positive patients should be tested for HBsAg and anti-HBs testing and if necessary, vaccination.
18. If a staff member or carer experiences a needlestick injury or exposure to blood or potentially blood-contaminated secretions from an infected patient, specialist opinion should be sought for management.

Vaccinations

1. **We recommend that patients should receive all recommended vaccinations including hepatitis B and varicella.**
2. **We recommend that all patients over the age of 5 years should receive pneumococcal vaccine (23vPPV).**
3. We suggest that influenza vaccine should be given annually before the beginning of the influenza season.

Multi-drug resistant organism (MRO) screening

1. **We recommend that dialysis units should institute the following measures to prevent transmission of MROs:**
 - a) Access to good clinical microbiology laboratory to ensure prompt detection of MROs including antimicrobial susceptibility.
 - b) Appropriate antimicrobial stewardship (optimal selection, dose, and duration of treatment).
 - c) Active surveillance cultures (screening) to identify patients colonized or infected with MROs.
 - d) Decolonization therapy where appropriate.

Management of patients infected or colonized with a MRO

1. Contact precautions is suggested for management of patients with the following because of increased risk of transmitting a MRO:
 - a) An infected/colonized wound that cannot be covered by a dressing.
 - b) Urinary incontinence.
 - c) Uncontrolled fecal incontinence or diarrhea or enterostomies.
 - d) Exfoliative skin conditions (e.g., dermatitis, psoriasis) and burns.
2. Contact precautions is suggested for all patients with a MRO when:
 - a) The incidence of a MRO is increasing despite correct adherence to infection control precautions.
 - b) First case or outbreak of an MRO in the unit.
3. For isolation, the following precautions is suggested in the given order of preference:
 - a) Dialyze MRO-positive patients in a separate room designated only for MRO-positive patients.
 - b) In a separate area in the main unit.

c) The main unit with ≥ 1 meter separation between beds/chairs.

d) Staff caring for these patients must wear a gown and clean nonsterile gloves for all interactions that with the patient or potentially contaminated areas in the patient's environment.

4. Patients with different MROs should be managed separately.
5. The room where MRO-positive patients have previously been dialyzed may be used for negative patients only after cleaning and the area is dry.
6. Transport equipment (e.g., wheelchairs, trolleys) should be cleaned with detergent and water or detergent or alcohol-impregnated wipes after use.

Prophylaxis for Staphylococcus aureus infection

1. The prevalence of *S. aureus* nasal carriage in many dialysis patients is higher than the normal population ($\geq 50\%$) and increases with duration of dialysis.
2. It is suggested that units should make efforts to ascertain rates of *S. aureus* nasal carriage among patients in their units by performing surveillance cultures of anterior nares.
3. If the prevalence is found to be high, we suggest regular surveillance for *S. aureus* carriage and treatment of positive patients with twice a day intranasal mupirocin for 7 days, repeated every 3 months.
4. Routine use of mupirocin in dialysis patients to prevent *S. aureus* carriage is not recommended because of risk of developing resistance.
5. There should a prominent display at entry to the unit or reception requesting that patients and individuals accompanying the patient promptly inform the staff if there are any symptoms of a respiratory infection (e.g., cough, flu-like illness); gastroenteritis (e.g., diarrhoea, nausea, vomiting); skin rash; or known exposure to a infectious disease (e.g., chickenpox, measles, pertussis).
6. Implementation of source containment measures is recommended to prevent transmission of respiratory infections. Coughing patients should be asked to wear a surgical mask or cover their cough.
7. All patients should perform hand hygiene as part of basic personal hygiene, including the use of alcohol-based hand rubs.

Staff training

We recommend training of all staff in dialysis units in infection prevention and control practices including

1. Proper hand hygiene technique.
2. Appropriate use of personal protection equipment.
3. Modes of transmission for blood borne viruses (BBV), pathogenic bacteria, and other microorganisms.
4. Infection control precautions for dialysis units.
5. Rationale for segregating patients.
6. Correct techniques for initiation, care, and maintenance of dialysis access sites.

We recommend that new and inexperienced staff should be supervised until they are considered competent to practice safely on their own.

Surveillance

We recommend that all units should develop methods to monitor, review, and evaluate all infection data including

1. Rates of infection with blood borne viruses and bacterial infections overall and individually.
2. Results of serological testing for blood borne viruses.
3. They should calculate incidence and conversion rates for blood borne viruses.

Unit in charge should regularly review adherence to infection control practices annually and more frequently if there is significant staff turnover.

Waste management

Wastes generated by the HD facility should be considered infectious and handled accordingly.

We recommend that solid medical wastes should be disposed of properly in an incinerator or sanitary landfill, according to and regulations governing medical waste disposal (Bio-Medical Waste Management and Handling Rules, 1998).

Annexure

SCHEDULE I: Categories of Bio-Medical Waste

Option	Waste Category	Treatment and Disposal
Category No. 1	Human Anatomical Waste (human tissues, organs, body parts)	Incineration @/deep burial*
Category No. 2	Animal Waste (animal tissues, organs, body parts carcasses, bleeding parts, fluid, blood, and experimental animals used in research, waste generated by veterinary hospitals colleges, discharge from hospitals, animal houses)	Incineration @/deep burial*
Category No 3	Microbiology and Biotechnology Waste (wastes from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human, and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biologicals, toxins, dishes and devices used for transfer of cultures)	Local autoclaving / micro-waving / incineration@
Category No 4	Waste sharps (needles, syringes, scalpels, blades, glass, etc., that may cause puncture and cuts. This includes both used and unused sharps)	Disinfection (chemical treatment @ 01/ auto claving / micro- waving and mutilation/ shredding”.
Category No 5	Discarded medicines and cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)	Incineration @/destruction and drugs disposal in secured landfills drugs disposal in secured
Category No 6	Solid Waste (Items contaminated with blood, and body fluids including cotton dressings, soiled plaster casts, lines, beddings, other material contaminated with blood)	Incineration @ autoclaving / micro-waving
Category No. 7	Solid Waste (wastes generated from disposable items other than the waste shaprs such as tubings, catheters, intravenous sets etc).	Disinfection by chemical treatment @ @ autoclaving/micro-waving and mutilation/ shredding##
Category No. 8	Liquid Waste (waste generated from laboratory and washing, cleaning, house-keeping and disinfecting activities)	Disinfection by chemical treatment@@ and discharge into drains.
Category No. 9	Incineration Ash (ash from incineration of any bio-medical waste)	Disposal in municipal landfill
Category No. 10	Chemical Waste (chemicals used in production of biologicals, chemicals used in disinfection, as insecticides, etc.)	Chemical treatment @@ and discharge into drains for liquids and secured landfill for solids

@@ Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfection. ## Multilation/shredding must be such so as to prevent unauthorised reuse. @ There will be no chemical pretreatment before incineration. Chlorinated plastics shall not be incinerated.

- Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.
- + Options given above are based on available technologies. Occupier/operator wishing to use other state-of-the-art technologies shall approach the Central Pollution Control Board to get the standards laid down to enable the prescribed authority to consider grant of authorization

SCHEDULE II: Color Coding and Type of Container for Disposal of Bio-Medical Wastes

Color Conding	Type of Container -I	Waste Category	Treatment options as per Schedule I
Yellow	Plastic bag	Cat. 1, Cat. 2, and Cat. 3, Cat. 6.	Incineration/deep burial
Red	Disinfected container/ plastic bag	Cat. 3, Cat. 6, Cat.7.	Autoclaving/microwaving/ chemical Treatment
Blue/White translucent	Plastic bag/puncture proof Container	Cat. 4, Cat. 7.	Autoclaving/microwaving/ chemical Treatment and destruction/shredding
Black	Plastic bag	Cat. 5 and Cat. 9 and Cat. 10. (solid)	Disposal in secured landfill

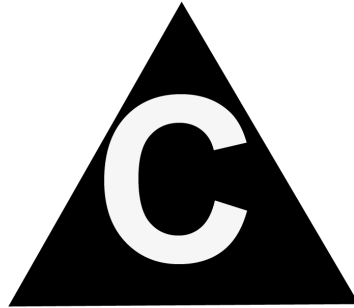
Notes:

1. Color coding of waste categories with multiple treatment options as defined in Schedule I, shall be selected depending on treatment option chosen, which shall be as specified in Schedule I.
2. Waste collection bags for waste types needing incineration shall not be made of chlorinated plastics.
3. Categories 8 and 10 (liquid) do not require containers/bags.
4. Category 3 if disinfected locally need not be put in containers/bags.

SCHEDULE III: Label for Bio-Medical Waste Containers/Bags



Biohazard



Cytotoxic

Handle with care

Note: Label should be non-washable and prominently visible.

SCHEDULE IV: Label for Bio-Medical Waste Containers/Bags

Day..... Month.....

Year.....

Date of Generation.....

Waste Category No.....

Waste Class

Waste Description

Sender's Name and Address

Phone No.....

Telex No....

Fax No.....

Contact Person.....

Receiver's Name and Address

Phone No.....

Telex No.....

Fax No.....

Contact Person.....

In case of emergency please contact

Name and Address:

Phone No.

Note: Label should be non-washable and prominently visible

Emergency Services

Although dialysis machines are equipped with a fail safe mode, a self-test, alarms and a safety profile of less than 1 event per 100 million treatments, emergencies related to human error, and patients' medical problems, ranging from minor discomfort to cardiac arrests have been reported in dialysis units.

Common hemodialysis emergencies are:

1. Hypotension
2. Dialyzer reactions
 - a. Type A (anaphylactic reaction)
 - b. Type B (nonspecific reaction)
4. Hemolysis
5. Air embolism
6. Disequilibrium syndrome
7. Chest pain, MI
8. Arrhythmias
9. Sudden cardiac death

We suggest that all units should have the following equipment to prevent and treat common emergencies:

1. Accurate weighing scale.
2. Micro-hematocrit tube for manual measurement.
3. Activated clotting time machine.
4. Glucometer.
5. Multichannel cardiac monitor, signal-averaged ECG (SAECG), and defibrillator.
6. Laryngoscopes, endotracheal tubes, suction apparatus or wall mounted suction, central oxygen supply and suction tubes, mouth gag and Ambu bag.
7. Ryles tube.
8. Long lumbar puncture needle (for puncturing the ventricle in case of air embolism).
9. 24-hour emergency power generator to ensure uninterrupted power supply.

We suggest that HD unit should have access to the following optional equipments:

1. Arterial blood gas analysis machine.
2. Ambulatory blood pressure monitor.
3. Implantable cardioverter-defibrillator.
4. Portable ultrasound for abdominal emergencies.
5. Hand held doppler device for vascular access assessment.

We recommend that the following medicines to be available for emergency use:

1. Ionotropes: Injections: Dopamine, Dobutamine, Noradrenaline, vasopressin.
2. Solutions: 25% dextrose; 3% saline; 5% dextrose.
3. Injection Protamine.
4. Injections: Lignocaine, amiodarone.
5. Injection Hydrocortisone.
6. Injection Adrenaline.
7. Injection Atropine.
8. Injection and tablet Pheniramine maleate.
9. Capsule and tablet Nifedepine.
10. Tablets: Clonidine, paracetamol, sorbitrate.
11. Injection Nitroglycerine.
12. Injections: Ondansetron, metoclopramide, pantoprazole, ranitidine.
13. Injection vitamin K.
14. Anticonvulsants Medazolam, Dilantin.
15. Salbutamol.

All medicines should be stocked in Crash Carts in adequate quantities depending on patient load.

Expiry dates of medicines should be verified periodically.

Stocks are to be verified every morning and replaced if used.

An intensive care and a respiratory care unit should be within reach.

Laboratory Support

Assessment of adequacy of dialysis, nutritional status, bone mineral disorders, anemia, and monitoring for infections all require frequent laboratory investigations. As a result of the differences in the test methodologies and the standardization and calibration of equipments, widespread inter-laboratory variation is often observed. It is therefore necessary for a unit performing HD to have access to a laboratory with reliable and reproducible results and to establish protocols of investigations.

We recommend access to laboratories where the following tests required for monitoring the management of patients on HD can be carried out.

Investigations recommended for patients on maintenance hemodialysis

Monthly

Blood urea, serum creatinine, sodium, potassium, hemoglobin, platelet count¹, TLC.

Every 3 months

Serum calcium², phosphate², alkaline phosphatase, albumin, uric acid, alkaline phosphatase, SGOT, SGPT.

Every 6–12 months

iPTH⁴, 25 (OH) vitamin D, iron studies⁵.

¹Once in 2 weeks if heparin induced thrombocytopenia is suspected.

²Once a month if the patient is on calcitriol/doxercalciferol/paricalcitol. Weekly after starting cinacalcet until stable values reached.

³More frequently in malnourished patients who are being treated.

⁴More frequently when being treated for SHPT.

⁵Once a month if Hb target not achieved on EPO.

We recommend that the dialysis unit should have access to the following equipments:

1. Semi auto analyzer/Bench Top auto analyzer.
2. Electrolyte Analyzer (Ion selective electrode).
3. Semi auto coagulation analyzer.
4. 500 ma X-ray.
5. Ultrasound, echocardiography, Doppler.
6. Cell counter.
7. Urine analyzer/binocular microscope.
8. pH meter.

Nutrition

Protein energy malnutrition is common among dialysis patients and predicts morbidity and mortality. In India, protein intake of an average middle-class individual is less than 0.7g/kg/d. This goes down further in CKD, and many patients are virtually on nil protein diets and are severely malnourished by the time they start HD. Goals of nutritional therapy in dialysis patients are (i) to prevent malnutrition, (ii) improve nutritional status, (iii) build up body stores for good transplant outcome, and (iv) improve quality of life.

Assessment and treatment should begin much before the start of dialysis, preferably by a dietician. However, the services of an experienced nutritionist are not available in most dialysis centers in India. Nephrologists and dialysis doctors therefore need to be aware of the principles of nutritional assessment and intervention. Nutrition has several domains, namely, protein–energy nutrition, acid–base balance, divalent ion metabolism, anemia management, and micronutrient management.

Recommendations for dietary intake are similar to those of Western population. However, variations in dietary habits, particularly vegetarianism, make intervention a challenge. A constant conversation with the patient is the key to ensure compliance and success of implemented measures.

1. We recommend that nutritional status be assessed with a combination of valid complementary measures rather than by any single measure alone.
2. We recommend that a history of dietary habits, physical examination for signs of deficiency, hydration status, difference between actual weight and dry weight should be done at every visit.
3. We recommend that serum albumin, percent of usual edema free postdialysis weight, dietary diaries should be evaluated monthly.
4. We recommend assessment of muscle mass by measuring body mass index (BMI), mid-upper arm circumference skin-fold thickness (biceps, triceps, subscapular, suprailliac), and waist/hip ratio every 3 months.
5. We suggest that dialysis units implement a protocol of subjective global assessment (SGA) once every 3 months.

Adjusted edema free body weight

Body weight should be obtained postdialysis. For individuals whose edema free body weight is between 95th and 115th percent of median standard weight, the actual edema free body weight may be used. Following equation can be used to calculate edema free adjusted body weight (aBW_{ef})

$$aBW_{ef} = BW_{ef} + SBW - BW_{ef} \times 0.25$$

Where BW_{ef} is the actual edema free body weight and SBW is standard body weight as determined from NHANES II data. Because of interdialytic weight gain, aBW_{ef} should be calculated based on post dialysis values.

Subjective Global Assessment (SGA) gives a comprehensive overview of nutritional intake and body composition including a rough assessment of both muscle and fat mass and because it is correlated with mortality rates. It is recommended that SGA scoring be determined by 4 item, 7-point scale used in the CANUSA study. SGA score correlates with objective measures (albumin/weight/intake/anthropometry). Change in SGA rating by 1 point decreases relative risk of death by 25%. A higher SGA score is associated with a lower RR of death and fewer hospitalized days/year SGA should be done at 6 monthly intervals.

6. We suggest that dietary intake should be assessed using diet history questionnaires, food weighing, and direct observation. The frequency of assessment may need to be increased in poorly compliant patients.
7. We recommend not using bioelectric impedance or DEXA for nutritional assessment routinely.

Low values of the following might suggest more rigorous examination of protein energy wasting: Predialysis creatinine, blood urea nitrogen, cholesterol, serum and urine electrolytes, serum and urine urea nitrogen, serum and visceral protein. A low predialysis or stabilized serum urea level may indicate a low intake of protein and amino acids. A low predialysis or stabilized serum creatinine level in MHD patients suggests decreased skeletal muscle mass and or low dietary protein intake. Similarly, hypocholesterolemia is associated with chronic protein–energy intake/deficits and or the presence of co-morbid conditions including inflammation.

8. We recommend measurement of serum bicarbonate once monthly.
9. We recommend that the predialysis serum bicarbonate levels should be maintained at or above 22 mmol/L.
10. We recommend increasing basic anion concentrations in the dialysate and/or by use of oral bicarbonate in those with low values.

Low serum bicarbonate concentrations in MHD patient almost always indicate metabolic acidosis. Acidemia associated with metabolic acidosis is associated with increased oxidation of branched chain amino acids (valine, leucine and isoleucine), increased protein degradation and PNA and decreased albumin synthesis. Higher concentrations of bicarbonate in hemodialysate (38mmo/L) have been shown to safely increase predialysis serum bicarbonate concentrations. Oral dose of sodium bicarbonate usually about 2–4 g/d or 25–50 mEq/d can be used to increase bicarbonate concentration. Correction of acidemia due to metabolic acidosis increases serum albumin and decreases protein degradation rates.

11. We recommend that any potentially reversible or treatable condition or medication that might interfere with appetite or cause malnutrition should be looked for and corrected.

Anorexia is common in dialysis patients and can be due to (i) underdialysis (switch over to thrice weekly dialysis in place of twice weekly dialysis therapy), (ii) comorbidity, (iii) medication (in such circumstances discontinuing phosphate binders and iron and vitamin supplements for a short period of time helps improve appetite) and (iv) psychosocial factors. These factors should be eliminated.

12. We recommend that the dialysis regimen should be regularly monitored and modified to ensure adequacy.
13. We recommend that patients receive detailed nutrition counseling on first visit.
14. We recommend a dietary protein intake of 1.2 g/kgbw/d for stable patients on dialysis.

This amount is necessary to ensure neutral or positive nitrogen balance. At least 50% of protein should be of high biological value. Proteins of high biological value have an amino acid composition that is similar to human protein and is likely to be utilized more efficiently by humans to conserve body proteins. Egg white, fish, chicken, milk and milk products (curd, chenna/paneer), dehusked (without outer covering to prevent hyperphosphatemia) lentils kidney beans, soy protein (milk and cheese marketed as Tofu) are good sources of protein with high biological value.

15. We recommend that the caloric intake should be adequate so as to ensure utilization of protein. The recommended energy intake for MHD patients is 35 kcal/kgbw if the patient is less than 60 years of age and 30 kcal/kgbw if the patient is more than 60 years. It is recommended that 50–60% of total calories should come from carbohydrate, 30% of total calories should come from fat (saturated fats <7%), and 20% of total calories should come from protein. Energy intake of patients having diabetes mellitus should be 25–30 kcal/kg/d. This should be done by including two cereals in one meal, for example, rice and wheat, to improve protein quality the ratio of cereal protein to pulse protein should be 4:1.
16. We recommend that the dietary prescription should be individualized in terms of palatability, cost, co-morbid medical conditions, and cultural eating habits taking the patients personal food choices into account.
17. We recommend the following for treatment of undernourished patients:
- Patients who do not have adequate DPI should first receive dietary counseling and education. If DPI remains inadequate oral supplementation should be prescribed.
 - We recommend assessment of patient compliance to dietary prescription and nutritional intervention on every visit.

- Patients who are unable to meet protein/energy requirements with food for an extended period of time should be evaluated by an expert nutritionist for consideration of nutrition support. This may include tube feeding, intradialytic parenteral nutrition or total parenteral nutrition (TPN).
 - Nephrologist must explain the potential risks of worsening malnutrition and convince and motivate the patient and his attendants for tube feeding. With tube feeding, overnight enteral supplements can improve nutritional status. Tube feeding provides smaller water load than intravenous feeds, carries lower risk of infection than TPN, is less expensive, and overnight supplementation improves nutritional status.
 - Tube feeding should be started with 50–100 ml feeds every 6 hours and gradually increased to 300–400 ml per feeding. If continuous feedings are started, then start feeding from 20 to 50 ml/hour, then increase 20 ml every 2–8 hours until requirement is reached.
 - Intra dialytic parenteral nutrition (IDPN) should be considered if spontaneous intake of energy is >20 and <25 kcal/kg IBW and if protein is > 0.8 g but < 1 g/kg/IBW. An equivoluminous degree of UF should be added to regular UF rate to maintain fluid balance. Include sodium, potassium, and magnesium in the IDPN/TPN solution as per patient's requirement.
 - If combination of oral and IDPN is insufficient then TPN should be considered. TPN should be given if spontaneous intake is <20 kcal/kg IBW and < 0.8 g protein/kg IBW.
 - About 15–25% patients develop side effects with parenteral nutrition like nausea and vomiting. In such cases, (1) decrease infusion rate, (2) reduce total IDPN by half for 1–2 weeks. Intradialytic cramping may occur in rare cases of low plasma osmolality if sodium profiling is not used. It is recommended that 1gNaCl/250 ml of infusion should be added to IDPN. (3) Glucose metabolism should be checked. (4) Prevent hyperglycemia (>300 mg/dl) by administering 2–6 units short acting insulin.
18. We recommend that patients on HD should restrict sodium intake to no more than 2 g/d. Restrict foods with high salt content (papad, pickles, chutney, sauce), dry fruits, popcorns, coconut water.
19. We recommend a potassium intake of 1 mEq/kgbw/d. Patients should be advised to leach potassium from green vegetables. Fruit juices and vegetable soup should be avoided. Recommended fruits are apple, banana, pineapple, pear, orange, guava, and papaya (approximately 50–60 mg/d). Patients should avoid green leafy vegetables and vegetables with very high (>300 mg/g) potassium content.
20. We do not recommend use of supplements like carnitine or ketoanalogues for improving nutrition in dialysis patients.
21. We recommend that patients receive the recommended daily dietary intake of minerals and vitamins.

Cardiovascular Disease Monitoring and Therapy

The burden of cardiovascular disease (CVD) in CKD is very high in HD population. Nontraditional risk factors like volume overload, anemia, mineral and bone disease, inflammation, oxidative stress contribute significantly to very high prevalence of CVD.

Common types of CVD in HD population are atherosclerotic vascular disease especially involving coronary and intracerebral arteries, and LVH, CHF, and PVD.

1. We recommend that investigation for CVD should be deferred till the weight, Hb, volume, electrolyte, and divalent ion targets are achieved unless there are pressing indications.
2. We recommend 12 lead ECG, chest X-ray, and echocardiogram to assess their baseline status and to identify and stratify risk for future CVD.
3. We recommend that additional tests such as dobutamine stress echocardiography, radionuclide scintigraphy, or coronary angiogram should be decided in consultation with a cardiologist.
4. We suggest that any other test such as cardiac computed tomography (CT) scan or magnetic resonance imaging (MRI) should be done as a part of research protocol.
5. We suggest that any acute event be evaluated with 12 lead ECG and biochemical markers of ischemia. Once the event is controlled, every patient with acute event should be seen by a cardiologist.
6. We recommend using serum CPK MB, Troponin T/I or LDH to assess acute ischemia. Troponin I preferred over T, since they are cleared normally by the kidney, levels may be raised up to three times in HD population. These enzymes should be ordered when there is acute coronary ischemia is suspected; they have no role in routine screening for coronary artery disease.
7. We suggest annual 12 lead ECG and chest X-ray in all HD patients. The decision to perform additional tests including echocardiogram should be individualized in consultation with a cardiologist.

Mineral and Bone Disorder Monitoring and Therapy

Deranged mineral and bone metabolism as well as the therapy used to correct these abnormalities can lead to skeletal as well as extra skeletal, especially cardiovascular complications. There is a strong association between CKD-MBD, CVD, and mortality. The latter two have received increased attention recently. It is therefore, important to identify and correct these abnormalities in dialysis patients. The following recommendations are based on the Indian Commentary of KDIGO CKD-MBD Guidelines:

1. We recommend that serum levels of calcium, phosphorus, parathyroid hormone (PTH), and alkaline phosphatase should be monitored regularly.
2. We suggest basing the frequency of monitoring on the presence and magnitude of abnormalities. For stable levels, the monitoring should be at longer intervals and for unstable levels or after any change in treatment, more frequent monitoring intervals are recommended to monitor for trends and treatment efficacy and side-effects:
 - a. Serum calcium and phosphorus 1-3 months
 - b. Alkaline phosphatase 3 months
 - c. PTH 6-12 months.
3. We suggest monitoring of 25 (OH) Vitamin D at baseline and then annually.
4. We recommend therapeutic decisions on the basis of trends rather than on a single laboratory value and the entire clinical picture should be taken into consideration rather than just the one parameter.
5. We suggest that services of a laboratory that the nephrologist is familiar with should be used both for following a patient longitudinally and for comparing readings between patients.

Nephrologists should be aware of the methodologies used by the laboratories and request the laboratories to inform them of any change in assay method.

The person in-charge of drawing samples should be familiar with the requirement of sample source (whole blood, plasma or serum), drawing requirements (e.g., vacutainers, needle size, etc.) and sample handling specifications (such as storage and transport conditions, temperature, etc.) to prevent inappropriate interpretation.

6. We suggest that in case of inconsistent or variable results that are not consistent with the clinical picture, the laboratory should be contacted and the test repeated before making a therapeutic decision.
7. We do not recommend bone mineral density testing for

assessment of CKD-MBD.

8. We recommend an abdominal X-ray (lateral view) at baseline and repeated annually.
9. We suggest that echocardiogram should be done to detect the presence or absence of valvular calcification.
10. We recommend the following goals of treatment of CKD-MBD:
 - a) If the serum phosphorus levels are elevated, the goal should be to reduce them toward the reference range using phosphate binding agents.
 - b) Serum calcium levels should be maintained in the reference range.
 - c) The iPTH levels should be maintained in the range of approximately 2–9 times of the upper limit for the assay.
11. We recommend 25 (OH) vitamin D replacement in everyone with levels in insufficient or deficient range

Treatment of hyperphosphatemia

All patients with hyperphosphatemia (values above the reference range) should be started on dietary phosphate binders.

Patients should be expressly instructed to take phosphate binders with meals.

Calcium containing phosphate binders should be used as first choice agents unless contraindicated.

Noncalcium containing binders can be used either alone or in combination with each other or with calcium containing binders.

We suggest avoiding calcium-based phosphate binders in patients with persistent hypercalcemia or vascular/valvular calcification.

The dialysate calcium concentration should be kept between 5 and 6 mg/dl to allow optimal use of calcium-containing phosphate binders.

Limiting dietary phosphate intake for treatment of hyperphosphatemia should be considered in patients who do not show evidence of malnutrition.

If the serum phosphate levels do not come down with maximal doses of phosphate binders, dialysis duration and/or frequency should be increased.

12. We suggest that children and adolescents who continue to experience height deficits despite correction of malnutrition and biochemical abnormalities of CKD-MBD should be treated with recombinant human growth hormone when additional growth is desired.

Treatment of hyperparathyroidism

In patients with persistently high serum PTH levels, treatment with vitamin D analogs (calcitriol or doxercalciferol) should be initiated.

The iPTH levels should be maintained in the range of approximately 2–9 times of the upper limit for the assay. However, treatment should be initiated if the levels show a consistent increase or decrease in one direction, even when they are within this range. This is suggested to avoid progression to levels outside of this range.

In patients who fail to show a decline or show an increase in PTH levels despite use of vitamin D analogues, calcimimetics may be started, either alone or in combination with vitamin D analogs.

In selected patients, it might be appropriate to start cinacalcet as a first line therapy for hyperparathyroidism

The dose of phosphate-binder dosage should be adjusted to control changes in phosphorus and calcium levels that may occur following institution of vitamin D analogs or calcimimetics.

Patients who continue to exhibit high iPTH levels despite adequate vitamin D and/or calcimimetics should be worked up to evaluate for development of parathyroid adenoma using ultrasound and/or CT scan and myocardial perfusion (MIBI) scan..

Patient who continue to exhibit high iPTH levels and are found to have a solitary adenoma should be treated with alcohol injection by an experienced operator and/or surgical removal.

Patients with persistently high iPTH levels who do not show an adenoma should undergo a parathyroidectomy despite correction of malnutrition and biochemical abnormalities of CKD-MBD should be treated with recombinant human growth hormone when additional growth is desired.

Caution

Vitamin D analog use should be avoided in patients with hypercalcemia and/or if serum PTH levels are persistently low.

Vitamin D analogues should be reduced or stopped in patients with persistent hyperphosphatemia.

Vitamin D analogs, and/or calcimimetics should be reduced or stopped if iPTH levels decrease to less than two times upper limit of normal.

Calcimimetics be reduced or stopped in patients with hypocalcemia, especially if it is severe and/or clinical signs and symptoms appear.

Hypertension

MHD patients should have frequent interdialysis, predialysis and postdialysis BP monitoring. Blood pressure should be monitored every 30–60 min during a dialysis session and more frequently in unstable patients.

1. We recommend that target goals should be based on individual patient characteristics.
2. We recommend that the lowest BP values consistent with patient well-being and the absence of intradialytic hypotension should be the target.
3. We recommend a postdialysis blood pressure target of < 140/90 mmHg.
4. We suggest ambulatory blood pressure monitoring in patients with variable blood pressure during dialysis whose mean should be targeted at < 135/85 mmHg during day time and < 120/80 mmHg at night time.
5. We recommend achievement of “dry weight” using a combination of clinical assessment of edema, fluid in lungs, JVP and serous cavities, blood pressure, chest X-ray and echocardiography. This should be achieved over 3–6 weeks in young adults and 12–14 weeks in older individuals and those with vascular pathologies.
6. We recommend starting antihypertensive medications if the blood pressure remains elevated despite the attainment of ‘dry weight’.
7. We suggest that the choice of drug be based upon the benefits and adverse effect profile.
8. We suggest use of antihypertensive agent is preferably during the evening with a once per day dosing schedule.
9. We recommend use of ACE inhibitors or angiotensin II receptor blockers because they provide greater benefits, such as more LVH regression and cardiovascular benefits.
10. We suggest avoiding large interdialytic weight gains.
11. Management of increased fluid accumulation should be accomplished in consultation with dietician to achieve a low sodium intake, increased UF, and/or increased dialysis treatments.
12. Low initial doses of subcutaneous erythropoietin should be administered, and the target hematocrit should be slowly achieved
13. We suggest periodic clinical assessment to reassess dry weight.

Announcement

Android App



Download
**Android
application**

FREE

A free application to browse and search the journal's content is now available for Android based mobiles and devices. The application provides “Table of Contents” of the latest issues, which are stored on the device for future offline browsing. Internet connection is required to access the back issues and search facility. The application is compatible with all the versions of Android. The application can be downloaded from <https://market.android.com/details?id=comm.app.medknow>. For suggestions and comments do write back to us.

Diabetes

Patients on dialysis often require low or no antidiabetic medication. However other systemic complications of Diabetes may continue even after a patient has reached ESRD. Glucose control and monitoring may retard or prevent other complications.

1. We recommend education of ESRD patients about diabetes management with an emphasis on how to recognize and treat hypoglycemia.
2. We recommend that all patients should have a baseline measurement of their blood sugar levels (fasting and postprandial) and HbA1C at the time of initiation of dialysis therapy.
3. We recommend individualization of therapy for control of blood sugar control.
4. We recommend the following targets: HbA1C between 6% and 7%, fasting blood sugar < 140 mg% and postprandial blood sugar < 200 mg%.
5. We recommend use of insulin for diabetes control over

oral hypoglycemic agents.

6. We recommend using a combination of long acting insulin for basal requirements along with rapid acting insulin before meals two to three times daily.
7. We recommend the following starting insulin dosage:
 - a) Type 1 diabetes: 0.5 IU/kg
 - b) Type 2 diabetes: 0.25 IU/kg
8. Further adjustments to the regimen should be individualized based on the self monitored blood glucose testing.
9. The use of OHAs should be limited to glipizide, gliclazide, sitagliptin, saxagliptin, and pioglitazone with appropriate dose modifications for ESRD.
10. We recommended that diabetic ESRD patients should follow a fixed schedule for dialysis since the blood sugars are affected by dialysis.
11. We suggest to consult an endocrinologist with expertise in managing diabetes in ESRD.

Insulin preparations

Insulin preparation	Onset of action	Peak action	Effective duration	Dosing change in renal failure
Rapid-acting				
Regular	30–60 min	2–3 hour	8–10 hour	Reduce dose by 25% when glomerular filtration rate (GFR) is 10–50 ml/min, and by 50% when GFR < 10 ml/min
Lispro (Humalog)	5–15 min	30–90 min	4–6 hour	
Aspart (NovoLog)	5–15 min	30–90 min	4–6 hour	
Long-acting				
Neutral protamine Hagedorn (NPH)	2–4 hour	4–10 hour	12–18 hour	Reduce dose by 25% when GFR is 10–50 ml/min, and by 50% when GFR is less than 10 ml/min
Glargine (Lantus)	2–4 hour	None	20–24 hour	
Detemir (Levemir)	3–4 hour	3–14 hour	6–23 (19.9) hour	
Premixed				
70/30 human mix	30–60 min	3–12 hour	12–18 hour	Reduce dose by 25% when GFR is 10–50 ml/min, and by 50% when GFR is less than 10 ml/min
70/30 aspart mix	5–15 min	30–90 min	12–18 hour	
75/25 lispro mix	5–15 min	30–90 min	12–18 hour	

Dialysis in Intensive Care Unit

Acute kidney injury (AKI) occurs in about 50% of ICU patients, about a quarter of whom may need dialysis. AKI patients in ICU differ from ESRD patients on HD in the following ways: (1) the rate as well as the amount of nitrogenous waste products generated is higher due to increased catabolic rate and (2) cardiovascular instability is more likely. The choice of RRT should take in to account these factors:

1. We recommend that all forms of RRT (IHD, SLED, CRRT, or PD) may be used in ICUs [Table 1].
2. We suggest that adult patients who are septic and hypercatabolic should be treated with HD, SLED, or CRRT in preference over PD.
3. We suggest using PD for neonates and pediatric patients weighing < 10 kg except where expertise is available to perform CRRT.
4. We recommend use of alternate day HD.
5. We recommend use of SLED or CRRT in patients with hypotension or who require vasopressor drugs.
6. The duration of SLED should be determined by the requirement of UF.
7. We recommend choosing the modality of CRRT: veno-venous hemofiltration, (CVVH), veno-venous HD (CVVHD), or a combination (CVVHD F), according to clinician expertise and the capabilities of the machines.
8. We recommend not using arteriovenous techniques as efficacy and safety monitoring may be inadequate.
9. We recommend the use of dedicated machines with full safety features for CRRT.

VASCULAR ACCESS FOR DIALYSIS IN ICU

1. We recommend that internal jugular be the preferred vascular access.
2. The access should be a dedicated cannulae of a minimum of 12F in adults, and should not be used for administering drugs or TPN or measurement of central venous pressure.
3. If high volume hemofiltration or hemodiafiltration is being delivered a 14F cannulae or two cannulae in different veins should be used.
4. The vascular access should be distant from vascular cannulae delivering TPN, antibiotics or catecholamine infusions.

DIALYSATE AND REPLACEMENT FLUIDS

1. We recommend using bicarbonate-based dialysate for IHD and SLED.
2. We recommend bicarbonate or lactate-based dialysate in CRRT.
3. We recommend use of isotonic bicarbonate-based fluid as replacement fluid in CRRT.

4. If commercial replacement fluid is not available or is too expensive, we suggest the use of custom made replacement fluid as shown in Table 2.
5. We recommend not using lactate-based dialysate for CRRT in patients with liver failure and cachectic patients with poor muscle mass.
6. We recommend adjusting the potassium concentrate in the dialysate fluid and replacement fluid may vary from 0–4 mmol/L depending on the individual need. Patients with cardiac instability and those with arrhythmias should have dialysate and replacement fluids with K+ of 4 meq/L.

DIALYZERS AND HEMOFILTERS

1. We suggest that standard intermittent HD and SLEDD may be carried out with low flux dialyzers.
2. We recommend use of dialyzers made of biocompatible materials.
3. We recommend use of CRRT sets that are compatible with the machine.
4. The UF rate should be adjusted for individual patients.
5. The blood flow should be set so that the filtration fraction is < 15% of the blood flow (specially applicable to hemofiltration and hemodiafiltration).

ANTICOAGULATION

1. Unless contraindicated, we recommend unfractionated heparin as the anticoagulant of choice during intermittent HD and CRRT.
2. We recommend heparin as a continuous infusion in patients on CRRT with aPTT monitoring every 4–6 hours. After an initial loading dose of 1500–2000 units, an infusion of 250–500 units/hour may be initiated and adjusted according to the aPTT reports.

Table 1: Machines for ICU dialysis and SLEDD

Company	Intermittent hemodialysis	SLED	CRRT
Fresenius	4008 Series H and S	Arrt plus online	Multifiltrate
B. Braun Baxter/ Edwards	Dialog plus Tina	Dialog plus Tina	Diapact BM 25
	Nikisso DBB series	Nikisso DBB series	Acquarius
Minnotech	-	-	HF 400
Gambro	AK series	AK 200 ultra	Prisma and Prisma plus
Medica	-	-	Equasmart
Nx stage	-	-	Nx stage
Nipro	Surdial and Diamax	Surdial and Diamax	-

Table 2: Replacement Fluids for CRRT

Component	Lactated Ringers Solution	Dianeal (Peritoneal dialysis fluid)	Hemasol (Gambro)	In house prepared*
Glucose	-	1360mg%	-	May be added if risk of hypoglycemia is present.
K+	4 meq/L	-	-	4
Cl-	109 meq/L	96	109.5	87
Ca++	2.7 meq/L	3.5	3.5	2.6
Mg++	-	0.5	1	-
Lactate	28 meq/L	40	3	14
Bicarbonate	-	-	32	37.5

*The above solution is prepared by adding 75 ml of NaHCO₃ (3 ampoules) of 7.5% to 825 ml of 0.45% saline along with 2 ml of 15% KCL and 100 ml of 50% dextrose. This solution is alternated with equal amounts of lactated Ringers solution to which 10 ml of 10% calcium gluconate is added. Extreme asepsis must be maintained while mixing the above components. Calcium should never be added to any solution containing bicarbonate.

Table 3: Recommended dialyzers for pediatric population

Weight of the child	Filter (Surface area)	Blood flow (ml/min)	Total effluent volume (ml/hour)
Up to 5 kg	M10 (0.04 m ²)	25–30	100–150
5-20 kg	FX20 (0.2 m ²)	30–75	150–500
20-40 kg	M60 (0.62 m ²)	75–100	500–1000
>40 kg	M100 (0.95 m ²)	≥100	≥1000

- We recommend the aPTT should be maintained at between 45 and 60 seconds or around 1.5 times the control value.
- We suggest that IHD and SLEDD can be carried out without any anticoagulation in patients with DIC or who are bleeding.

ADEQUACY

- We recommend a Kt/V of ≥ 1.2 per session
- We suggest increasing the frequency of dialysis to achieve appropriate fluid balance or acidosis, hyperkalemia correction or for urea clearance if extremely hypercatabolic.
- SLED may be performed thrice a week with 8–12 hour sessions. More frequent or longer sessions will be determined by the need for UF and acidosis correction rather than enhanced urea clearance.

- For CRRT, we recommend a total effluent (dialysate plus UF) rate of 20–25 ml/kg/hour. A higher dose may be needed in extremely catabolic or septic patients.
- The proportion of diffusive and convective clearance in CRRT may vary. A proportion of 50:50 or 65:35 for diffusion (dialysate) and convection (UF) may be used for CRRT.

PEDIATRIC CRRT

CRRT is being used increasingly in pediatric ICU world over, and is the preferred modality of RRT in the developed world. No clear evidence-based recommendations are available for pediatric CRRT, but some recommendations may be made based on the experience of units doing pediatric CRRT. Recommendations for use of CRRT in children are summarized in Table 3.

Femoral catheter is preferred to jugular catheter in small children.

5F catheter may be used for small children of ≤20 kg weight.

There are no clear recommendations for the dose of dialysis in children. A Kt/V of 1/day may be a reasonable target dose in them. For example, if the weight of the child is 20 kg, total daily effluent may be equal to total body water, that is, 20 × 0.6 = 12 liters/day or 0.5 liters/hour.

GOALS OF RRT

- Steady level in CRRT and predialysis level in IHD or SLED of BUN of ≤60 mg/dl (Blood urea ≤120 mg/dl) should be achieved within 48 hours after initiating dialysis.
- Volume status as close to euvolemia as possible.
- Correction of acidosis to maintain pH ≥7.2.
- Maintain serum electrolyte levels within reasonably normal limits (sodium: 130–148 mmol/L, potassium: 3.5–5.5).

STOPPING RRT

Guidelines for termination of RRT in AKI are unclear and are empiric. An attempt may be made to withdraw RRT if urine output is consistently more than 30 ml/min for at least 6–12 hours and predialysis BUN is < 100 mg/dl (blood urea 200 mg/dl) and serum creatinine is <5 mg/dl and patient does not exhibit any uremic symptoms.

Indian Journal of Nephrology on Web

<http://www.journalonweb.com/ijn>

Indian Journal of Nephrology now accepts articles electronically. It is easy, convenient and fast.

Check following steps:

1 Registration

- Register from <http://www.journalonweb.com/ijn> as a new author (Signup as author)
- Two-step self-explanatory process

2 New article submission

- Prepare your files (Article file, First page file and Images, if any)
- Login into your area
- Click on 'Submit a new article' under 'New Article'
- Follow the steps (three steps for article without images and five for with images)
- On successful submission you will receive an acknowledgement quoting the manuscript numbers

3 Tracking the progress

- Click on 'In Review Article' under 'Submitted Articles'
- The table gives status of the article and its due date to move to next phase
- More details can be obtained by clicking on the ManuscriptID
- Comments sent by the editor and referee will be available from these pages

4 Submitting a revised article

- Click on 'Article for Revision' under 'Submitted Articles'
- Click on 'Revise'
- From the first window, you can modify Article Title, Article Type
- First Page file and Images could be modified from second and third window, respectively
- The fourth step is uploading the revised article file.
- Include the referees' comments along with the point to point clarifications at the beginning of the revised article file.
- Do not include authors' name in the article file.
- Upload the revised article file against New Article File - Browse, choose your file and then click Upload OR Click Finish
- On completion of revision process you will be able to check the latest file uploaded from Article Cycle (In Review Articles-> Click on manuscript id -> Latest file will have a number with 'R')

Facilities

- Submission of new articles with images
- Submission of revised articles
- Checking of proofs
- Track the progress of article in review process

Advantages

- Any-time, any-where access
- Faster review
- Cost saving on postage
- No need for hard-copy submission (except on acceptance images should be sent)
- Ability to track the progress
- Ease of contacting the journal

Requirements for usage

- Computer and internet connection
- Web-browser (preferably newer versions - IE 5.0 or NS 4.7 and above)
- Cookies and javascript to be enabled in web-browser

Online submission checklist

- First Page File (text/rtf/doc/pdf file) with title page, covering letter, acknowledgement, etc.
- Article File (text/rtf/doc/pdf file) - text of the article, beginning from Title, Abstract till References (including tables). File size limit 1 MB. Do not include images in this file.
- Images (jpeg, gif, bmp, png, etc.): Submit good quality colour images. Each image should be less than 4 MB in size

Help

- Check Frequently Asked Questions (FAQs) on the site
- In case of any difficulty contact the editor



PRESENTS

1ST TIME IN INDIA

Traps the Phosphorus

SevBait[®]-DT $\frac{400}{800}$

Sevelamer Carbonate Dispersible Tablets



Disperses in 15ml of water in 60 seconds



Reduces high pill burden



Available in strawberry flavour



Overcomes pill swallowing difficulties

B-1 Extn./G-3, Mohan Co-operative Indl. Estate, Mathura Road, New Delhi - 110 044, INDIA

Website: www.panaceabiotech.com

Disclaimer: Please refer to the prescribing information for complete details

Abridged Prescribing Information

SevBait-DT: Each uncoated dispersible tablet contains Sevelamer carbonate -400mg and 800mg. Indication: SevBait-DT is indicated for control of serum phosphorus in patients with chronic kidney disease on hemodialysis or peritoneal dialysis and patients with CKD not on dialysis with serum phosphate >5.5mg/dl. Contraindication: Hypersensitivity to the Sevelamer Carbonate or to any of the excipients, Hypophosphatemia or bowel obstruction. Adverse reaction: Common adverse reactions with Sevelamer carbonate are: vomiting, nausea, diarrhea, dyspepsia, abdominal pain, flatulence and constipation. Pregnancy: The effect of Sevelamer on the absorption of vitamins and other nutrients has not been studied in pregnant women. Pediatric: The safety and efficacy of Sevelamer carbonate has not been established in pediatric patients. Dosing recommendations: Patients who are not taking phosphate binder, the recommended dose of Sevelamer is 800 mg three times daily with meal if phosphorus levels are > 5.5 to 7.5mg/dl and 1600 mg three times daily with meal based, if serum phosphorus levels is > 7.5mg/dl. Patients who are switching from calcium acetate should be prescribed as per full prescribing information. Overdose: studied up to 14 gm/day for eight days with no adverse reaction in healthy volunteers. Storage: Store at 30 °C, Protect from moisture. FOR MORE INFORMATION PLEASE REFER TO FULL PRESCRIBING INFORMATION