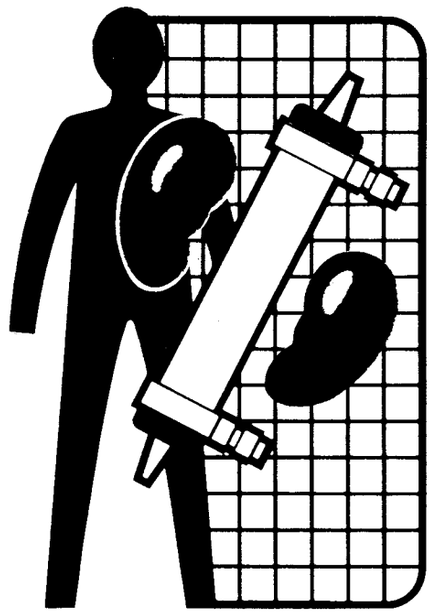
On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.



QUALITY ASSURANCE GUIDELINES for Hemodialysis Devices

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health

CDRH PUBLICATIONS - MEDICAL DEVICES

Publications of the Center for Devices and Radiological Health (CDRH) are available as paper copies from either the U.S. Government Printing Office (GPO) or the National Technical Information Service (NTIS) as indicated by the GPO or PB prefix, respectively, on the ordering number. Publications are also available in microfiche from NTIS at $8.00 per copy. To receive all CDRH reports in microfiche, at $1.40 each, you may establish a deposit account with NTIS and request automatic distribution of "FDA/HFZ" reports under the "Selected Research in Microfiche" program. Publications without GPO or PB numbers are available only from the Center for Devices and Radiological Health.

Addresses for ordering are: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402; National Technical Information Service, Springfield, VA 22161 (**outside North America, prices are double those listed**); and Center for Devices and Radiological Health, Food and Drug Administration (HFZ-265), 5600 Fishers Lane, Rockville, MD 20857. All prices are subject to change.

FDA 86-4201 Problem Definition Study: Rubella Antibody Testing (PB 86-131935/AS, $9.95, 40 pp.).

FDA 86-4202 To Cement or Not to Cement? or Has the FDA Approved the Use of This Device? (flyer).

FDA 86-4204 An Interlaboratory Comparison of Analytical Methods for Ethylene Oxide (PB 86-181856/AS, $9.95).

FDA 86-4205 Accidental Breathing Systems Disconnections (January 1986/Final Report) (PB 86-185204/AS, $22.95).

FDA 86-4208 Medical Device Federal Register Documents (Revised June 1986) (PB 87-115481/AS, $13.95).

FDA 86-4209 An Introduction to Transcutaneous Electrical Nerve Stimulation: TENS (PB 87-107884/AS, $11.95).

FDA 86-4210 A Comprehensive Review of Hemodialysis Equipment and Related Peripheral Support Equipment: Efficacy, Efficiency and Safety (Volumes I and II) (PB 86-245404/AS, $28.95).

FDA 86-4211 Hemodialysis Equipment and Practices in Massachusetts (PB 86-242427/AS, $11.95).

FDA 86-4212 Protocol for the Study of Hemodialysis in Ohio (PB 86-245370/AS, $22.95).

FDA 86-4213 State Participation in Dialysis System Investigation (PB 87-108825/AS, $24.95).

FDA 87-4002 Impact Resistant Lenses: Questions and Answers - June 1972 (FDA 81-4002) (Revised September 1987) (PB 88-123021/AS, $12.95).

FDA 87-4179 Device Good Manufacturing Practices Manual (Revised November 1987) (GPO 017-012-00330-3, $18.00) (PB 88-132139, $38.95).

FDA 87-4188 Need Help With Medical Device Regulations? Contact DSMA (supersedes FDA 84-4188) (pamphlet).

FDA 87-4199 Medical Device Establishment Registration - Information and Instructions - May 1987 (supersedes FDA 85-4199) (PB 88-123666/AS, $12.95).

FDA 87-4214 Premarket Approval (PMA) Manual (October 1986) (GPO 017-012-00329-0, $7.50) (PB 87-154365/AS, $18.95).

FDA 87-4215 Orthopaedic Device Labeling -- Guideposts for Concerned Physicians (January 1987) (flyer).

(Continued on inside back cover)

HHS Publication FDA 91-4161

Quality Assurance Guidelines for Hemodialysis Devices

Douglas L. Vlchek, BA, CHT
Sally Burrows-Hudson, MSN, RN, CNN
Dialysis Management Incorporated
Conifer, CO

•

Nancy Pressly, Project Officer
Office of Training and Assistance

This work was carried out under FDA contract number 223-89-6021

February 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857

Foreword

In October 1982, the Food and Drug Administration established the Center for Devices and Radiological Health (CDRH) by merging the Bureau of Medical Devices and the Bureau of Radiological Health.

The Center develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical devices, to control unnecessary human exposure to potentially hazardous ionizing and nonionizing radiation, and to ensure the safe, efficacious use of such radiation.

The Center publishes the results of its work in scientific journals and in its own technical reports. These reports provide a mechanism for disseminating results of CDRH and contractor projects. They are sold by the Government Printing Office and/or the National Technical Information Service.

We welcome your comments and requests for further information.

Walter E. Gundaker
Acting Director
Center for Devices
and Radiological Health

Preface

The Center for Devices and Radiological Health's (CDRH) mission under the 1976 Medical Device Amendments and the 1990 Safe Medical Devices Act is to develop and implement national programs to protect the public from unsafe or ineffective medical devices. One important aspect of the Center's activities is the development of educational programs for health professionals and consumers in the proper use of medical devices.

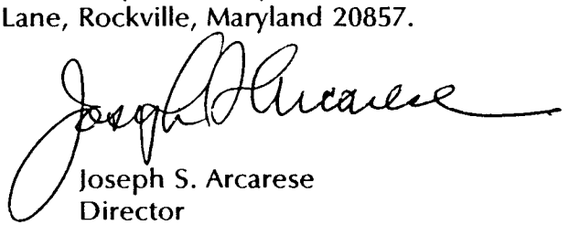
Hemodialysis is a critical care medical technique which sustains the lives of thousands of patients who suffer from acute or chronic kidney failure. However, due to the inherent complexity and risk of the technique, a few patients experience adverse events which are avoidable. Most adverse events are caused by user error or a combination of user error and medical device malfunction. A comprehensive device quality assurance program would help avoid many of these adverse events.

This publication, "Quality Assurance Guidelines for Hemodialysis Devices," is an integral part of the Center's educational program in hemodialysis. It discusses quality assurance for water treatment equipment, equipment used to evaluate the acceptability of the dialysate concentrate, dialysate delivery equipment with its associated monitors and alarms, extracorporeal blood components, dialyzers, dialyzer reprocessing and testing equipment, and all other equipment associated with the dialysis procedure.

We hope that this manual will help dialysis facility personnel become more familiar with quality assurance procedures for dialysis equipment. The manual will assist the facility in developing and implementing a facility-specific quality assurance program or in refining an existing quality assurance program. Each chapter describes quality assurance methods and also provides examples of forms which can be adapted for each facility's specific needs.

In addition to this manual, the Center has published another manual entitled "A Manual on Water Treatment for Hemodialysis" and has produced educational videotapes on various aspects of user safety in hemodialysis. The videotapes have been produced as a cooperative effort among manufacturers, professional associations, and the Center and were sent free of charge to each dialysis facility in the United States.

For further information, please contact Ms. Nancy A. Pressly (HFZ-240), Center for Devices and Radiological Health, 5600 Fishers Lane, Rockville, Maryland 20857.



Joseph S. Arcarese
Director
Office of Training and
Assistance

Acknowledgements

Interim drafts of this manual were reviewed by the following individuals. The authors are indebted to them for their careful and constructive reviews and many useful suggestions. The reviewers are:

Barbara Bednar, RN, CNN
Renal Treatment Centers
Berwyn, PA

Lee Bland, MS
Centers for Disease Control
Atlanta, GA

George Buffaloe, PhD
CGH Medical, Inc.
Lakewood, CO

Vera Buffaloe
CGH Medical, Inc.
Lakewood, CO

Larry M. Day, BA
Dialysis Management Inc.
Golden, CO

Martin Favero, PhD
Centers for Disease Control
Atlanta, GA

Leroy J. Fishbach
Minntech/Renal Systems
Minneapolis, MN

Karen Stalla, RN
Fresenius, Inc.
Concord, CA

Robert Fortner, MD
Bainbridge Island, WA

Frank A. Gotch, MD
Ralph K. Davies Medical Center
San Francisco, CA

Consuelo F. Hill, BS, RN, CHN
ESRD Network of New England
New Haven, CT

Martin V. Hudson, CHT
V.A. Medical Center
Palo Alto, CA

Douglas Luehmann
Regional Kidney Disease Program
Minneapolis, MN

Donna Mapes, MSN, RN
Transpacific ESRD Network
Sausalito, CA

Mark Neumann
Nephrology News and Issues
King of Prussia, PA

During the initial research phase of this project a number of dialysis facilities, manufacturers, and other organizations were contacted and contributed information used in this manual. The authors are indebted to them for their willingness to assist in this project and share their information. These contributors are:

Abbott Laboratories
American Nephrology Nurses Association
Amgen, Inc.
Amuchina
Associates of Cape Cod
Association for the Advancement of Medical Instrumentation
Automata, Inc.
B. Braun Medical Equipment, Inc.
Baxter Healthcare, Renal Division
Bicarbolyte Corporation
Board of Nephrology Examiners-Nursing and Technology
CD Medical, Inc.
Church and Dwight Co.
Clarkson Kidney Center
Centers for Disease Control
Cleveland Clinic Foundation
CGH Medical, Inc (Cobe-Gambro-Hospal)
CompuMod Software
Continental Water Systems Corporation
Culligan International Co.
Dial Medical, Inc.
El Camino Hospital
Emergency Care Research Institute
Enka, AG
Environmental Water Technology
ESRD Networks (all 18)
Filmtec Corporation
Fresenius USA, Inc.
Fresno Community Hospital
W.L. Gore & Associates, Inc.
HemoTec, Incorporated
Charlotte Hungerford Hospital
Impra, Incorporated
Individual State Departments of Health (all 50 states)
Institute of Medicine
International Standards Organization
Health Care Financing Administration
Robert Wood Johnson University Hospital
Joint Commission on Accreditation of Healthcare Organizations
Mayo Clinic
Medro Systems, Incorporated
Mesa Medical Inc.
Mistebar Computer Consultants
National Association of Nephrology Technologists
National Kidney Foundation
National Medical Care, Medical Products Division
National Medical Care, Dialysis Services Division
Northwest Kidney Center
Occupational Safety and Health Administration
Organon Teknika Corporation
Oshner Clinic
Polymetrics, Incorporated
Porter Memorial Hospital
Quantitative Medical Systems
Quinton Instrument Company
Renal Physicians Association
Renal Systems, Division of Minntech Corp.
Renal Treatment Centers
Separation Technology, Inc.
Seratronics, Inc.
Serim Research Corp.
Shiley, Incorporated
Sporicidin International
Surgikos, Incorporated
Terumo Corporation, USA
University of Pennsylvania Outpatient Dialysis Unit
V.A. Medical Center, Palo Alto
Vas-Cath Incorporated
Whittaker Bioproducts
Zyzatech Water Systems, Inc.

Finally, the authors wish to acknowledge the assistance in manuscript preparation by Pamela Jajko (El Camino Hospital Library & Information Center), Peggy Layton (Dialysis Management Inc.), Joan Solano (Dialysis Management Inc.), Jason Vlchek (Douglas L. Vlchek & Associates), Patricia Vlchek (Douglas L. Vlchek & Associates), Colin Beaty, and Darlene Lamun (Executive Secretarial Service).

Abstract

Vlchek, D.L., S. Burrows-Hudson, and N.A. Pressly. Quality Assurance Guidelines for Hemodialysis Devices. HHS Publication FDA 91-4161 (February 1991)(233 pp).

This manual is designed to help dialysis facility personnel become more aware of quality assurance practices for hemodialysis devices. Device areas covered include water treatment equipment, equipment used to evaluate the acceptability of the dialysate concentrate, dialysate delivery equipment with its associated monitors and alarms, extracorporeal blood components, dialyzers, dialyzer reprocessing and testing equipment, and all other equipment associated with the dialysis procedure.

This manual can also be used as a basic guide for designing a new quality assurance program. The manual includes examples of forms which can be adapted for each facility's specific needs.

Contents

Introduction

Quality Assurance in renal care covers a wide range of areas and applications. Some of these include: monitoring appropriateness of therapy; analysis of resource utilization and pursuing resulting necessary adjustments; assessing patient satisfaction; measuring morbidity and mortality with the subsequent implementation of attempted solutions; staff credentialing; and monitoring of technical and clinical processes with suitable modifications when standards are not met.

Since the title of this manual is *Quality Assurance Guidelines for Hemodialysis Devices,* the reader must be aware that only the **technical aspects** of hemodialysis are discussed herein. As authors, we suggest two reasons for this focus.

First, promoting the safe and effective use of medical devices is a mission of the Center for Devices and Radiological Health, Food and Drug Administration—the contracting agency for this manual.

Second—and probably more important—assuring the technical safety in hemodialysis continues to be one of the most critical facets of renal care. A number of incidents that result in patient injury continue to occur every year—incidents that could be prevented with proper user training, conscientious attention to the manufacturers' instructions for use and common industry practice, and a well-planned quality assurance program carried out at the facility level.

As authors we wish to convey to the reader/user of this manual our intent regarding what this publication "is" and what it "is not" meant to be:

This manual ***is*** meant to be:

- A first step in assisting the facility to develop and implement a facility-specific quality assurance approach (or to refine one, if already in place).
- A source of basic background information of the current risks and hazards associated with the use of certain devices in hemodialysis today. Suggestions are made as to how to minimize those risks, as well as how to implement quality assurance measures used to monitor and control the success of those actions.
- A source of easy-to-use forms, monitoring instruments, and other useful tools that can be immediately utilized in the facility-based quality assurance program.

This manual *is not* meant to be:

- A complete "cookbook" quality assurance program for the dialysis facility. It does contain many components of the comprehensive, facility-based quality assurance program. A number of monitoring instruments, forms, and other tools presented in this manual can immediately be utilized. However, a truly meaningful QA program for dialysis facilities must include areas that are beyond the scope of this document, including patient care, medical, dietary, social services, patient satisfaction and others.
- A training manual for the technical aspects of dialysis. Again, this publication does contain materials that will help train personnel; but much more in-depth knowledge of each of these technical areas is essential for most dialysis staff members. An annotated bibliography appears at the end of the manual to assist the facility in finding other resources needed to complete that training.
- Standards of technical practice for hemodialysis. This manual refers to various "standards" and "guidelines" that are already in existence. Some are voluntary standards, others are regulations. This manual should not be construed as a new set of standards to be followed by the

facility. The facility's own policies and procedures are the basic standards by which its QA program should be built and functions judged and monitored. In accordance with Quality Improvement principles, those facility standards (Policies and Procedures) should continuously be scrutinized and improved upon.

The authors would like to express their gratitude to all those who have assisted in the preparation of this manual who are, literally, too numerous to name individually: the manufacturers who supplied materials and reviewed drafts of individual sections; dialysis facilities that provided information on their quality assurance programs; physicians, nurses, administrators, and technicians who provided personal experiences; the regulatory agencies, networks, and other governmental entities that provided input; and the professional organizations and voluntary standards associations.

It is our hope that this manual will provide a means to assist all dialysis facilities in improving the quality of renal care.

Chapter 1

BACKGROUND

CONTENTS

Chapter 1 Background

GENERAL

The ultimate purpose of this publication—*Quality Assurance Guidelines for Hemodialysis Devices*—is to provide generic quality assurance and quality control procedures for each type of equipment used in an End Stage Renal Disease facility.

The U.S. Food and Drug Administration (FDA) has a history of encouraging the development of quality assurance (QA) programs in facilities that use medical devices. Wherever medical devices are used, QA programs should be established to ensure that the devices are properly used and maintained. Incorporating effective QA programs into hemodialysis facilities helps assure safe and effective therapy.

- **Quality assurance** may be defined as those actions that provide adequate confidence that a facility will administer consistently high-quality policies, procedures, and practices.
- **Quality control**, as it relates to medical devices, comprises monitoring, testing, and maintenance.
- **Quality administration** comprises management actions taken to guarantee that quality control procedures are performed properly, their results analyzed, and appropriate corrective measures taken.

Hemodialysis, a therapeutic process in which several medical devices are used, has been an area of focus for the FDA for many years. In 1978, the FDA began a study of the problems associated with dialysis devices, resulting in a report that discussed the problems associated with all aspects of the system. The FDA's interest continued with active participation in the Association for the Advancement of Medical Instrumentation (AAMI), Renal Disease and Detoxification Committee, resulting in voluntary American National Standards for hemodialysis devices.

In 1984, the FDA awarded four contracts to study the practice of hemodialysis. The contractors were the Health Departments of Ohio, California, Massachusetts, and District of Columbia. Results from these studies and data from the FDA's Device Experience Network (DEN) system suggest that the quality of dialysis treatment could be improved by increasing the utilization of quality assurance in several areas:

- the treatment of water and in the design, operation, and maintenance of water systems;
- the handling and dilution of concentrates;
- the reuse of disposable components
- the operation and maintenance of dialysis delivery systems;
- the practice of Universal Precautions to control the spread of human immunodeficiency virus (HIV) and hepatitis B virus (HBV);
- other areas including patient care, patient education (including home dialysis patients), personnel training, and adequate record keeping.

The Center for Devices and Radiological Health (CDRH)—a component of the FDA—has had an educational program geared toward the safe and effective use of medical devices in hemodialysis facilities. CDRH believes that the overall safety and effectiveness of the hemodialysis process will be improved if facilities voluntarily establish and implement QA programs.

The CDRH contracted to have this publication—*Quality Assurance Guidelines for Hemodialysis Devices*—developed and written as guidelines for establishing quality assurance programs in hemodialysis facilities. These guidelines can be helpful in optimizing patient care and controlling the spread of infectious diseases in dialysis facilities. This publication covers the information required to ensure that appropriate equipment is specified, pur-

chased, operated, calibrated, and maintained properly, and that administrative controls are effectively executed, thereby ensuring a safe and effective hemodialysis process.

In a typical hemodialysis facility, the various pieces of equipment can be grouped according to use, namely:

1. Water treatment equipment;
2. Equipment to monitor operation of the water treatment system;
3. Equipment to evaluate the acceptability of the dialysate concentrate;
4. Dialysate delivery equipment with its associated monitors and alarms;
5. Extracorporeal blood components (including blood access, blood tubing, blood pumps (if appropriate), infusion pumps, and air/foam detectors);
6. Dialyzers;
7. Dialyzer reprocessing and testing equipment;
8. Any other equipment associated with the dialysis procedure.

Each piece of equipment requires written quality control procedures that include maintenance and calibration procedures. The procedures should include:

1. Selecting appropriate parameters to monitor;
2. Selecting and specifying measurement techniques (electronic, or manual);
3. Determining appropriate intervals at which to monitor (continuous or periodic).

These procedures need to be accomplished periodically to ensure that equipment operates in accordance with the manufacturers' specifications. Some of the necessary written procedures, particularly for maintenance and calibration, may accompany the equipment when it is received from the manufacturer. However, these may need to be modified and additional procedures may have to be developed for a particular hemodialysis facility. Specific facility procedures may be needed because:

1. The circumstance of use of the equipment are unusual (application or type of patient);
2. The equipment is used in conjunction with other equipment from another manufacturer;
3. Qualifications, credentialling, or training of personnel differ from facility to facility;
4. The original accompanying procedures may be inadequate (unclear, not detailed enough, too detailed, etc.).

OVERVIEW OF RECENT ACTIVITIES AND PARTICIPANTS IN QUALITY ASSURANCE

Over the years, there have been a number of Quality Assurance and Quality Control activities undertaken. Among the entities involved are: the manufacturers, the Association for the Advancement of Medical Instrumentation (AAMI), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC), the Health Care Financing Administration (HCFA), the Occupational Safety and Health Administration (OSHA), the ESRD Networks, and the facilities themselves. Briefly, the contribution of each:

Manufacturers

The manufacturers are responsible for complying with Good Manufacturing Practice (GMP) regulations enforced by the FDA. These regulations include: written procedures, validation of procedures, monitoring of performance, documentation of results, review of records, and action implementation. The GMP regulation is intended to assure that the manufacturer produces devices that are safe and effective and otherwise compliant with the federal Food, Drug and Cosmetic Act. The GMP regulation is described in the Code of Federal Regulations, Title 21, Part 820, Good Manufacturing Practice for Medical Devices. The GMP is intended to ensure that devices are fit for their intended use. The device GMP is primarily concerned with the quality of conformance of a device; that is, the extent to which a device conforms with its design specifications.

Association for the Advancement of Medical Instrumentation (AAMI)

AAMI, a volunteer organization, also assisted significantly in improving the quality assurance and quality control of dialysis facilities. Since 1980, AAMI has introduced and published:

- The American National Standards for Hemodialysis Systems, which includes standards for concentrate for hemodialysis, hemodialysis systems equipment, water treatment equipment, dialysate supply systems, and monitors of the blood circuit.
- The AAMI Recommended Practice for Reuse of Hemodialyzers (incorporated by reference into the Code of Federal Regulations in 1987).
- Standards for First Use Hemodialyzers.
- Standards for Hemodialyzer Blood Tubing.

AAMI continues to update and refine these standards on an ongoing basis. AAMI also provides a variety of educational resource materials, training sessions, technology analysis and review sessions, and workshops several times yearly. For the past several years, AAMI has, at least once per year, provided courses on hemodialyzer reuse and on water quality for hemodialysis.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

JCAHO—a non-governmental organization primarily involved with accreditation of hospitals—has also had impact on dialysis facilities in that all dialysis facilities who are a department of hospitals have been inspected according to JCAHO "Special Care Units" criteria. Additionally, JCAHO has begun to require implementation of, and to inspect for, incorporation of the "10-Step Process" for quality assurance programs in dialysis facilities, as well as in other specialty areas within hospitals. Chapter Two, The Basics of Quality Assurance, provides the reader with details of this process.

Food and Drug Administration (FDA)

The FDA has also been extremely active in assisting, investigating, and ensuring the safety of medical devices through several programs.

1. **The Investigation of Risks and Hazards Associated with Medical Devices.** This report is a result of a study performed under contract by the Regional Kidney Disease Program in Minneapolis, Minnesota. Published in 1980, this study reviewed water purification, concentrate used for dialysate preparation, dialysate delivery systems, access to recirculation, blood tubing and accessories, blood pumps, infusion pumps for anticoagulation, air/foam detectors, dialyzers, and the reuse of dialyzers.
2. **Hemodialysis System Investigation Reports:.** As noted earlier, in late 1984, the FDA issued contracts which resulted in Hemodialysis System Investigation Reports from California, the District of Columbia, Massachusetts, and Ohio. These contractors reported that serious problems existed in various areas of current hemodialysis practice: water treatment systems; dialysate delivery systems and dialysate concentrate; dialyzers; extracorporeal blood circuits; reuse of disposables; orientation training programs of staff; qualification and experience of patient care staff; manufacturers' literature; and home dialysis patients. The recommendations were comprehensive for each area studied.
3. **Educational Projects.** Over the past several years, the Center for Devices and Radiological Health Office of Training and Assistance has, with the assistance of the manufacturers and several other professional groups, produced educational materials and video tapes including: *Human Factors in Hemodialysis*, *Water Treatment in Hemodialysis*, *Infection Control for Hemodialysis*, and *Reprocessing of Hemodialyzers*. Facilities have enthusiastically received these materials, and the importance of the issues handled therein certainly have been underscored. The Office of Training and Assistance also published *A Manual on Water Treatment for Hemodialysis* early in 1990.

4. **Other FDA Activities:** The FDA also gathers information through other programs such as the Problem Reporting Program (PRP) and the Medical Device Reporting Program (MDR). The FDA is also able to provide important feedback through the Device Experience Network regarding all of the device related problems mentioned above.

Centers for Disease Control (CDC)

Since the early 1970's, the CDC has conducted surveillance of hepatitis in hemodialysis centers. Through a cooperative effort with HCFA, the CDC has been able to determine and report the frequency with which hepatitis and other infectious diseases occur over time, factors associated with the occurrence of these diseases, and the effect various infection control measures have had in preventing transmission of disease in hemodialysis.

As a result of these surveillance efforts, the CDC established initial recommendations for control measures for hepatitis-B (HBV) in dialysis centers. Issued in November, 1977, the measures focused on: serologic testing, record keeping, staff and patient education, control and prevention, housekeeping and sterilization, and disinfection. These recommendations have been continuously updated and revised to reflect current technological practice and new problems.

The CDC's approach has been to educate and monitor, reporting their findings, each year to the nephrology community. Networks and other organizations adopted the CDC recommendations as standards encouraging facility compliance. As a result, these precautions, when employed, have demonstrated a significant reduction in the incidence of HBV infection.

The CDC has further developed their infection control recommendations to include HIV (human immunodeficiency virus). Utilizing lessons learned from the dialysis field, the CDC issued the current Universal Precautions for all areas of health care. Because use of serologic testing for HIV is not universally employed, the CDC has focused on the education of all health care workers in the application of Universal Precautions.

Health Care Financing Administration (HCFA)

By definition, the Health Care Financing Administration (HCFA) administers the Medicare funds for reimbursement of End Stage Renal Disease treatment. An important aspect of that function is assuring quality and appropriateness of care associated with that treatment.

In the final rulemaking for the End Stage Renal Disease (ESRD) program, the June 3, 1976, Federal Register described the further conditions of coverage of suppliers of ESRD services:

These Health Care Financing Administration (HCFA) regulations (Part 405 of Chapter IV of Title 42 Subpart U) established the initial standards by which facilities would be allowed to provide services to ESRD patients: network membership; compliance with federal, state, and local laws and regulations; governing body and management; patient care planning (long term and short term); patient rights and responsibilities; medical records; physical environment; director and staff qualifications; and minimal service requirements.

These conditions of coverage, as interpreted by HCFA, are used by the state and federal surveyors to evaluate dialysis facilities. These federal standards have been the only guide for all subsequent quality assurance activities undertaken.

Occupational Safety and Health Administration (OSHA)

During the past three years OSHA regulations have also had a direct impact on dialysis facilities:

In December of 1987 OSHA published a Final Rule on Occupational Exposure to Formaldehyde which includes exposure limits, required monitoring, regulated areas, emergency procedures, medical surveillance, special record keeping requirements, communications with and training of employees, and other actions.

Additionally, OSHA has published a Notice of Proposed Rule Making regarding Occupational Expo-

sure to HIV and HBV. The final rule is to be published in the very near future.

OSHA's Hazard Communication Standard also requires employers to provide information to their employees about hazardous chemicals used in the work place.

End Stage Renal Disease (ESRD) Networks

In June, 1976, the final ESRD regulations included a mandate to the Secretary of Health, Education and Welfare (HEW) to regulate health care being provided to persons with ESRD. In order to monitor and regulate the care provided to these patients, the ESRD Networks were established with the mandate that each Network was to organize its own medical review program. Some changes have occurred since that time, but the Network functions established by HCFA are primarily to:

1. Develop Network goals for placing patients in settings for self-care and transplantation;
2. Encourage the use of medically appropriate treatment settings most compatible with patient rehabilitation;
3. Develop criteria and standards relating to the quality and appropriateness of patient care;
4. Evaluate the procedures used by facilities in assessing patients for placement in appropriate treatment modalities;
5. Make recommendations to member facilities as needed to achieve Network goals;
6. Conduct on-site reviews of facilities as necessary;
7. Collect, validate, and analyze data.

Each Network has functioned independently of the others allowing considerable autonomy and creativity to best meet the HCFA requirements as well as community need. A significant amount of focus for the Networks has been those technical aspects attracting national attention; i.e., water treatment, infection control, dialyzer reuse, et cetera.

In 1984, the HCFA specified that each Network would encourage the development of facility specific QA programs. This effort continues to be a priority for Networks.

End Stage Renal Disease (ESRD) Facilities

As the reader will note from the above, dialysis facilities have had to not only learn and grow with the technological advancements in the field, but also comprehend and ***apply*** the various standards, guidelines, and recommendations put forth.

Facilities tend to be eager for information, forms, models and/or programs that will help them with all aspects of quality assurance. It is the intention of this manual, *Quality Assurance Guidelines for Hemodialysis Devices*, to fill some of that need.

OVERVIEW OF PROBLEMS AND INCIDENTS

The past few years have seen an increase in the concern that quality of care be maintained as the basic cornerstone of dialysis delivery.

Events that have seriously jeopardized patient safety in several different dialysis facilities have occurred during the past three to four years. These incidents have focused attention on the absolute necessity of completely competent, well-trained, medical, nursing, and technical staffs, and on well-designed use of today's technology and diligent quality assurance programs. Occasionally, incidents have occurred during this time that have received national media (newspapers, magazines, national television) exposure:

- In late September 1987, 44 patients in one facility were treated for hemolysis due to chloramine contamination of dialysate. It was later found that facility staff lacked adequate information regarding water treatment and water treatment system planning. Furthermore, inadequate staff monitoring, and an overall lack of ongoing performance appraisal contributed to this incident.
- A few months later, a serious incident occurred where injectable lidocaine was confused with

mannitol. In this incident, one patient died and another was seriously injured. Proper storage and labeling techniques, as well as protocols for administration of medication, among other issues, were implicated.

- In early 1989, patient injury occurred when a germicide and preservative (sodium azide) was not completely removed from a component of a water treatment system (ultrafilter). In this case, again, improper design and use, as well as inadequate training and monitoring were involved.
- In mid-1989, 30+ patients were treated for metabolic acidosis in a dialysis facility when acid dialysate concentrate was used with dialysis delivery systems in the acetate mode. The machines were all functioning according to specifications, but the pre-dialysis safety checks specified by the manufacturer were not performed, and other gaps in quality assurance and quality control contributed to this incident.

During these periods, the Centers for Disease Control and other federal agencies investigated scores of other similar incidents which did not appear in the media: bacterial contamination of water treatment systems, pyrogen reactions, HIV and HBV exposure, problems with improper use of dialysate concentrate, other contaminations of water treatment systems and water storage. The list is long and serious. Further, during this same period of time, the controversy regarding the reuse of hemodialyzers continued, and this has been reviewed often in the media.

Appendix A provides the reader the opportunity to review the hundreds of other incidents that have occurred in recent years related to device malfunction. More often than not, these were related to improper use, improper user training, improper preventative maintenance, and other issues normally monitored and corrected by a quality assurance program.

The combination of all of these factors has drawn significant national attention from the public, legislature, regulatory agencies, and even dialysis facilities, and health care professionals. The importance of strong and effective quality assurance programs in an effort to enhance safety and reduce the risk of these sorts of incidents is on everyone's mind.

Please note that most of the following chapters in this manual, *Quality Assurance Guidelines for Hemodialysis Devices*, contain a section on adverse incidents--both pre-1980, as well as incidents found in the FDA's Medical Device Reporting files. These are offered to the readers as background for consideration as to whether or not such incidents could occur in their facility.

Chapter 2

THE BASICS OF QUALITY ASSURANCE

CONTENTS

Chapter 2

The Basics of Quality Assurance

DEFINITION

Quality assurance is a cyclical process by which problems and opportunities for improvement are identified and analyzed, solutions are developed and implemented, and reassessment occurs. If the cycle is not completed, that is, if only the assessment component takes place, quality assurance (QA) will not occur (see Figure 1).

QUALITY ASSURANCE METHODS

Many hemodialysis facilities have successfully developed and implemented quality assurance programs. Some use quality assurance methods that they have developed themselves, modifying various models and plans; some use the Joint Commission on Accreditation of Healthcare Organizations' ten-step process for monitoring and evaluation; while a few use specific models developed by other people, including Carolyn Smith-Marker's, "Unit-Based Quality Assurance Model."

In this manual, the quality assurance cycle previously described, the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) ten step process for monitoring and evaluation, the Smith-Marker model for quality assurance, and Deming's continuous improvement concepts are offered to facilitate a comprehensive examination of quality for the hemodialysis facility. It is recommended that the references listed at the end of this chapter be used to provide more comprehensive assistance with QA programming.

JCAHO 10-Step Process for Monitoring and Evaluation

A. Getting Started

1. **Assign responsibility.** The governing body of the facility is the ultimate authority responsible for the QA program. The governing body delegates the responsibility of conducting the QA activities to a committee.

2. **Form a committee.** Committee members should include the dialysis unit's medical director, head nurse, chief technician, dietitian, and social worker. If the unit is very large and has multiple shifts, the charge nurses responsible for each shift must be included. When a QA coordinator is employed or a staff nurse is assigned the position on a part-time basis, that person should be involved and attend each QA committee meeting.

   Committee members must be those individuals that have the authority to make decisions and implement the necessary actions to assure correction of a problem. A chairperson for the committee must be elected or appointed. The position is usually assigned to the head nurse or someone who can carry out the various coordinating activities involved.

3. **Develop a plan.** A plan must describe the facility's QA program purpose and goals. The plan should include the scope of the QA program, how to achieve the purpose and goals that are outlined, and the mechanisms to be used.

   The plan also delineates the organization, responsibility and authority of the QA program: who is to be involved in the QA program, committee membership, the reporting mechanism, and the ultimate authority responsible for the QA program for the facility (see Figure 2).

4. **Organize and meet.** The committee must organize itself and educate members who are not familiar with the QA process. The appropriate resources need to be provided, such as articles, books, and educational programs.

   Once organized and prepared, the committee must meet. To assure a continuous monitoring process and commitment to improving quality, the committee should meet on a monthly basis.

5. **Minutes.** Minutes of all QA committee meetings must be written and handled in a confiden-

tial manner and should be maintained in a file that is not within public access. It is highly recommended that each QA committee review their specific state statute pertaining to the confidentiality of the QA committee minutes.

B. Define Scope of Care

In the first step, critical indicators of care are developed defining the scope of care provided by the facility. Table 1 provides an example list describing the scope of care in a hemodialysis unit. This list was developed by using the brainstorming technique to answer a number of questions:

1. **Types of patients served.** What are the characteristics of the patient population, such as age, residence, ethnicity, length of time on dialysis, or other unique characteristics?
2. **Conditions and diagnoses treated.** Are specific types of renal diseases treated? Are the patients' conditions medically complex? Are the patients all paraplegic? Diabetics? Hepatitis positive? Do the patients have multiple healthcare problems?
3. **Services provided.** What treatments or activities are performed in the dialysis unit? All of the activities that go into the hemodialysis process should be listed: patient orientation, vascular access care, venipuncture, heparinization, equipment maintenance, reuse, water treatment, infection control, environmental control, environmental safety, et cetera.
4. **The types of practitioners providing care.** Who are the people involved in the care of the end stage renal disease patient in the dialysis unit?
5. **Sites where the care is provided.** Is this an outpatient facility? An in-hospital facility? Or an outpatient clinic associated with the hospital? Is it a freestanding facility? Or is it home dialysis?
6. **Times when care is provided.** Are there different shifts available for patients?

C. Identify Important Aspects of Care

The next step is to identify the important aspects of care. These are the things that we do that are **most important**. Consider these three aspects:

1. **The aspect occurs frequently or affects a large number of patients.** In a facility this particular factor is very important. There are a number of things done that affect large numbers of patients. Examples include: the hemodialysis procedure itself; water treatment; reuse; and venipuncture.
2. **Patients are at risk of serious consequences or are deprived of substantial benefit if the care is not provided correctly, in a timely fashion or as properly indicated.** In other words, if the hemodialysis treatment is not provided adequately or properly the patients may suffer the serious consequences of uremia or be put at risk for other injury.
3. **The aspect of care has tended in the past to produce problems for staff and patients.** In the hemodialysis unit this may include infection control, water treatment, venipuncture, et cetera. HBV and HIV pose numerous problems for both staff and patients. Venipuncture is another aspect of care that has produced problems for both patients and staff.

High volume, high risk and problem prone areas that have been identified must be considered the most important aspects of care and require ongoing monitoring and evaluation.

D. Identify Indicators

Indicators are chosen directly from those aspects of care that have been identified as being most important. Using these indicators, important aspects can then be monitored and evaluated on an ongoing basis.

Among the indicators that are finally chosen, the most current standards and regulations, as outlined in Table 2, must be included. Rather than monitoring each specific entity of a regulation or standard, only those that are most important and have direct impact upon a patient should be selected. The monitoring process should be both broad and selective to provide an overview of the entire scope of facility operations.

An indicator may also come from the unit's policy and procedure manual. Policies and procedures that are current with regulations and standards and are up-to-date with all the equipment and supplies used in the unit, can serve as an immediate resource for developing indicators.

To be comprehensive in this process, the QA committee should monitor a mix of structure, process, and outcome indicators.

- **structure** is that which holds the organization together; i.e., policies, building structure, equipment.
- **process** is that which is performed or provided by the facility; i.e., the performance of procedures; and,
- **outcome**, the end result of what has been done.

All staff, if not directly involved in the identification of indicators, must be informed and have an opportunity for input. Monitoring instruments will be most successful if all staff participate in the development of and are aware of indicator expectations. Examples of monitoring instruments designed according to these guidelines and the additional information presented below are included in many of the chapters in this manual, *Quality Assurance Guidelines for Hemodialysis Devices.*

E. Establish Thresholds for Compliance

As indicators are identified and monitoring instruments are developed, the committee must establish thresholds by which the compliance level is expected. A threshold is simply that percentage of compliance with the indicators that you expect to find when monitoring the activities of your facility. It is recommended that a threshold for action begin at 85%. While highly desirable, a 100% threshold is not recommended at first. Compliance of 100% is not necessarily achievable in the beginning stages of monitoring. Begin at 85% and work towards continuous improvement.

F. Collect and Analyze the Data

After the indicators have been identified, thresholds established and the monitoring instrument has been developed, the sources of information that will be needed should be identified. Table 3 describes where a variety of information might be found. It is important to keep in mind that the sources must match the required data and that there are multiple sources already available in the dialysis unit.

The collection process is also very important. Data collection or the gathering of information must be conducted in an accurate and speedy manner. The collection process includes the identification of the indicator to be monitored, an assignment of the staff person to do that monitoring, and the appropriate space and time provided. The staff person should not try to care for a patient at the same time he/she is reviewing activities of their coworkers or trying to conduct a chart audit.

Once the monitoring activity has been completed and the data collected, it must be displayed in such a way as to ensure that the QA committee can read it and accurately interpret the findings. Displaying the data is another difficult task to complete; the Problem Tracking Form shown in Figure 3 can accurately track problems over time and display the results of the QA monitoring activities.

G. Evaluate the Results

Problems identified by the monitoring activities (i.e., failure to achieve expected compliance threshold) must be analyzed. In some cases, there may not be a clearly defined problem. It is important, however, to assure that areas for improvement are acted upon. There may be problems that are readily solved. These actions should be implemented quickly. Some problems may be extremely complex and long term in resolution. Decision making must focus on those pieces of the problem that will have a direct impact upon patient safety. A threat to patient safety must be tackled swiftly. When time permits, the committee must carefully review the remaining pieces of the problem.

As problems are identified through monitoring, it is important that the QA committee document or "track" the identified problems. One method is the use of a Problem Tracking Form (Figure 3). By noting the problems on a tracking form, the committee will be able to track a specific problem, the activities required, and the person responsible for assuring that the solution is implemented. Each time the QA committee reviews the status of a problem, a notation of the review date should be made on the form. The detailed committee discussion relating to the problem can be noted in the minutes. Until the problem is resolved, the committee should make similar notations on the form at each meeting. When the problem is finally resolved, the problem can be removed from the form. Note, however, that the past forms should be retained in the minutes of the QA committee meetings.

H. Develop Solutions to Problems and Take Action

Analysis of the problems or areas for improvement will generate solutions. It is important to consider the ***best*** solution. What is its value? Is it cost effective? Is it feasible to implement? Are resources readily available to implement this solution? And, will the solution be accepted by staff and patients alike? Staff and patient involvement must be considered in the development of solutions.

A plan of action must be developed by identifying the steps involved in implementing the solution. A target date for implementation and reevaluation must also be determined. The person responsible for implementing that solution must be aware of the expectations, responsibility, and authority required to carry out the plan. The plan must then be implemented. If the solution is not implemented and if all activity stops at this point, the problem will not be resolved and the assurance of quality will not occur.

I. Reassess

Reassessment and documentation of improvement is required to "bring the QA loop to a close" (see Figure 1). This occurs after the solution has been given enough time to make a change or to correct a problem. The reassessment monitoring instrument should not be significantly different from the one used to identify the original problem. Through follow-up monitoring activity, the QA committee will be able to determine if the problem has been solved. The monitoring process should be continued over a period of time to assure sustained resolution.

J. Communicate

The results of all QA activities need to be communicated to all dialysis staff. It is not enough that the head nurse, the medical director and the chief technician and possibly the administrator decide what to do about certain problems that they have identified. Further, when problems are resolved and/or improvement opportunities are acted upon and resolved, the staff must be made aware of the outcome and they must be congratulated on a job well done.

SUMMARY

The process described for monitoring and evaluation includes the assignment of responsibility, defining scope of care, identifying important aspects of care, identifying key indicators, establishing thresholds for evaluation, collecting and organizing data, evaluating care, taking action, assessing and documenting improvement, and communicating relevant information.

Comprehensive Quality Assurance Program: The Smith-Marker "Unit-Based Quality Assurance Model"

A comprehensive QA program involves all aspects of unit activity and integrates each under one "umbrella". A comprehensive QA program includes nine activities: development of standards, staff credentialing, performance appraisal, risk management, utilization review, concurrent monitoring, continuous and focused monitoring, active problem identification, and continuing education.

A. Development of Standards

This includes the use of the professional standards of practice for medicine, nephrology nursing, social workers, renal dietitians, and technicians. Federal and state regulations also form the standards for many of the technical activities and structural aspects in the dialysis unit.

B. Staff Credentialing

Staff credentialing, by either a professional license or certification, is an important means of screening personnel. It provides an assurance that the individual is capable of providing a recognized level of skill and expertise. This means that for all staff, where licensure or certification are appropriate, the dialysis unit administration must assure that the documentation is current and maintained according to state laws.

Other types of certification renewal or credentialling are also important to validate and maintain on file. For example, all direct patient care staff should be certified for cardiopulmonary resuscitation, continu-

ing education requirements, preventive back care orientation, hazardous materials communication, and other programs required by facility policy.

C. Performance appraisal

Performance appraisal must flow from the role description and the QA program. Standards of practice, the role description and the performance appraisal process must tie together and create one unified method of evaluating professional employee behavior.

D. Risk management

Risk management is focused on financial liability awareness. Risk management activities include disaster planning, infection surveillance and control, the use of universal precautions, facility structural aspects such as handrails on the walls and non-skid floors in the unit. The informed consent process is also a risk management activity, along with patient relations, incident reporting, adverse occurrence reporting, safety and hazardous materials education, and a grievance process for the facility.

An up-to-date policy and procedure manual is also an important component of risk management. A well written manual ensures that the policies and procedures expected to be used in the delivery of services follow all current standards, guidelines, and regulations.

E. Utilization review

When examining utilization factors related to the dialysis facility, the QA committee may focus on repeat dialyses, unscheduled acutes, emergency room visits, blood utilization, and medication administration.

F. Concurrent monitoring

Concurrent monitoring is the process of observing what is happening at the time of its occurence. Examples of this include: observing staff or patients perform procedures; querying patient satisfaction or a patient's sense of quality of life; reviewing treatment and care outcomes, especially functional status. There are a number of concurrent monitoring instruments included throughout this manual.

G. Retrospective monitoring

Monitoring retrospectively focuses on that which has already occurred. Information found in the medical record is most commonly used for retrospective monitoring. Infection control, special problem focused studies, kinetic modeling, outcome monitoring, mortality review, infections, vascular access problems, and technical audits can all be performed retrospectively. There are a number of retrospective monitoring instruments included throughout this manual.

H. Active problem identification

Active problem identification flows from the results of monitoring activities: staff credentialing, performance appraisal, risk management, utilization review, concurrent monitoring, and retrospective monitoring, with the addition of comments and problems presented by patients, staff, and management personnel.

I. Continuing education

Continuing education should focus on the problems that are identified. Continuing education should come from and focus on those problems or opportunities for improvement that have been identified through the ongoing monitoring and evaluation process.

Quality Control

Control is the process of regulating an activity to verify its conformance to a standard. Quality control (QC) is the process for those activities that measure a product's performance. Quality control is an important component of quality assurance.

In the hemodialysis unit, the purpose of QC is to assure that the equipment/devices used are safe and effective. This goal is met by the application of a cyclic process; that is, by establishing standards, measuring performance, and correcting deviations.

A major aspect of quality control is reliability. Reliability is the ability of the product to perform its intended function over a period of time. A product that "works" as it is designed, without mechanical

failure or errors, for a long period of time is a reliable one.

There are four aspects of reliability:

1. The device will not fail during a particular time; i.e., during dialysis.
2. The device is able to perform those applications for which it has been designed and as it is expected to perform, i.e., accurately prepare, monitor and deliver dialysate.
3. The device's "life expectancy" is known, and the device lasts as long as expected.
4. The device will function in an appropriate environment.

Maintenance of all equipment has an important role in assuring reliability. When maintenance is performed according to the manufacturer's guidelines or facility policies and procedures it may save the dialysis unit substantial dollars in costly repair or replacement work. Preventative maintenance also assures a safe and adequate dialytic therapy.

Periodic monitoring and evaluation are required for prevention programs. They are essential to determine whether or not the equipment is operating satisfactorily. These periodic monitoring activities simply review the operation of the device in much the same manner as monitoring the medical record or personnel performance. They should be scheduled and performed by the technical personnel who know how to operate the equipment. The results of the monitoring activity are, of course, written and circulated within the dialysis program.

A. Establishing Standards

Throughout this manual, standards that are pertinent to the components or devices discussed in each chapter have been identified. In relatively few cases do dialysis personnel need to develop new standards. The vast number and scope of standards and regulations that already exist must be used (See Table 2).

B. Measuring Performance

Equipment/device performance measurements are performed pre-dialysis (pH, conductivity, dialysate flow rate, temperature), during dialysis (blood flow rate, heparin infusion rate, volumetric controlled fluid removal rate), and during maintenance and repair procedures (ohms, volts, amps, flow rates).

C. Correcting Deviations

Each measurement taken must be evaluated against an existing standard. These standards may be found in the manufacturer's literature/recommendations for use or other sources as described in Table 2. When a deviation from the standard occurs, the problem must be analyzed and corrected.

Throughout this manual a number of quality control instruments, procedures and measures will be described. It is important that quality control be incorporated into the facility's quality assurance program.

Continuous Improvement Concepts: Deming's Principles

"Quality must be built into a product or service, it cannot be inspected in." (Deming, 1982). The theory of continuous improvement is crucial for successful dialysis unit operations. The following is offered for consideration in the development of a facility QA program.

Key points for improving quality:

- Top to bottom organizational consistency of purpose towards improvement of service.
- Find problems. It is our job to work continually on the system--towards continual improvement.
- Eliminate inspections and substitute meaningful measures of quality.
- Take immediate action to remove barriers to quality service.
- Institute long-range planning; cease focus on short-term profits.
- Eliminate barriers between staff groups; substitute team work.
- Introduce modern training methods.
- Make use of practical statistical techniques and tools (control charts, flow diagrams, run charts, etc.) to facilitate learning and action.
- Recognize achievement.

The careful integration and implementation of various models and methods of quality assurance will promote and enhance the high quality of care.

REFERENCES

1. *Joint Commission Guide to Quality Assurance.* Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Chicago, IL (1990).

2. *Quality Assurance for Nephrology Nursing.* American Nephrology Nurses Association, Pitman, NJ (1989).

3. WALTON, M., *The Deming Management Method.* Putnam Publishing, New York, NY (1986).

4. SMITH-MARKER, C. *Monitoring Professional Nursing Practice.* Aspen Publications, 1:3, Rockville, MD (1987).

5. MICHNICH, M.E., HARRIS, L.J. WILLIS, R.A. and WILLIAMS, J.E. *Ambulatory Care Evaluation: A Primer for Quality Review.* UCLA School of Public Health, Los Angeles, CA (1976).

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic .

FIGURE 1

THE QUALITY ASSURANCE PROCESS

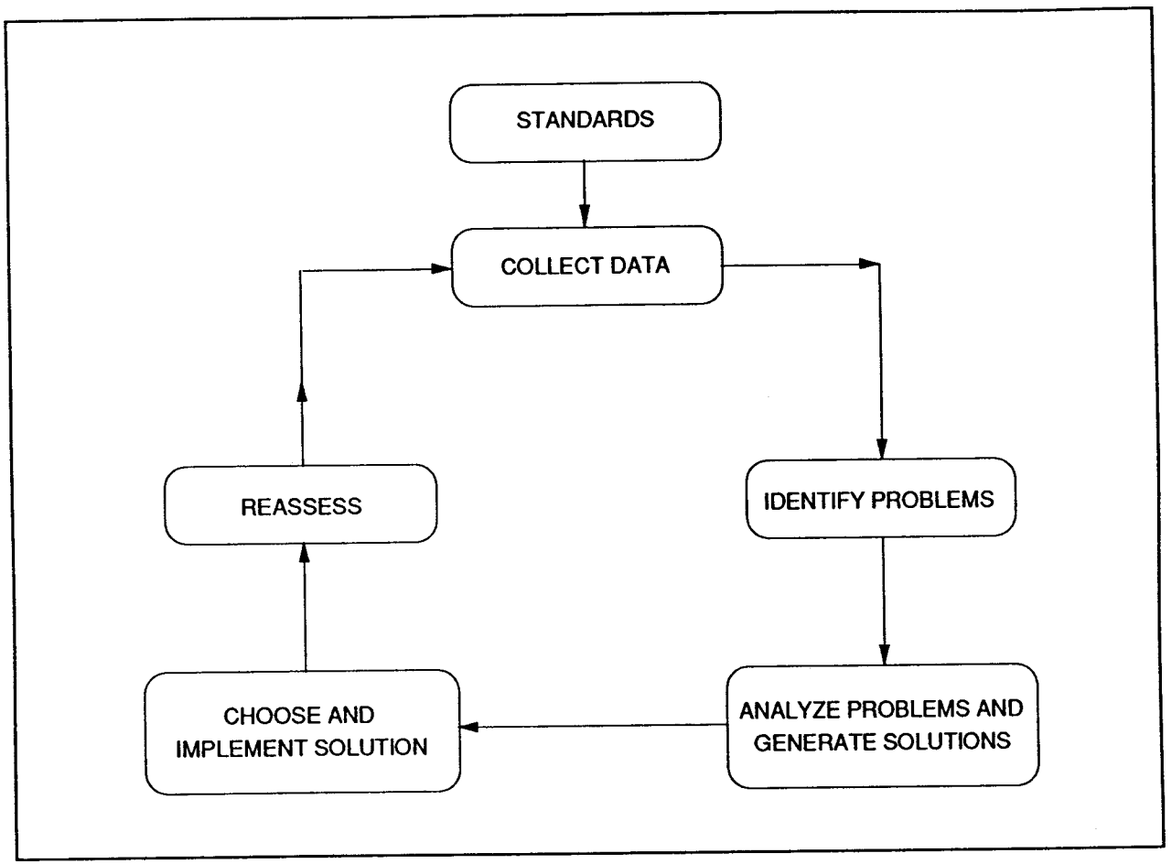


FIGURE 2

SAMPLE QUALITY ASSURANCE PLAN

I. PROGRAM PURPOSE AND GOALS

The overall goal of _____ dialysis/transplant program is to provide high quality services in an environment that is safe to both patients and providers and in a manner that will optimally benefit the patient's well-being. The purpose of the Quality Assurance Program is to objectively, systematically, and comprehensively monitor and evaluate the quality and appropriateness of patient care, to reveal opportunities to improve patient care, and to resolve identified problems.

II. ORGANIZATION AND AUTHORITY

The Governing Body of _____ is responsible for assuring that a planned and systematic process for monitoring and evaluating the quality and appropriateness of patient care services is in place, implemented, and is effective. A Quality Assurance (QA) Committee, consisting of at least the key members of the multidisciplinary team: medical director, head nurse, social worker, dietitian, chief technician, and a representative from any other service provided, is established to assure completion of activities consistant with the purpose and functions of the QA Program.

III. OBJECTIVES

The QA program shall be:

A. Comprehensive in scope, reflective of the diversity of providers and services.

B. Designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

C. Responsible for defining effective mechanisms for reviewing and evaluating patient care, as well as for an appropriate system for responding to such findings that emphasizes correction of identified problems.

D. Designed and expected to demonstrate verifiable improvement in patient care and clinical performance.

E. Defined in a written plan that shall be re-evaluated on an annual basis.

IV. PROGRAM COMPONENTS

A. Data Gathering: the QA program shall facilitate the identification on a regular, ongoing basis of known or suspected problems in patient care through the establishment of a comprehensive and coordinated system of information exchange and record maintenance regarding quality of care issues. Sources of problem identification can be based on either continuous monitors or on case-specific referrals.

FIGURE 2 (cont.)

SAMPLE QUALITY ASSURANCE PLAN

B. Problem Analysis: the QA program shall facilitate the collection, analysis, and presentation of appropriate data. Patient care issues brought to the attention of the QA program shall be screened and acted upon according to:

1. degree of adverse impact on patients;
2. feasibilty objective analysis; and
3. potential for risk/benefit

C. Reporting: the QA program shall assure the reporting of data results to respective provider groups.

D. Problem Resolution: the QA program shall facilitate and assure an appropriate plan for action including solution identification and implementation, problem tracking, and reassessment.

V. REPORTING AND CONFIDENTIALITY

Minutes of QA committee meetings shall be recorded. Indicator monitoring results, actions taken, and follow-up monitoring will be fully documented. The documentation of all QA activities will be updated on an ongoing basis and will reflect current status of each identified problem. On a routine basis, a summary of all QA activities will be reported to the Governing Body and integrated (as appropriate) into the organization-wide program. All information, analyses, records, and proceedings of the QA committee shall be protected as confidential records.

VI. PROGRAM EVALUATION

The QA committee will evaluate the QA program at least annually to assure that it meets the quality assurance needs and goals of the facility. Pre-established written objectives shall be used and a written report shall be submitted to the Governing Body.

Reviewed and Approved by:

_____ _____

Date

Director of _____

_____ _____

Governing Body Representative Date

FIGURE 3

QUALITY ASSURANCE PROBLEM TRACKING FORM

DATE	PROBLEM	ACTION PLAN	PERSON RESPONSIBLE	DATES REVIEWED	DATE RESOLVED

TABLE 1

SCOPE OF CARE

1. Chronic Adult Hemodialysis Outpatients with ESRD

- Elderly
- Non-ambulatory
- Drug Abusers
- Diabetics
- Patients of Various Ages
- Nursing Home Patients
- Patients with Ethnic/Cultural Diversity
- Patients with Various Disabilities
- Patients of Low Economic Status

2. Treatment and Care

- Hemodialysis
- Conventional Hemodialysis
- IV Med Administration
- Psych/Social Support
- Transportation
- Financial Counseling
- Patient Education
- Staff Inservice
- Primary Nursing
- Equipment Maintenance
- Safety Management
- Handling Patient Grievances
- Purchasing
- Home Training
- Rehabilitation
- Transfusions
- Family Support
- IDPN Therapy
- Laboratory Tests
- Disaster Planning
- Staff Support
- Reuse
- Universal Precautions
- Water Treatment
- Entertainment and Socialization
- Coordinate Care with Nursing and Medicine
- High Flux Hemodialysis
- EPO Therapy
- Dietary Counseling
- Continuous Therapies
- Self Care
- Quality Assurance
- Comfort Measures
- Medication Review
- Patient Scheduling
- Isolation
- Educate Students
- Research
- Travel Arrangements for Vacations

Then, subcategories, under #2 above, such as *Hemodialysis*, can be divided into "Important Aspects of Care": For example:

Hemodialysis

- Venipuncture
- Water Treatment
- Reuse
- Kinetic Modeling
- Anticoagulation
- Equipment Maintenance
- Nutritional Counseling
- Ultrafiltration
- Patient Monitoring During Treatment

3. Providers

- Physicians
- Social Workers
- Aides
- Laboratory Personnel
- Business Personnel
- Nurses
- Renal Nutritionists
- Chief Executive Officers
- Transport Personnel
- Surgeons
- LV/PN's
- Secretaries
- House Keeping Personnel
- Volunteers
- Technicians (Reuse, Equipment, Patient Care)

Used with Permission by Transpacific ESRD Network, Sausalito, CA

TABLE 2

REGULATIONS, GUIDELINES, AND STANDARDS

- 42 CFR Part 405, Subpart U (Conditions for Coverage of End-Stage Renal Disease (ESRD) Services
    - HCFA/AAMI Recommended Practice for Reuse of Hemodialyzers (plus Final Rule in October 2,1987 Federal Register)
    - HCFA Final Rule: Medicare Program: Protocol for the Reuse of Dialysis Bloodlines (42 CFR Part 405, Federal Register May 2, 1990, Vol. 55, No. 85, p. 18331-18335)
- Standards of Clinical Practice for Nephrology Nursing (ANNA)
- American National Standard (ANSI/AAMI) for Hemodialysis Systems
- 29 CFR OSHA Regulation including: formaldehyde, infections materials, and other chemicals
- Various ESRD Network Standards of Patient Care
- FDA Safety Alert: Chloramines, 1987
- Various State Standards, including:
    - Minimum Standards to Comply with Existing Federal and State of California Regulations ("Chloramines Removal from Renal Dialysis Water Supplies")
    - California Standard for Water Piping Systems in Hemodialysis
- Various Local Statutes
- JCAHO Standards
- Facility Policies
- Manufacturers' Instructions for Use

TABLE 3

DATA SOURCES

It is usually not necessary to create new data sources for quality assurance purposes. Existing sources include:

- Medical Record
- Dialysis Record/Log Sheets
- Patient Care Plans
- Hospitalization Record
- Laboratory and other Diagnostic Records
- Incident Reports
- Adverse Occurrence Reports
- Equipment Maintenance Reports
- Water Quality Monitoring Reports
- Culture Reports: Water, Reused Dialyzers, Dialysate, Environmental
- Hepatitis Surveillance Reports
- Electrical Safety Testing Reports
- Reuse Master File
- Patient Satisfaction Surveys
- State and Federal Survey Reports
- Medical Device Alerts
- Manufacturers' Recalls
- Performance Appraisals
- Utilization Review Reports

Chapter 3

WATER TREATMENT

CONTENTS

Chapter 3

Water Treatment

TECHNICAL DESCRIPTION OF DEVICE

Prior to the 1970's, chronic hemodialysis was performed using tap water to prepare the dialysate. In these early days, medical instability of the chronic renal failure patient in combination with the multiple problems related to other components of the dialysis therapy tended to mask problems that may have been due to impurities in the tap water.

As the practice of hemodialysis progressed and the equipment and other apparatus involved in the therapy improved, it became apparent that various chemical and microbiological contaminants present in tap water were indeed responsible for a number of the deleterious effects seen in the chronic hemodialysis population. Table 1A presents a list of the most common contaminants found in tap water, and Table 1B presents the clinical effects related to these contaminants.

Today, virtually all chronic hemodialysis facilities in the United States employ some type of water treatment system to purify water before using it to produce dialysate.

Water treatment systems are a combination of a variety of components, each with varying roles and effectiveness in removing contaminants commonly present in drinking water. Table 2 briefly reviews the most common water treatment system components used for producing purified water for hemodialysis.

In 1989 the FDA produced and released a videotape entitled *Water Treatment in Hemodialysis* and in 1990 a manual entitled *A Manual on Water Treatment for Hemodialysis.* Both have been distributed to all dialysis facilities in the United States.

RISKS AND HAZARDS

The literature prior to 1980 contains reports of patient complications attributed to malfunctions or misuse of water treatment systems in hemodialysis. These incidents or complications can be summarized by focusing on problems that occurred with each component.

- **Filters:** Bacterial growth, resulting in pyrogen reactions; hemolysis, due to elution of formaldehyde from media; particle breakthrough, causing damage to downstream equipment.
- **Carbon Absorption:** Bacterial growth, causing pyrogen reactions; chloramine breakthrough, due to inadequate sizing or exhaustion of the media resulting in hemolysis; release of carbon fines, damaging the reverse osmosis (R.O.) membrane; inappropriate bypassing of carbon filter.
- **Softeners:** Bacterial contamination, resulting in pyrogen reactions; hypercalcemia and hypermagnesemia, due to inadequate regeneration, improper connections, and poor salt quality; hypernatremia, due to mistiming of regeneration while patients were on dialysis.
- **Ion Exchange:** Bacterial contamination, causing pyrogen reactions; elution of floride, toxic residues, and acidic effluent, due to continued use of exhausted deionization system; elution of chemical toxins and impurities, due to the use of industrial grade resins; sloughing of fines, due to poor quality of resins; patient exposure to toxic chemicals, due to inadequate rinsing of disinfectant; low pH, due to acidic effluent; nitrosamines from use without carbon filter.
- **Reverse Osmosis:** Bacterial contamination, due to inadequate disinfecting or membrane breakthrough; premature failure of membrane, due to inadequate or improper pretreatment.
- **Storage:** Bacterial contamination, resulting in pyrogen reactions; zinc toxicity, due to leaching from storage tank.
- **Distribution:** Bacterial contamination, causing pyrogen reactions; back-siphoning of germicide from one machine to another, due to improper distribution design.

Literature review from 1980 through 1989 and the more recent MDR files indicate the following additional incidents/problem areas:

- Inadequate removal of aluminum in the water purification process for dialysis, resulting in aluminum-induced fracturing osteodystrophy and dialysis dementia.
- Bacteremia and pyrogen reactions, resulting from improper placement of water heater "downstream" of reverse osmosis.
- Contamination of water used for the reuse of dialyzers with non-tuberculous micobacterium, due to inadequate design and/or disinfection of water treatment system and distribution piping.
- Ethylene glycol intoxication, due to accidental attachment of air conditioning system to dialysis water treatment system.
- Nitrate induced anemia in a home dialysis patient, due to inadequate water treatment (softener only).
- Metabolic acidosis, due to improper water treatment and low pH of purified water.
- Pseudomonas stutzeri bacteremia and pyrogen reactions, due to contamination of deionizers.
- Generation of dimethylnitrosamine (a carcinogen) in mixed-bed deionizer, due to non-use of pre-carbon filter.
- Accidental over-fluoridation of municipal (tap) water combined with inadequate monitoring of deionization, resulting in use of exhausted tanks and subsequent toxic patient reactions (including death) from fluoride contamination.

Many of the incidents could have been avoided through routine testing, observations, a more thorough understanding of water treatment, proper system design, and quality control procedures. Although only a few of these incidents resulted in patient death, almost all had the potential to cause death.

EXISTING GUIDELINES

There are four standards/guidelines pertaining to water for dialysis purposes:

1. The Code of Federal Regulations 42 CFR Subpart U, Part 405.2140 (a) (5) states that "Water used for dialysis purposes is analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Records of test results and equipment maintenance are maintained at the facility."
2. The second set of guidelines is contained in the American National Standards for Hemodialysis Systems (AAMI: RD5-1981). In this document the standards are related to the manufacturer and to the user. A summary of the standards for the manufacturers is found in Table 3 and a summary of the standards for the user is contained in Table 4. Recommendations to enable users to achieve the standards are summarized in Table 5.
3. The third standard, in the Code of Federal Regulations 42 CFR Part 405.2150, is related to reuse of hemodialyzers and other dialysis supplies. This section adopts, by reference, the AAMI Recommended Practice for Reuse of Hemodialyzers. Table 6 summarizes this standard.
4. The fourth guideline is the Safety Alert issued by the Food and Drug Administration (FDA) that issued recommendations regarding chloramines and their removal (February 19, 1988). This document states that the use of granular activated filters for removal of chloramines should include the following:

   a. Whenever a change is made in the exisiting water treatment system, ascertain the capacity of the carbon filter to cope with that change by consulting with a water treatment engineer, contractor, or consultant who is experienced in the operation of hemodialysis water treatment systems. This is to assure that the maximum expected level of chloramines from the municipal water supply can be effectively removed with the carbon filter being used.

   b. Use charcoal filters containing granular activated carbon (GAC) and replace rather than regenerate the filters when exhausted. It is recommended (California law requires) that the water treatment system contain two carbon filters in series.

   c. Test the water for chloramines as it exits the first filter at least once per patient shift. If the level of chloramines exceeds the 0.1 ppm standard, there should be an immediate test for the chloramine level in the water used to prepare dialysate.

d. Establish a systematic plan for replacing the filters as they become exhausted. With the filters in series, the exhausted first filter can be replaced with the second, and a new carbon placed in the second position.

e. Whenever a carbon filter is replaced, disinfect and thoroughly rinse the filter housing before the new filter is installed.

QUALITY ASSURANCE FOR WATER TREATMENT SYSTEMS

Policies and Procedures

An essential facility quality assurance activity is the development, writing, implementation, and evaluation of policies and procedures for the water treatment system. All standards previously described must be incorporated into these policies and procedures. Specifically, the policies and procedures must address the scope of treatment, components and related equipment and monitors, and testing expectations.

Comprehensive policies and procedures must also address the interrelationships of each component of the water treatment system, as well as the various related components, such as the dialyzer, delivery system and patient. The risks involved must be clearly identified and considered, and appropriate safety measures and preventative systems developed.

Policies and procedures must also address safe and effective operation of the water treatment system, including:

- basic technical operation
- use of the equipment
- safety checks
- preventative maintenance
- cleaning and disinfection
- scheduled monitoring
- troubleshooting and repair
- record keeping
- patient monitoring.

Staff Training and Continuing Education

Role descriptions should include all personnel responsibilities for water treatment: supplies and equipment, testing and monitoring, and other similar responsibilities. Each responsibility should stem from a specific policy or procedure.

Staff training should be a well-defined and organized process. Content should be clearly defined for the learner and be based on behavioral objectives. The behavioral objectives can be used to accurately and objectively measure learning. At the end of the didactic session(s), the instructor should confirm by a written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. Documentation of testing results should be placed in personnel files.

Comprehension of the purpose and function of each component of the water treatment system requires a basic understanding of normal physiological concepts, as well as responses associated with uremia and the hemodialysis therapy. Content should include principles of dialysis and water treatment, patient response to therapy and related complications, and monitoring and evaluation. The interrelationships of each system component, the delivery system, dialysate, dialyzer, etc. must be incorporated into the training process.

Need for further education, such as inservices or intensive educational sessions, can be determined from the routine quality assurance monitoring process (see Form 1, "Water Treatment System Monitoring Form", used for concurrent quality assurance monitoring) and the ongoing staff performance appraisal process. When problems are identified, staff should be made aware of the problems and be involved in their resolution. This nearly always includes problem-specific continuing education.

The medical director of the dialysis facility must verify that the individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual performance evaluation has been performed.

Monitoring and Evaluation

A. Daily Monitoring

To continually confirm that water produced by the system is suitable for hemodialysis purposes as well as to confirm the integrity and proper functioning of all system components, an aggressive monitoring process must be followed. Form 2, "Water Treatment System Log," provides a useable format for the recording of these data:

(Please note that this form is provided as a model only; actual content may need to be altered to fit the specific system of the individual facility.)

1. Temperature: Daily confirmation of temperature should be performed.

2. Pressure Monitoring: Monitoring of pressure levels and pressure drops across components assures proper operating conditions.

3. Softener timer check: In installations where a timer is used to actuate automatic regeneration of the water softener, a daily check of clock set time should be performed.

4. Reverse osmosis feed flow and permeate flow: Substantial reduction in product flow rate is an indication that there may be problems with a pretreatment component or the reverse osmosis membrane may be degrading due to scaling or other types of membrane failure associated with inadequate pretreatment.

5. Feed water total dissolved solids (TDS), product water TDS, percent rejection: AAMI Standards state that (for new R.O. systems) "percent rejection should be continuously monitored." This provides an indication of the condition of the R.O. membranes as well as helping monitor against any catastrophic compromise in membrane integrity.

   The performance shall be such that the salt passage rate (100% minus the rejection rate) does not exceed two times the salt passage rate of the equipment at the time of its initial qualification.

   Calculate the salt rejection by the following formula:

$$\% \text{ rejection} = \frac{(\text{Feed Conductivity} - \text{Product Conductivity})}{\text{Feed Conductivity}} \times 100$$

6. Post water softener hardness: The AAMI American National Standard for Hemodialysis Systems also recommends that post waters oftener hardness be checked daily before dialysis begins. This confirms that water being delivered from the softener is at acceptable limits at that time. Some experts recommend, however, that post softener hardness also be tested at the end of the treatment day in order to confirm proper softener sizing and regeneration protocols.

7. Chloramines testing: Testing for chloramines should be performed as the water exits the first granular-activated carbon filter. Using the recommended DPD (N. N-diethyl-p-phenylene diamine) method, results should always be less than 0.1mg/L. If chloramine levels exiting the first tank exceed 0.1mg/liter, a test of the effluent of the second tank should be immediately performed. Dialysis should not proceed if the water used for production of dialysate contains more than 0.1 mg/L.

8. Audit: The reader will note the final line at the bottom of the "Water Treatment Log" indicates "Audit." On a daily basis, someone who is knowledgeable about the tests, measurements, and limits for the water treatment monitoring, as well as the acceptable limits set forth in the facility's policies and procedures for each one of those measurements, should review the results. The person performing the tests should be aware of the acceptable limits and should have performed proper notification and taken appropriate action if the tests/measurements performed indicated results outside of acceptable limits.

B. Monthly monitoring

1. Conductivity meters require recalibration monthly, following the manufacturers recommendations.

2. Microbiological testing of system components and the distribution system must be performed monthly in the following manner:

   a. **Post carbon filtration:** AAMI (American National Standards for Hemodialysis Systems) recommends that "carbon tanks be monitored for excess bacterial levels." Although there is no standard for bacterial levels exiting a carbon tank, very high levels may indicate a load so high that downstream components are unable to adequately remove them.

   b. **Post reverse osmosis:** If a reverse osmosis system is used as a primary method for attaining microbiologically acceptable water, bacterial levels should be assessed immediately after the R.O. to ascertain that this goal is being achieved.

c. **Post storage tank:** If a storage tank is used in the water treatment system, bacterial levels should be cultured directly from this tank in order to ascertain proper tank design and disinfection protocols.

d. **Post deionizer:** If the deionizer is used without reverse osmosis, or placed post reverse osmosis without any downstream bacterial or endotoxin protection (an ultrafilter), microbiological integrity of the effluent must be confirmed.

e. **Post ultrafilter:** If an ultrafilter is used as a final bacterial/endotoxin filter, integrity and proper disinfection of the ultrafilter must also be confirmed.

f. **End of "return loop":** A sample should be performed at the end of the "return loop," if used, as a final measurement of bacterial colonization anywhere in the system.

3. Any incident related to the water treatment system should be handled immediately, and should be included in monthly quality assurance meetings.

C. Patient Monitoring

The following monitoring activities relate to patient response as it pertains to water treatment:

1. Routine blood chemistries may indicate improper inorganic chemical concentrations or organic chemical contaminates.

2. Normal intra-dialytic monitoring of patients and patient symptomology during the dialysis session can also provide indications of chemical water contamination. Symptoms seen with improper water treatment are presented in Table 1A.

D. Home Dialysis Monitoring

All of the monitoring procedures described above should be performed by the home dialysis patient, home dialysis support personnel, and reviewed by the medical director, as appropriate.

E. Other Monitoring

The following water treatment system monitoring should be performed on at least a quarterly basis:

1. **Safety supplies.** All safety supplies related to personnel handling of chemical toxins or biological contaminants should be inspected.

2. **Trend analysis.** A trend analysis comparing microbial monitoring and system function should be performed. A tool for assisting the facility in this activity is shown as Form 3.

F. Prevention

1. Audit recordkeeping procedures semiannually.

2. Policies and procedures related to water treatment and water treatment equipment should be reviewed annually.

3. Facility standards related to the water treatment system should be reviewed annually.

4. Maintenance and repair logs related to the water treatment system should be reviewed annually.

5. Any utility (water, drain, electricity) requirements related to the water treatment system should be reviewed annually.

G. Purchasing Guidelines

1. Establish quality specifications for all equipment used.

2. Estimate quantity requirements; allow for future growth and possible membrane degradation.

3. Cite applicable standards.

4. Require system validation by the vendor to assure specifications are met.

5. Require the vendor to test for and/or disclose adverse conditions/substances that may effect the membrane.

6. Request a detailed manual for operation, maintenance, monitoring, disinfection, and safety.

7. Evaluate need for service contract.

As recommended by the Food and Drug Administration in the February 19, 1988 Safety Alert, a qualified water engineer or consultant familiar with the special needs of dialysis facilities should be consulted when designing or installing a new water treatment system or changing an existing one. Whenever changes are made, it is essential to re-evaluate the design of the water system as a whole in order to be certain that it is adequate. The engineer or consultant, along with the facility, should be familiar with pertinent chemical and bacteriological standards such as the AAMI standard and/or local, state, and federal requirements.

Additionally, the design and specification guidelines contained in the FDA publication, *A Manual on Water Treatment for Hemodialysis*, should be reviewed.

REFERENCES

1. Association for the Advancement of Medical Instrumentation. *American National Standard for Hemodialysis Systems* (AAMI: RD5-1981). Arlington, VA (1982).

2. KESHAVIAH, P., LUEHMANN, D., SHAPIRO, F. and COMTY, C. *Investigation of Risks and Hazards Associated with Hemodialysis Systems* (Technical Report, Contract #223-78-5046). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/ Bureau of Medical Devices, Silver Spring, MD (1980).

3. EASTERLING, R. *Mechanical Aspects of Dialysis Including Dialysate Delivery Systems and Water for Dialysate.* in Clinical Dialysis. A.R. Nissenson, R.N. Fine and D.E. Gentile, eds. Appleton-Century-Crofts, Norwalk, CT (1984).

4. LUEHMANN, D.A., KESHAVIAH, P.R., WARD, R.A., KLEIN, E. and THOMAS, A. *A Manual on Water Treatment for Hemodialysis* (FDA Contract #223-87-6027). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/Centers for Devices and Radiological Health, Rockville, MD (1989).

5. *Water Treatment in Hemodialysis* (Videotape). Food and Drug Administration (1989).

6. VASQUEZ, L. and McELROY, V.L. *Validation Protocols for Hemodialysis Water Systems.* Continental Water System Corp., San Antonio, TX (1988).

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigationfor the purpose of training or research on this topic .

TABLE 1A

WATER CONTAMINANTS AND THE LOWEST CONCENTRATIONS ASSOCIATED WITH TOXICITY IN THE HEMODIALYSIS SETTING

Contaminants	Lowest Concentration Associated with Toxicity (mg/L)
Aluminum	0.06
Chloramines	0.25
Fluoride	1.0
Copper	0.49
Zinc	0.2
Nitrate	21 (as N)
Sulfate	200
Calcium/Magnesium	88 (Ca^{**})
Sodium	300
Microbial	—

Luehmann, et al. (1989)

TABLE 1B

SIGNS AND SYMPTOMS AND POSSIBLE WATER CONTAMINANT-RELATED CAUSES

Sign or Symptom	Possible Water Contaminant-Related Cause
Anemia	Aluminum, chloramines, copper, zinc
Bone disease	Aluminum, fluoride
Hemolysis	Chloramines, copper, nitrates
Hypertension	Calcium, sodium
Hypotension	Bacteria, endotoxin, nitrates
Metabolic acidosis	Low pH, sulfates
Muscle weakness	Calcium, magnesium
Nausea and vomiting	Bacteria, calcium, copper, endotoxin, low pH, magnesium, nitrates, sulphates, zinc
Neurological deterioration and encephalopathy	Aluminum

Luehmann, et al. (1989)

TABLE 2
WATER TREATMENT SYSTEM

COMPONENT NAME	COMPONENT FUNCTION	OPERATOR REQUIREMENTS
Blending Valve	Mixes hot and cold water to a fixed predetermined temperature to achieve optimal performance from the reverse osmosis device.	Water temperature downstream of blending valve should be monitored at least daily to maintain optimum R.O. output, and to protect R.O. membrane and patients from excess temperature.
Bed Filter	Sand, multi-media, or diatomaceous earth filter used to remove suspended matter or colloidal material before downstream components.	Filter should be backwashed at frequent intervals. Pressure drop across filter should be monitored at least daily.
Carbon Absorption	Activated carbon in tanks used to remove chlorine, chloramine, and some organics. Two tanks, each containing granular activated carbon in series, are recommended. Each tank should have an empty bed contact time of 3 to 5 minutes. Carbon tanks should be followed by particle filters to remove carbon fines from tank effluent. Do not install bypass piping.	Test water for chloramines after the first tank before every patient dialysis shift. If chloramines are > 0.1 mg/L (AAMI Standard), immediately test water exiting the second tank. If these levels exceed AAMI limits, dialysis should not proceed. When chloramine levels reach AAMI limit after first tank, replace carbon tank. Monitor bacterial levels.
Water Softener	A tank containing insoluble spheres or beads, called "resin." The resin exchanges cations (positively charged sodium ions) to remove calcium and magnesium from incoming hard water. Most facilities use "permanent" softeners which incorporate a brine tank containing concentrated sodium chloride solution and a control system to regenerate the softener at preset intervals.	Test upstream for baseline. Maintain volume of salt in brine tank. Test post-softener water for hardness at least once daily. Check timer from proper setting at least once daily.
Reverse Osmosis	A membrane separation process for removing solvent from a solution; this system pressurizes feedwater on one side of a membrane. By creating a pressure high enough to exceed osmotic pressure, reverse osmotic flow of water occurs across a semipermeable membrane, giving "product water" essentially free of dissolved solids, microorganisms, and endoxin. Variation in pH and temperature can affect performance.	Periodic and validated disinfection and cleaning should be performed to protect the R.O. membrane from scale deposition, particulate and colloidal fouling, and bacterial growth. Feed and product water pressures, flow rates, and ionic content (conductivity) should be monitored according to the manufacturer's recommendations, but at least daily. Post-R.O. bacterial levels should be measured at least monthly.

TABLE 2
WATER TREATMENT SYSTEM (cont.)

COMPONENT NAME	COMPONENT FUNCTION	OPERATOR REQUIREMENTS
Deionization	Tank containing insoluble spheres, or resin, which remove all types of anions and cations and replace them with hydrogen and hydroxide ions which combine to form water. Deionizers may be categorized as "mixed bed," containing both cation and anion resin in a single vessel, or "dual bed," where each resin type is in a separate vessel. Due to the possibility of formation of carcinogenic nitrosamines when chlorine contacts the resin, carbon filtration should be used upstream of deionizers.	Deionizers should be equipped with continuous monitors (temperature compensated) indicating water ionic quality of at least 1 megohm/cm, and a visual and audible alarm, should the effluent fall below that level. Due to the propensity for bacterial growth in deionizers, they should be followed by a downstream component which removes bacteria and endotoxin.
Storage Tanks	A water tank that stores product water; required/desired in some installations. A water level detector controls the R.O. delivery to the tank and a recirculation pump maintains adequate flow and pressure to the distribution loop. The Centers for Disease Control has recommended against use of storage tanks due to hazards related to bacterial contamination. However, a number of facilities have been able to successfully use storage tanks that are properly designed and effectively disinfected at validated intervals.	Monitor bacterial levels of tank effluent. Disinfect tank and distribution system at intervals which have been validated to maintain acceptable levels of microbiological contaminants. Monitor proper performance of level sensors. Confirm proper tank design: airtight tank with 0.2m hydrophobic air filter; constant flow with no stagnant areas; able to be adequately disinfected and rinsed (bowl-shaped bottom with drain); tank material should not add chemical contaminants, etc.
Ultraviolet Radiation	A low pressure mercury vapor lamp protected by a quartz sleeve which emits a bactericidal wavelength light to water flowing past it. It should be noted, however, that certain bacterial species are resistant to ultraviolet irradiation and that this method does not remove endotoxins. Biofilm will decrease effectiveness.	Monitor loss of radiant energy output. Perform regular maintenance, including lamp replacement and cleaning.

TABLE 2
WATER TREATMENT SYSTEM (cont.)

COMPONENT NAME	COMPONENT FUNCTION	OPERATOR REQUIREMENTS
Ultrafilter	A membrane filter capable of working solely off of existing circuit pressure (no special pressurization pump is required (as with R.O.)) which will remove smaller particles than depth filters. Ultrafilter membranes can be configured as hollow fibers or spiral wound flat sheets, and they can be operated in either a "dead-end" or "cross-flow filtration" mode. Ultrafilters are capable of removing bacteria *and* endotoxin.	Pressure drop and flow rate across the filter should be monitored on at least a daily basis. Filter should be cleaned and disinfected on a routine and validated interval. Post-filter bacterial levels should be monitored.
Distribution Loop	The distribution loop includes all piping from other water treatment system components, distribution pumps, pressure tanks, etc. Current acceptable industry design suggests: • constant flow through all distribution piping, most commonly achieved via "recirculating loop" • pipe materials which do not degrade the chemical or microbiological quality of the water • a minimum flow velocity in piping of 1.5 ft/sec to discourage bacterial colonization • avoidance of any dead-ends in piping.	At least monthly monitor bacterial levels in distribution piping at point where dialysis delivery systems connect. Disinfect distribution system at intervals which have been validated to maintain acceptable levels of microbiological contaminants.

TABLE 3
AAMI REQUIREMENTS FOR MANUFACTURERS

GENERAL

- Device labeling
- Product literature
- Initial validation
- Materials compatibility

SUPPLIER: AUTOMATIC REGENERATION DEVICES

- Shall prevent excess levels of contaminants from entering downstream during regeneration

SUPPLIER: CARBON FILTERS

- 5μ filter downstream
- Discard and replace exhausted GAC

SUPPLIER: DEIONIZATION

- Continuous resistivity monitor (>1 megohm/cm)
- Temperature compensated monitor
- Visual and audible alarm
- GAC upstream (nitrosamines)

SUPPLIER: PIPING, STORAGE TANKS

- Shall not contribute contaminants (i.e., copper, zinc, lead, bacterial, etc.)

SUPPLIER: REVERSE OSMOSIS

- Capable of AAMI spec. water
- Monitor salt passage (2x initial) (salt passage = 100 - rejection rate)
- Audible and visual alarms (at highest rejection coefficient where contaminants reach unsafe levels)

SUPPLIER: SEDIMENT FILTERS

- Opaque housings

TABLE 4
AAMI STANDARDS FOR FACILITIES/USERS

MICROBIOLOGICAL MONITORING

- Should be performed at least monthly
- Total viable microbial counts shall not exceed 200/ml in water used to prepare dialysate, or 2000/ml in proportioned dialysate exiting the dialyzer.

CHEMICAL CONTAMINANTS MONITORING

- Should be performed at least yearly if prepared by DI or RO, more frequently if prepared with lesser level of treatment.
- AAMI maximum levels of chemical contaminants*:

Contaminant	Suggested Maximum Level (mg/L)
Calcium	2 (0.1 mEq/L)
Magnesium	4 (0.3 mEq/L)
Sodium**	70 (3 mEq/L)
Potassium	8 (0.2 mEq/L)
Fluoride	0.2
Chlorine	0.5
Chloramines	0.1
Nitrate (N)	2
Sulfate	100
Copper, Barium, Zinc	0.1 each
Aluminum	0.01
Arsenic, Lead, Silver	0.005 each
Cadmium	0.001
Chromium	0.014
Selenium	0.09
Mercury	0.0002

* The physician has ultimate responsibility for determining the quality of water used for dialysis.

** 230 mg/L (10 mEq/L) where sodium concentration of the concentrate has been reduced to compensate for the excess sodium in the water, as long as conductivity of water is being continuously monitored.

TABLE 5
AAMI RECOMMENDATIONS FOR USERS

CARBON FILTRATION
- Disposable carton
- Monitor for bacteria
- Monitor for exhaustion

DEIONIZATION
- Don't use "industrial" or process resins
- One megohm resistivity minimum quality with temperature compensated monitor
- Be aware of preservatives and anti-freeze solutions
- Carbon filtration for protection against nitrosamines

DISINFECTION
- Good procedures for all equipment and systems
- Monitor for bacteria

MONITORING PROGRAM
- Periodic water analysis
- In-line continuous monitoring
- Test kits for daily monitoring
- A procedures manual

PIPING, STORAGE, ETC.
- Don't use copper, galvanized iron, or iron materials
- Monitor for bacteria

REVERSE OSMOSIS
- Monitor pretreatment
- Monitor operation

SEDIMENT FILTERS
- Opaque filters
- Monitor pressure drop (ΔP)
- Change filters periodically and/or monitor for bacteria

WATER SOFTENER
- Automatic regeneration with bypass during regeneration
- Pellet salt designed for softeners
- Check timer before dialysis
- Check hardness before dialysis

TABLE 6

AAMI RECOMMENDED PRACTICE FOR REUSE OF HEMODIALYZER: WATER REQUIREMENTS

WATER TREATMENT SYSTEM

- Must meet requirements (pressure, flow rate, chemical quality, microbiological quality, etc.) of reprocessing equipment operating under peak conditions.

WATER USED FOR RINSING/CLEANING DIALYZER

- The water should have a bacterial colony count of less than 200/ml and/or bacterial lipopolysaccharide concentration of less than 1 ng/ml (5EU/ml), as measured by the Limulus amebocyte lysate assay.

WATER USED TO PREPARE (DILUTE) GERMICIDE

- The water should have a bacterial colony count of less than 200/ml and/or bacterial lipopolysaccharide concentration of less than 1 ng/ml (5EU/ml), as measured by the Limulus amebocyte lystate assay.

PROCEDURE FOR WATER TREATMENT SYSTEM MONITORING FORM (FORM 1)

The purpose of this audit is to monitor technical staff compliance with standard practices and procedures related to the water treatment system. When staff are aware of the importance of the policies and well trained in the procedures, compliance should be very high.

Before the Audit

1. Provide adequate and appropriate inservice to assure total staff awareness and education of all components associated with water treatment for dialysis.
2. Assure staff awareness of all elements of the concurrent audit and how performance will be observed and evaluated.
3. The QA committee specifies the standard (expected percentage compliance) desired for the audit; begin not lower than 85%.
4. Schedule the audit with appropriate personnel (head nurse, charge nurse, chief technician).
5. Make copies of the audit for each auditor/observer.
6. Assign code letters for each staff member to be observed; for example:

   Employee A: Glenn Close
   B: Tom Hanks
   C. William Hurt
   etc.

7. Determine how many staff are to be observed. It is recommend that one auditor should observe no more than three to four staff at one time.
8. Define the length of time for observation. It is recommended that the audit be conducted during peak activity times (daily start-up, shift changeovers, etc.). The time frame should be long enough to observe each staff member completely perform the listed activity.
9. Assign a staff member to perform the audit. Auditor should not be assigned to other responsibilities during the audit.

Perform the Audit

1. On the actual audit sheet, write in the date, auditor's name, patient shift (or time of day), and standard.
2. Read each indicator carefully.
3. Observe staff for actual *performance*. Auditor should not interfere with staff activities, be obtrusive, or preceptibly obvious.
4. Under each staff code letter, write Y for yes if indicator is met, N for no if indicator is not met, or N/A for not applicable, not observed.

   To achieve a Y (yes, indicator was met), staff should be observed with complete compliance for each encounter. For example, for a Y to appear in the "Post-Softener Hardness Done" box, the staff member must perform the test before any patient dialysis is done ***and*** perform the test exactly according to the instructions for use of the test manufacturer ***and*** record the results as per facility policy.
5. Complete all observations within timeframe specified. Assure that each indicator has one response.

After the Audit

1. Under each employee code letter, add total number of Ys and Ns; do not count NAs.
2. For each employee, calculate compliance percentage by dividing the total Ys by the total observations; again, do not count NAs.
3. Calculate total compliance percentage for the audit by dividing total Ys (all employee Ys) by the total observations; do not count NAs.
4. For each indicator, calculate compliance percentage by using the same method as above; again, do not count NAs.
5. Report results to QA committee and clinical management team with additional comments and/or recommendations.

FORM 1

WATER TREATMENT SYSTEM MONITORING FORM

Date	Patient Shift	Auditor

Day/Date									
Staff Member (initials)									
DAILY MONITORING/SYSTEM CHECKS								**Threshold**	**% Compliant**
All gauge readings recorded									
Post-softener hardness done									
Pre-softener hardness done									
Chloramines tested: Before 1st patient shift									
Chloramines tested: Before 2nd patient shift									
Chloramines tested: Before 3rd patient shift									
Blended water temperature recorded									
Feed and product TDS, % rejection recorded									
Feed and product flow rates recorded									
Daily audit of log form done									
MONTHLY FUNCTIONS	**Staff Member**							**Threshold**	**% Compliant**
System disinfection logged									
Bacterial samples done/results recorded: Site									
Bacterial samples done/results recorded: Site									
Bacterial samples done/results recorded: Site									
Bacterial samples done/results recorded: Site									

Q.A. Committee Recommended Action: _____

_____

_____

WATER TREATMENT SYSTEM LOG

	Mon	Tue	Wed	Thu	Fri	Sat
DATE						
GAUGE READINGS						
Pressure gauge #1 (psi) (pre-mix bed)						
ΔP-mixed bed						
Pressure gauge #2 (psi) (pre-softener)						
ΔP-softener						
Pressure gauge #3 (psi) (pre-carb 1)						
ΔP-carbon tank #1						
Presure gauge #4 (psi) (pre-carb 2)						
ΔP-carbon tank #2						
Softener timer check						
Temperature (°F)						
Pressure gauge #6 (psi) (pre-filter)						
Pressure guage #7 (psi) (post-filter)						
ΔP-R.O. pre-filter						
Feedwater TDS						
Product water TDS						
Percent rejection						
Feed flow						
Permeate flow						
Feed pressure						
Permeate pressure						
WATER TESTS						
Pre-softener hardness						
Post-softener hardness (p.m.)						
Post-softener hardness (a.m.)						
LOGGED BY						
CHLORAMINES TESTS (<0.1 mg/L)						
Before 1st patient shift (initials)						
Before 2nd patient shift (initials)						
Before 3rd patient shift (initials)						
AUDIT (initials)						

FORM 3

WATER TREATMENT SYSTEM TREND ANALYSIS

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DATE												
BACTERIAL SAMPLES												
Station #1												
Station #2												
Station #3												
Station #4												
Station #5												
Station #6												
Station #7												
Station #8												
Station #9												
Station #10												
SOFTENER												
Pre-hardness												
Post-hardness (a.m.)												
Post-hardness (p.m.)												
CHLORAMINES												
City Water												
Post GAC 1st shift												
Post GAC 2nd shift												
Post GAC 3rd shift												
Post GAC 4th shift												
REVERSE OSMOSIS												
Feed flow rate												
Product flow rate												
Percent recover												
Feed TDS												
Product TDS												
Percent rejection												
Feed temperature												

Chapter 4

DIALYSIS DELIVERY SYSTEM

CONTENTS

Chapter 4

Dialysis Delivery System

TECHNICAL DESCRIPTION OF DEVICE

The dialysis delivery system (delivery system) supplies dialysate to the hemodialyzer, maintaining proper concentration, temperature, pressures, and flow in the dialysate circuit. The delivery system also monitors various functions related to the dialysate compartment and the blood compartment: dialysate pressure, ultrafiltration rate, blood leaks 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. Dialysate is produced from proportioning dialysate concentrate and water. Normally, single patient systems, also called "negative pressure systems," maintain a subatmospheric ("negative") dialysate pressure in order to accomplish fluid removal.

The central delivery system maintains a single "central" dialysate proportioner which prepares dialysate for a number of bedside consoles or bedside stations. Both the single patient/single pass systems and the multi-patient/single pass systems require a continuous supply of purified water and a continuous source of concentrate. "Spent," or "exhausted" dialysate is discarded to the drain after it has made a single pass through the dialyzer.

The sorbent or regenerative dialysis system involves reprocessing dialysate through a cartridge to remove toxins from the spent dialysate, as well as adjusting electrolytes to the desired level. The standard volume used in regenerative dialysis is approximately 6 liters. This process does not require a continuous supply of water or concentrate and does not drain spent dialysate.

The basic functions of a dialysate delivery system are summarized below:

- Appropriate dilution/proportioning of concentrate.
- Heating dialysate to physiological range.
- Continuous monitoring of conductivity (and in some machines pH) and interruption of dialysate flow to the dialyzer if these parameters differ from preset limits.
- Perfusing the dialyzer's dialysate compartment at a desired flow rate.
- Monitoring desired dialysate circuit pressures.
- Controlling and/or monitoring ultrafiltration rate.
- Pumping the blood from the patient through the dialyzer and back to the patient.
- Monitoring pressure in the extracorporeal blood circuit.
- Monitoring for blood in the effluent dialysate.
- Monitoring for appearance of air in the blood circuit.
- Interrupting power to the blood pump in such situations as blood leaks, incorrectly heated dialysate, incorrect dialysate pressures, incorrect blood compartment pressures, air in the blood.

Table 1 provides a summary of dialysis delivery system components.

RISKS AND HAZARDS

The literature prior to 1980 contains a large number of reports of patient complications attributed to problems with dialysis delivery systems. Included are those that contributed to serious patient injury or death:

- Dialysate mixing errors
- Improper setting/resetting of alarm limits

•• Proportioning pump failure

• Conductivity monitor failure

•• Temperature alarm failure

•• Dialysate pressure alarm failure

•• Blood circuit dysfunction

Incidents reported in the literature or through the Medical Device Reporting Program since 1980 are summarized in Appendix A. A total of 160 incidents were reported. Sixteen were related to central delivery systems and 144 were related to single patient delivery systems.

Of the 160 incidents, 77 were related to user error. Of the remaining, 70 included some component of user error in addition to malfunction of the equipment itself. Unfortunately, some of these problems resulted in patient death.

Incidents related to user error, or combination of user error and machine malfunction included:

Blood Circuit

•• Blood line clamp not completely occluding blood line; air introduction into blood circuit, resulting in air embolism.

•• Patient injury or death from air embolism, due to an unarmed or bypassed air/foam detector.

•• Uncontrolled blood pump operation, resulting in vascular damage and/or excessive extracorporeal circuit pressures.

•• Patient bleeding, caused by excess heparin administration due to lack of heparin pump preventative maintenance.

• Blood pump stopped working during dialysis; condition had occurred previously with no action; caused clotting of extracorporeal circuit

Dialysate Conductivity/Electrolytic Concentration

•• Machine malfunction causing hypertonic or hypotonic dialysate. Hypernatremia due to grossly maladjusted conductivity. These events resulted in hemolysis, vomiting, seizure, and death.

• Machine operated in bypass mode without attaching concentrate, resulting in hemolysis.

•• Hemolysis, due to empty concentrate jug concurrent with no alarm or by-pass.

•• Adverse reaction, due to improper pH, alarm improperly set or disabled.

•• Hypercalcemia, due to improperly proportioned concentrate.

•• Improper concentrate used concurrently with inappropriately adjusted conductivity circuit, resulting in hyponatremia and hemolysis.

• Hypernatremia, due to high dialysate sodium (248mEq/l) caused by facility personnel reversing plumbing inside of machine.

• Hemolysis, due to the machine in bypass during dialysis and technically altered so water flowed through dialyzer.

•• Patient death due to hypernatremia after staff member responded to conductivity alarm by recalibrating conductivity circuit while patient was dialyzing.

Toxic Chemicals

•• Formaldehyde back-siphoned from one machine to another (one machine set with high negative pressure while the next machine, not in operation, yet in line on the water distribution system still contained formaldehyde); resulted in patient toxic chemical exposure.

• Toxic reactions due to patient exposure to germicide used for disinfectant in delivery system.

Bacterial Contamination

•• Pyrogen reaction due to contaminated delivery systems.

Ultrafiltration Control

•• Improper ultrafiltration rate due to machine malfunction concurrent with lack of personnel intervention, resulting in hypovolemic hypotension.

Dialysate Temperature

- Flow through dialysate circuit despite temperature alarm or rinse setting resulting in hemolysis.
- Dialysate at 42°C instead of 37°C with no alarm; caused hemolysis.

Equipment failure alone is not necessarily dangerous if appropriate user monitoring and interventions are utilized. When inadequate monitoring and/or inappropriate interventions are implemented, the malfunction may exacerbate into a lethal situation.

Of particular note, 147 of the incidents could have been averted had the user followed manufacturer's instructions for use, preventative maintenance, repair, and/or troubleshooting.

EXISTING GUIDELINES

The American National Standards for Hemodialysis Systems were developed by the Association for the Advancement of Medical Instrumentation (AAMI) and approved by the American National Standards Institute in May 1982 (see Table 2).

The most complete guideline for the operation of dialysis delivery systems, however, comes from the manufacturer's instructions for use. These instructions should be incorporated into the facility's policies and procedures.

QUALITY ASSURANCE FOR DIALYSIS DELIVERY SYSTEMS

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, equipment, disposables, and supplies used in the dialysis facility.

Comprehensive policies and procedures must also address the interrelationships of each component of the delivery system, as well as the various related components, such as dialysate, the dialyzer, blood lines, and transducer protectors. The risks involved must be clearly identified, considered, and appropriate safety measures and preventative systems developed.

Policies and procedures must also address safe and effective operation of the delivery system:

- basic technical operation
- set up and use of equipment and related components
- safety checks
- preventative maintenance
- cleaning and disinfection
- troubleshooting and repair
- record keeping
- patient monitoring.

Staff Training and Continuing Education

Role descriptions should include all personnel 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. Each responsibility should stem from a specific policy or procedure.

Staff training should be a well-defined and organized program. Content should be clearly defined for the learner and based on behavioral objectives. The behavioral objectives can be used to accurately and objectively measure learning. At the end of the session(s), the instructor must confirm by a written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. Documentation of test results should be recorded in the personnel file.

Comprehension of the purpose and function of the dialysis delivery system requires a basic understanding of kidney disease, fluids and electrolytes, principles of dialysis, infection control, and complications of the hemodialysis treatment. Content should include theory of operation, pre and post

operational procedures, parameters of safety, cleaning and disinfection, electrical safety, emergency procedures, troubleshooting, and water treatment.

Need for further education, such as inservices or intensive educational sessions, can be determined from the ongoing quality monitoring process and the continuous staff performance appraisal process. When problems are identified, staff should be made aware of the problem and involved in its resolution. This nearly always includes problem specific continuing education.

The medical director of the dialysis facility must ascertain that the individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual performance appraisal has been performed.

Monitoring and Evaluation

The following section provides a summary of recommendations for monitoring that should be performed to enhance safety and reduce the level of risk of patient injury due to incidents related to malfunction and/or improper use of dialysis delivery systems:

A. Daily Monitoring

1. Conductivity of the final dialysate being delivered to the dialyzer should be checked before every treatment. When used, the pH of bicarbonate dialysate should also be confirmed before each treatment. Conductivity must be within the manufacturer's stated specifics. If the pH is below 6.5 or above 7.5, dialysis should not be started, even when conductivity is within acceptable limits.

   According to manufacturers' instructions, the conductivity should be checked with an independent reference meter which is known to be properly calibrated. The pH can be checked with a similar meter or pH paper.

   These readings should be documented on the patient's daily dialysis record. The actual numerical readings should be recorded and initials of the person performing the test should be noted (see Form 1 for sample recording format).

2. Temperature should also be within the manufacturer's specifications. Temperature may be checked with an independent reference meter or with a reference thermometer. As with pH and conductivity, the actual numerical readings should be recorded on the patient's daily dialysis record and initials of the person performing the test noted (see Form 1).

3. Absence of residual germicide should be verified on all delivery systems connected to a single water treatment "loop" before dialysis begins. Such testing must be performed with an assay known to detect the minimum standard level. The test results should be documented on the patient's daily dialysis record. The actual result should be recorded and initials of the person performing the test noted (see Form 1).

4. A test of proper functioning of the air/foam detector should be performed before dialysis is initiated. 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. Test results should be documented on the patient's daily dialysis record. The actual result should be recorded and initials of the person performing the test noted (see Form 1).

5. The blood detector must be checked for proper armed status according to the method recommended by the manufacturer. Test result should be documented on the patient's daily dialysis record. The actual result should be recorded and initials of the person performing the test noted (see Form 1).

6. If the delivery system employed is equipped with ultrafiltration control, the user should perform applicable tests of the ultrafiltration control system as prescribed by the manufacturer. Documentation of that testing should be performed (see Form 1).

7. All other alarms must be tested according to the manufacturer's instructions for use before every treatment including low and high conductivity alarm, low and high temperature alarm, dialysate pressure alarm, water pressure alarm, etc.

Documentation of that testing should be performed (see Form 1).

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 some of the vital functions of specific alarms.

8. Observation of dialysate flow should be made while the machine is in a "dialyzing" mode. Absence of dialysate 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.

B. Monthly Monitoring

1. **Microbiological testing:** In accordance with the AAMI American National Standard for Hemodialysis Systems and in keeping with accepted industry standards, water for production of dialysate and actual dialysate proportioned and exiting the dialyzer should be monitored for bacterial levels on no less than a monthly basis. Microbiological monitoring is performed to establish ongoing validation of proper disinfection protocols.

   Regular monitoring of a representative sample of delivery systems will suffice once protocols are validated.

   As indicated in the American National Standard for Hemodialysis Systems, the sampling should be done "at the termination of dialysis at the point where dialysate exits the dialyzer". Results for total microbial counts shall not exceed 2,000 colony forming units per ml. The facility must assure that the American National Standard for Hemodialysis Systems assay protocol is followed.

2. **Assessing trends**: Pertinent information, i.e., 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 an extended period of time. This tool makes it possible to compare current readings to those taken during the past several days/weeks/months. Any untoward trends thus become immediately obvious (see Form 2 for sample trend chart).

3. **Preventative Maintenance (PM):** Monitoring documentation of all PM should be performed to assure that it is completed within the scheduled time frame and performed according to the manufacturer's recommendations (see Form 3).

C. Patient Monitoring

1. Routine intradialytic monitoring of patient's physiological parameters and symptoms during the dialysis treatment can provide indications of improper delivery system function. A few primary types of symptoms seen are:

   - **Nausea, vomiting,** and **headache** may be related to incorrect electrolyte composition of the dialysate due to an incorrect dialysate or improper proportioning of the delivery system.

   - **Hypotension** or **hypertension** may be related to improper ultrafiltration either through failure of the ultrafiltration controller or improper blood or dialysate circuit pressure.

   - **Pyrogen reaction** (shaking chills, increase in patient temperature of more than 1°C during treatment) or septicemia (identified through blood cultures) may occur from patient exposure to endotoxin or bacteria due to improper disinfection of the dialysate circuit.

   - **Hemolysis** (cherry red blood in venous blood tubing, chest pain, dyspnea, hypotension, increased serum potassium, decreased hematocrit) may occur due to improper dialysate composition, machine malfunction resulting in water only in the dialysate circuit, or very high dialysate temperature.

   - **Acute blood loss** (obvious source of blood spill, shock, vomiting, convulsions) may result from extreme pressures in the blood circuit causing line separation.

   - **Air embolism** (evidence of air in blood lines, chest pain, dyspnea, coughing, cyanosis, visual problems, confusion, coma, etc.) may result from air entering the blood circuit due to failure of the air detection/line clamping system.

   - **Altered mental status** (confusion, convulsions, and coma) may occur due to improper dialysate concentration.

D. Home Dialysis Monitoring

All of the monitoring procedures described above should be performed by the home dialysis patient, home dialysis support personnel, and reviewed by the medical director, as appropriate.

E. Other Monitoring

1. At the prescribed recommendations of the manufacturer, or at least quarterly, dialysate flow rate, blood pump flow rate, and proper calibration of the heparin pump should be tested directly. Actual flow rate should be measured over a prescribed time using precise volume measurements.

2. An annual review of all policies and procedures related to dialysis delivery systems should be performed.

3. All incidents or adverse occurrences related to dialysis delivery systems should be documented and reported at the monthly quality assurance meetings.

4. Quarterly monitoring of actual implementation of dialysis delivery system procedures should be performed (see Form 4 for sample Pre-dialysis Checks Monitors and Form 5 for sample Technical Equipment Audit).

F. Prevention

1. **Maintenance:** Chapter 42 of the Code of Federal Regulations, §405.2140(a)(2) requires that "All electrical and other equipment used in the facility is maintained free of defects that could be a potential hazard to patients or personnel. There is established a planned program of preventative maintenance of equipment used in dialysis and related procedures in the facility."

   Each manufacturer provides comprehensive directions pertaining to preventative maintenance requirements for the entire dialysis delivery system. Maximum time intervals—either in number of hours of operation of the system or in calendar days—between preventative maintenance procedures are also specified. The schedules and procedures established must be followed.

2. **Recordkeeping**: 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 (see Form 3 for sample Master Preventative Maintenance Schedule).

   A history file of all repairs and maintenance for each piece of equipment should be maintained in a separate file. This file describes all technical operations performed on the equipment, including date, parts used, actions taken, tests performed to assure proper functioning before and after maintenance/repair, and person performing maintenance/repair.

   A log of all maintenance/repair work for each piece of equipment should be kept at the front of the "history file." This log includes a very brief description of the maintenance/repair (e.g., "500 hr maintenance" or "adjusted conductivity" or "repaired inoperable blood pump," etc.), date, and person performing action. 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.

3. **Repair & Troubleshooting:** Even when dialysis delivery systems are properly designed, monitored, and maintained, the entire system may unexpectedly fail or a component of the system may fail. Although these failures cannot be foreseen and occur very infrequently, when they do occur, it is important that patients are not at risk. The most important aspect of system failure is to have an established and agreed upon plan of action. This plan should be approved by the medical director and communicated to all facility staff.

   Repair and maintenance on a delivery system should be performed by "qualified personnel." The definition of "qualified personnel" may differ from facility to facility, and that definition is the final responsibility of the medical director. Consider the following recommendations:

   a. Facility personnel trained by another facility personnel member who has been certified by the manufacturer as competent to perform such training, or

   b. Facility technical personnel who have successfully completed (certified) the manufacturer's technical training program, or

   c. Manufacturer's technical service personnel.

G. Purchasing Guidelines

The following is a list of pertinent questions to ask when purchasing a delivery system:

- What are the electrical, water flow, pressure, and drain requirements?
- Has the system proved safe and reliable in other facilities? Seek and verify references.
- Does the manufacturer provide complete clinical training in use of the device?
- Does the manufacurer provide acceptable technical maintenance and repair? Does the manufacturer provide technical maintenance and repair training to facility personnel?
- Does the system comply with existing standards, i.e., AAMI?

After finding the answers to these questions the facility should:

1. Choose the two or three different manufacturers' systems best suited to the facility's current and future needs and desires, and
2. Request one of the chosen systems from each manufacturer for an on-site trial of one to four weeks duration, and
3. Obtain subjective opinion from the technical and patient care staff, as well as from the patients, and
4. Obtain objective information from the patient care and technical staff. Using a form such as the one included at the end of this chapter may be helpful (Form 6).

This process will enhance the likelihood of selecting a delivery system which suits the needs of the medical, clinical, and technical staffs. It also helps to assure a system that is safe and effective in the facility's hands.

REFERENCES

1. Association for the Advancement of Medical Instrumentation. *American National Standard for Hemodialysis Systems* (AAMI RD5-1981). Arlington, VA (1982).

2. KESHAVIAH, P., LUEHMANN, D., SHAPIRO, F. and COMTY, C. *Investigation of Risks and Hazards Associated with Hemodialysis Systems* (Technical Report, Contract #223-78-5046). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/ Bureau of Medical Devices, Silver Spring, MD (1980).

3. SHALDON, S. and LARSSON, L-A. *Hemodialysis Monitors and Monitoring*, in Replacement of Renal Function by Dialysis. William Drukker, Frank M. Parsons, and John F. Maher, eds. Martinus Nijhoff, The Hague, The Netherlands (1988).

4. GOTCH, F. and KEEN, M. *Dialyzers and Delivery Systems* in Introduction to Dialysis. MG. Cogan and M. Garovoy, eds. Churchill Livingston, New York (1985).

5. KEEN, M., LANCASTER, C. and BINKLEY, C. *Concepts and Principles of Hemodialysis* in Core Curriculum for Nephrology Nursing. L.E. Lancaster, ed. American Nephrology Nurses' Association, Pitman, NJ (1990).

6. Emergency Care Research Institute. *Improper Dialysate* in Health Devices Report (1984).

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic .

TABLE 1
DIALYSIS DELIVERY SYSTEM

COMPONENT NAME	COMPONENT FUNCTION	OPERATOR REQUIREMENTS
Dialysate Proportioner	Mix dialysate concentrate(s) and water to produce final dialysate of predetermined and precise electrolytic composition.	Use correct concentrates; calibrate conductivity circuit; measure conductivity and pH of final dialysate before treatment.
Fixed Ratio	Cylinders of known volume proportion dialysate concentrate and treated water in exact, predetermined amounts; cyclic filling and emptying of each cylinder controlled through a series of valves.	
Servo-controlled	A control sensor monitors conductivity of final dialysate and regulates flow of dialysate concentrate within specific conductivity limits. Flow can be regulated using variable speed pumps, variable orifice devices or other mechanisms.	
Dialysate Pump	Maintains appropriate dialysate flow rate through dialyzer.	Visually confirm dialysate flow through dialysate tubing and/or dialyzer. Confirm dialysate flow rate per manufacturer's recommendations.
Blood Circuit Pressure Monitors		
"Pre-pump"	Monitors extracorporeal pressure between patient's "arterial" access and the blood pump. Alerts operator to collapse in tubing that has the potential to cause hemolysis, damage to vascular access, or partial collapse in tubing, resulting in inaccurate blood flow readings.	Before every treatment: test monitors/alarms to confirm proper function; confirm that any limits are properly set, secure all connections to blood tubing, transducer protectors, etc.
"Post-pump"	Monitors extracorporeal pressure between blood pump and dialyzer. Alerts operator to tubing separations and tubing obstructions. Also useful in calculating transmembrane pressures (TMP).	
"Venous"	Monitors extracorporeal pressure between dialyzer and patient's "venous" vascular access. Alerts operator to tubing separations and tubing obstructions. Also useful in calculating TMP.	

TABLE 1
DIALYSIS DELIVERY SYSTEM (cont.)

COMPONENT NAME	COMPONENT FUNCTION	OPERATOR REQUIREMENTS
Ultrafiltration Control	Precisely controls amount of ultrafiltration from the patient's blood during the hemodialysis treatment.	Perform predialysis tests of the ultrafiltration control system per manufacturer's instructions for use. Immediately investigate proper functioning of this component if a patient's actual weight loss varies from expected weight loss by more than the percentage indicated in the manufacturer's specifications.
"Volumetric ultrafiltration control"	A controlled and measured amount of dialysate is removed, generally via a volumetric pump, from a closed, fluid-filled, non-compliant dialysate circuit.	
"Servo-Feedback"	Dialysate inflow and dialysate outflow are precisely measured using sensitive flow meters. By subtracting dialysate inflow rate from outflow rate, a microprocessor calculates ultrafiltration rate and adjusts the machines' TMP to achieve desired ultrafiltration rate.	
Blood Leak Detector	A "flow through" sensor, with adjustable sensitivity that detects the presence of blood in the effluent dialysate. When the amount of blood detected by the device exceeds the limit set during calibration, audible and visual alarms occur, and the blood pump stops. In some systems, bypass of dialysate flow to the dialyzer also occurs.	Before every treatment: set sensitivity as per manufacturer's procedures, confirm proper audible and visual alarms, as well as blood pump and dialysate pump action in alarm condition.
Air/Foam Detector	Monitors the extracorporeal circuit for potentially lethal quantities of air—in either the venous blood tubing or the venous bubble trap. Employs ultrasonic device which measures changes in acoustic transmission or photo-optical device which detects change in optical density between a light source and a photocell. Upon detection of a quantity of air, audible and visual alarms are activated, the blood pump is stopped, and the venous blood tubing is occluded.	Before every treatment: confirm proper audible and visual alarms, as well as blood pump interlock and venous line clamp in alarm condition; confirm that air/foam detector is armed and that tubing is in the clamp assembly.

TABLE 2

SUMMARY OF AAMI DELIVERY SYSTEM REQUIREMENTS

(MANUFACTURER STANDARDS)

Device Markings

- Trade name of device
- Manufacturer name and address
- Model Number; serial Number
- Requirement for external ground, if any
- Identification of controls and displays

Product Literature

- List of monitors and warnings regarding that they must be used.
- Procedures for minimizing bacterial growth.
- Warning to check dialysate concentration with independent method.
- Accuracy and sensitivity of monitors.
- Preset monitor limits.
- Statement regarding microbiological isolation of blood circuit pressure monitors.
- Time delay to initiation of blood leak alarm.
- Specifications and test methods for deaerator.
- Normal pressure drop specifications.
- Method of TMP measurement.
- Warning to check dialysate concentration (batch systems).
- Identification of materials in contact with dialysate circuit.
- Specifications regarding air/foam detector.
- Alarm adjustment procedures for maximimizing sensitivity of blood leak detector.
- Warning regarding malfunctions that could lead to hemolysis and how to react.

Monitors and Alarms

- General (visible to patient; temperature in °C; pressure in mmHg).
- Temperature: monitor on-line; maintain range of 36-40 °C; redundant safeties; audible and visual alarms; alarm condition activates bypass; automatic heat sterilization prohibits dialysis mode.
- Dialysate Pressure: pressure entering dialyzer monitored ± 20%; high/low limits; audible and alarms.
- TMP monitors: accuracy ± 20%; high/low limits; audible and visual alarms.
- Blood circuit pressure: venous pressure monitoring required; accuracy ± 10% of indicated pressure; high/low limits; audible and alarms; blood pump deactivated in alarm condition; instructions for validation.
- Concentration: on-line monitor; audible and visual alarms and bypass if dialysate concentration ± 5%; redundant safeties; temperature compensated; high/low limits.
- Blood leak detector: required in all machines; meets AAMI-dictated blood leak amount parameters; test functions; calibration ability; audible and visual alarms; alarm condition inactivates blood pump.
- Air/Foam detector: required on all systems where ingress of air is possible; audible and visual alarms; alarm condition stops blood pump and occludes venous line; audible and visual warning when not armed; shall not cause chemical changes to blood.

Safety Requirements

- General: safe configuration; monitors minimize false alarms and inadvertent resetting; monitors cannot be disabled when patient at risk; audible alarms at least 70 decibels and unable to mute for > 180 sec; design facilitates cleaning.
- Electrical Safety: meet "nonisolated" patient connection requirement of ANS, Safe Current Limits for Electro-medical Appartatus; electrical ground provided; corrosion resistant metals; electrical circuits separate from hydraulic circuits and isolated from fluid leaks; main electrical failure indicated by audible alarm.

FORM 1

PATIENT DAILY DIALYSIS RECORD
XYZ DIALYSIS CENTER

Date _____ **Patient Name** _____

DIALYSIS PRESCRIPTION

Dialyzer _____

QB _____ QD _____

Heparin Rx:

Prime _____

Infusion _____

Time off _____

Dialysate Rx _____

Expected clotting time _____

Actual clotting time _____

Time on _____

Actual time off _____

Rx time off _____

Rx dialysis length _____

Actual dialysis length _____

Dry weight _____

Predialysis weight _____

Desired weight loss _____

Postdialysis weight _____

UF rate _____

DIALYSATE		MACHINE CHECKS		REUSE	
Conductivity	_____	***Blood leak alarm***	_____	Patient ID	_____/_____
pH	_____	***Air foam detect (check)***	_____	Use number	_____
Temperature	_____	***Air foam detect (armed)***	_____	Dialyzer structure/aesthetic	_____
Special Rx	_____	***UF check***	_____	Germicide dwell	_____
Mixed	_____	***Art/Ven press set***	_____	Germicide presence	_____
Dispensed	_____	***Machine number***	_____	Germicide absence	_____

DELIVERY SYSTEM TREND ANALYSIS

FORM 2

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DATE												
BACTERIAL CULTURES												
Machine #1												
Machine #2												
Machine #3												
Machine #4												
Machine #5												
Machine #6												
Machine #7												
Machine #8												
Machine #9												
Machine #10												
CONDUCTIVITY												
Machine #1												
Machine #2												
Machine #3												
Machine #4												
Machine #5												
Machine #6												
Machine #7												
Machine #8												
Machine #9												
Machine #10												
pH												
Machine #1												
Machine #2												
Machine #3												
Machine #4												
Machine #5												
Machine #6												
Machine #7												
Machine #8												
Machine #9												
Machine #10												

DELIVERY SYSTEM TREND ANALYSIS (cont.)

FORM 2

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DATE												
BLOOD FLOW RATE												
Machine #1												
Machine #2												
Machine #3												
Machine #4												
Machine #5												
Machine #6												
Machine #7												
Machine #8												
Machine #9												
Machine #10												
DIALYSATE FLOW RATE												
Machine #1												
Machine #2												
Machine #3												
Machine #4												
Machine #5												
Machine #6												
Machine #7												
Machine #8												
Machine #9												
Machine #10												
TEMPERATURE												
Machine #1												
Machine #2												
Machine #3												
Machine #4												
Machine #5												
Machine #6												
Machine #7												
Machine #8												
Machine #9												
Machine #10												
OTHER PROBLEMS (SPECIFY)												

DELIVERY SYSTEM MASTER PREVENTATIVE MAINTENANCE SCHEDULE

FORM 3

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
200 HOUR P M												
Machine #1	X/		X/		X/		X/		X/		X/	
Machine #2		X/		X/		X/		X/		X/		X/
Machine #3	X/		X/		X/		X/		X/		X/	
Machine #4		X/		X/		X/		X/		X/		X/
Machine #5	X/		X/		X/		X/		X/		X/	
Machine #6		X/		X/		X/		X/		X/		X/
Machine #7	X/		X/		X/		X/		X/		X/	
Machine #8		X/		X/		X/		X/		X/		X/
Machine #9	X/		X/		X/		X/		X/		X/	
Machine #10		X/		X/		X/		X/		X/		X/
Machine #11	X/		X/		X/		X/		X/		X/	
Machine #12		X/		X/		X/		X/		X/		X/
500 HOUR P M												
Machine #1	X/				X/				X/			
Machine #2		X/				X/				X/		
Machine #3			X/				X/				X/	
Machine #4				X/				X/				X/
Machine #5	X/				X/				X/			
Machine #6		X/				X/				X/		
Machine #7			X/				X/				X/	
Machine #8				X/				X/				X/
Machine #9	X/				X/				X/			
Machine #10		X/				X/				X/		
Machine #11			X/				X/				X/	
Machine #12				X/				X/				X/

PROCEDURE FOR CONCURRENT MONITORING FORM: PREDIALYSIS TECHNICAL CHECKS (FORM 4)

The purpose of this audit is to monitor technical staff compliance with standard practices and procedures related to the water treatment system. When staff are aware of the importance of the policies and well trained in the procedures, compliance should be very high.

Before the Audit

1. Provide adequate and appropriate inservice to assure total staff awareness and education of all components associated with water treatment for dialysis.
2. Assure staff awareness of all elements of the concurrent audit and how performance will be observed and evaluated.
3. The QA committee specifies the standard (expected percentage compliance) desired for the audit; begin not lower than 85%.
4. Schedule the audit with appropriate personnel (head nurse, charge nurse, chief technician).
5. Make copies of the audit for each auditor/observer.
6. Assign code letters for each staff member to be observed; for example:

   Employee A: Glenn Close
   B: Tom Hanks
   C. William Hurt
   etc.

7. Determine how many staff are to be observed. It is recommend that one auditor should observe no more than three to four staff at one time.
8. Define the length of time for observation. It is recommended that the audit be conducted during peak activity times (daily start-up, shift changeovers, etc.). The time frame should be long enough to observe each staff member completely perform the listed activity.
9. Assign a staff member to perform the audit. Auditor should not be assigned to other responsibilities during the audit.

Perform the Audit

1. On the actual audit sheet, write in the date, auditor's name, patient shift (or time of day), and standard.
2. Read each indicator carefully.
3. Observe staff for actual *performance*. Auditor should not interfere with staff activities, be obtrusive, or preceptibly obvious.
4. Under each staff code letter, write Y for yes if indicator is met, N for no if indicator is not met, or N/A for not applicable, not observed.

   To achieve a Y (yes, indicator was met), staff should be observed with complete compliance for each encounter. For example, for a Y to appear in the "Post-Softener Hardness Done" box, the staff member must perform the test before any patient dialysis is done ***and*** perform the test exactly according to the instructions for use of the test manufacturer ***and*** record the results as per facility policy.
5. Complete all observations within timeframe specified. Assure that each indicator has one response.

After the Audit

1. Under each employee code letter, add total number of Ys and Ns; do not count NAs.
2. For each employee, calculate compliance percentage by dividing the total Ys by the total observations; again, do not count NAs.
3. Calculate total compliance percentage for the audit by dividing total Ys (all employee Ys) by the total observations; do not count NAs.
4. For each indicator, calculate compliance percentage by using the same method as above; again, do not count NAs.
5. Report results to QA committee and clinical management team with additional comments and/or recommendations.

PREDIALYSIS TECHNICAL CHECKS MONITOR

FORM 4

Date	Patient Shift	Auditor													
	Station Number	1	2	3	4	5	6	7	8	9	10	11	12	13	
	Staff Member (initials)														
FUNCTION														Threshold	% Compliant
Verify and record correct concentrate(s) labeling															
Dialyzer checks performed and recorded															
Conductivity checked and recorded															
Conductivity alarm window set															
pH checked and recorded															
Auto alarm function test performed and recorded															
Confirm proper T° and external flow pattern															
Venous chamber adjusted															
Air/foam detector armed															
U.F. system check done															

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

Date _____ **FORM 5** Machine type and no. _____

Auditor _____ Serial number _____

Meter reading _____

Last maintenance:

Date _____

Type _____

Meter _____

DIALYSIS EQUIPMENT AUDIT

STAFF RESPONSIBLE: Chief Technician, Medical Director, Head Nurse

OBJECTIVE: To assure that equipment is fully functional and safe for treatment use

A. SURVEY OF EQUIPMENT TECHNICAL RECORDS

	YES	NO	N/A
1. Do equipment maintenance records include documentation of an electrical safety check performed in accordance with interval recommended by manufacturer?	____	____	____
2. Is the documentation of maintenance on each dialysis machine current and complete?	____	____	____
3. Is monthly bacteriological testing of each dialysis machine performed and the results documented in a permanent record?	____	____	____
4. Is each dialysis machine disinfected in accordance with unit policy or as indicated by bacterial testing?	____	____	____
5. Are the following machine functions calibrated at least every three months?			
a. Blood pump	____	____	____
b. Heparin pump	____	____	____
c. Air bubble detector/line clamp	____	____	____
d. Blood leak detector	____	____	____
e. Audio/visual alarms	____	____	____
f. Temperature	____	____	____
g. Conductivity	____	____	____
h. Negative pressure/ultrafiltration pump	____	____	____
i. Arterial pressure monitor	____	____	____
j. Venous pressure monitor	____	____	____
6. Have the screen filters been cleaned/replaced during maintenance procedures?	____	____	____
7. Have the internal transducer protectors been changed during maintenance procedures?	____	____	____

DIALYSIS EQUIPMENT AUDIT (cont.)

B. EQUIPMENT VISUAL INSPECTION

	YES	NO	N/A
1. Outside of machine			
a. Are all the switches, knobs, and the venous clamp functioning properly?	____	____	____
b. Do the drip chamber level adjust knobs/lever operate properly?	____	____	____
c. Is the blood pump roller assembly secured tightly to its shaft, and do both rollers turn freely?	____	____	____
d. Is the mechanical zero of the drip chamber meters operating properly?	____	____	____
e. Are the Hansen connectors free of leaks?	____	____	____
f. Are the o-rings of the concentrate connectors free of cracks and leaks?	____	____	____
g. Is the acid concentrate connector free of residue buildup?	____	____	____
h. Is the bicarbonate connector free of residue buildup?	____	____	____
i. Is the air bubble detector housing clean?	____	____	____
j. Is the venous clamp clean?	____	____	____
k. Is the machine free of blood, salt crystals, etc?	____	____	____
l. Does the heparin pump carriage move freely?	____	____	____
m. Are all the lamps functioning?	____	____	____
2. Inside of machine			
a. Free of water leaks (no puddle at bottom of unit, connections)	____	____	____
b. Hoses and tubing assembly clear cnd clean	____	____	____
c. Check valves free of leaks	____	____	____
d. Fuses o.k.	____	____	____
e. Tie-wraps around all hydraulic tubing pressure points	____	____	____

C. GENERAL FUNCTIONS/MAINTENANCE

1. Is measured dialysate flow (ml/min) at the drain within the following specifications:			
a. Machine #1 (570 ± 50)	____	____	____
b. Machine #2 (560 ± 70)	____	____	____
c. Machine #3 @ 300	____	____	____
d. Machine #4 @ 500	____	____	____
e. Machine #5 @ 800	____	____	____
2. Is the test alarm battery serviceable:			
a. Machine #1 (9.0 ± 0.5 V)	____	____	____
b. Machine #2 (9.0 ± 0.5 V)	____	____	____
c. Machine #3 (1.6 ± 0.25 V)	____	____	____
d. Machine #4 (9.0 ± 0.5 V)	____	____	____
3. Is the no-water alarm functioning?	____	____	____
4. Is the no-power alarm functioning?	____	____	____
5. Is the bypass function working?	____	____	____

DIALYSIS EQUIPMENT AUDIT (cont.)

D. ARE THE FOLLOWING MACHINE FUNCTIONS CALIBRATED ACCORDING TO THE MANUFACTURER'S SPECIFICATIONS?

		YES	NO	N/A
1. Values for conductivity and temperature:				
a. Temperature	(37.0 ± 0.5 °C)	____	____	____
b. Na = 1 and Bicarb = 30	(2.65 ± 0.1 mmho/cm)	____	____	____
c. Na = 1 and Bicarb = 35	(3.05 ± 0.1 mmho/cm)	____	____	____
d. Voltage at TP1	(1.25 V)	____	____	____
e. Na = 1 and Bicarb = 35	(12.50 ± 0.1 mmho/cm) (acid and bicarb)	____	____	____
f. Na = 3 and Bicarb = 35	(13.50 ± 0.2 mmho/cm)	____	____	____
g. Na = 5 and Bicarb = 35	(14.50 ± 0.2 mmho/cm)	____	____	____
h. Na = 3 and on acetate	(13.50 ± 0.2 mmho/cm) (bicarb off)	____	____	____
2. Was acid rinse procedure performed within the last 1000 hrs of operation?		____	____	____
3. Has the effluent pump been oiled within the last 1000 hrs of operation?		____	____	____
4. Are the effluent pump stators serviceable (at least -525 mmHg)?		____	____	____
5. Is the pressure vent/sampling port working properly (positive pressure dialysate alarm, pressure not in excess of +475 mmHg before venting)?		____	____	____
6. Is the concentrate pump occlusion o.k. (at least -550 mmHg)?		____	____	____
7. Was the stabilizer recharged during maintenance procedures?		____	____	____
8. Does the four-way bypass valve/fluidic capacitor indicate that there is no leak?		____	____	____
9. Does the hydraulic leak test indicate that there are no leaks?		____	____	____
10. Visual inspection (inside):				
a. Fluidic capacitor free of residue		____	____	____
b. Stabilizer and air bypass lines free of residue		____	____	____
c. Cooling fan free of dust and lint		____	____	____
d. Air vents (top and bottom at back of unit) lint-free		____	____	____
e. pH probe free of residue		____	____	____
f. All cells (conductivity control mixer, monitor conductivity and temperature, electrode conductivity cell) free of residue		____	____	____
g. Pump segments free of discoloration or flattening		____	____	____
h. All pump rotor arm pins correctly aligned		____	____	____
i. Neucleation chamber material clear		____	____	____
j. Pump header and manifold blocks free of cracks and leaks		____	____	____
k. Drip chamber level tubes free of cracks		____	____	____
l. Effluent pump cover vents free of lint		____	____	____
m. Blood leak detector is clean		____	____	____
TOTALS		____	____	____

PROBLEMS IDENTIFIED: _____

_____

Used with permission by Artificial Kidney Center, Palo Alto VA Medical Center, Palo Alto, CA

FORM 6

DELIVERY SYSTEM EVALUATION CHECKLIST

1. CONDUCTIVITY

A) What type proportioning system is used? _____ _____ _____
B) Can proportions be altered? _____ _____ _____
C) High and low limits? _____ _____ _____
D) Can limits be tested? _____ _____ _____
E) What type of readout (monitor) is used? _____ _____ _____
F) What type of internal monitoring? _____ _____ _____
G) Does it have a bypass mode? _____ _____ _____
H) Will blood pump run in bypass? _____ _____ _____
I) Can conductivity be falsified? _____ _____ _____
J) Will machine bypass if probe fails? _____ _____ _____
K) _____ _____ _____ _____
L) _____ _____ _____ _____
M) _____ _____ _____ _____

2. TEMPERATURE

A) High and low limits? _____ _____ _____
B) Can limits be easily tested? _____ _____ _____
C) How is temp adjusted? _____ _____ _____
D) What type readout? Scale? _____ _____ _____
E) What type of heating element is used? _____ _____ _____
F) Redundant monitoring? _____ _____ _____
G) Utilize bypass? _____ _____ _____
H) Will pump run in bypass mode? _____ _____ _____
I) _____ _____ _____ _____
J) _____ _____ _____ _____

3. DIALYSATE FLOW

A) Can it be altered? _____ _____ _____
B) Type readout? _____ _____ _____
C) Is there a (no water) alarm? _____ _____ _____
D) _____ _____ _____ _____
E) _____ _____ _____ _____

4. ARTERIAL/VENOUS MONITORS

A) What type readout? _____ _____ _____
B) What measurements used? Scale? _____ _____ _____
C) Transducer inlet type? _____ _____ _____
D) Type of gauge? _____ _____ _____
E) Sequential alarms? _____ _____ _____
F) Can limits be moved? Preset? _____ _____ _____
G) Can limits be tested? _____ _____ _____
H) Does indicator float with movement? _____ _____ _____
I) How does the alarm system work? _____ _____ _____
J) _____ _____ _____ _____
K) _____ _____ _____ _____

DELIVERY SYSTEM EVALUATION CHECKLIST (cont.)

5. DEAERATION

A) How is it accomplished? _____ _____ _____
B) How effective is it? _____ _____ _____
C) How is air relieved? _____ _____ _____
D) _____ _____ _____ _____
E) _____ _____ _____ _____

6. BLOOD LEAK DETECTOR

A) Comparative? _____ _____ _____
B) Effects of air? Scum? _____ _____ _____
C) Cleaning? _____ _____ _____
D) Can limits be tested? _____ _____ _____
E) Sensitivity? (adjustalble) _____ _____ _____
F) Do limits need to be altered, adjusted each dialysis? _____ _____ _____
G) How does alarm system work? _____ _____ _____
H) _____ _____ _____ _____
I) _____ _____ _____ _____

7. AIR DETECTOR

A) Sensitivity _____ _____ _____
i. Adjustment? _____ _____ _____
ii. Testing _____ _____ _____
B) Will it accomadate drip chamber? _____ _____ _____
C) What type system? _____ _____ _____
D) How does alarm system work? _____ _____ _____
E) Line clamp incorporation? _____ _____ _____
F) _____ _____ _____ _____
G) _____ _____ _____ _____

8. BLOOD PUMP

A) Type roller head used? (self occlufing?) _____ _____ _____
B) How is occlusion set? _____ _____ _____
C) What type of readout? _____ _____ _____
D) What scale is used? _____ _____ _____
E) Cleaning? _____ _____ _____
F) Cover? _____ _____ _____
G) Maximum blood flow rate? _____ _____ _____
I) _____ _____ _____ _____
H) _____ _____ _____ _____

9. HEPARIN PUMP

A) Syringe size used? _____ _____ _____
B) Delivery rate variation/scale? _____ _____ _____
C) What type pump used? _____ _____ _____
D) How does system work? _____ _____ _____
E) _____ _____ _____ _____
F) _____ _____ _____ _____
G) _____ _____ _____ _____

DELIVERY SYSTEM EVALUATION CHECKLIST (cont.)

10. RESET SYSTEM

A) Automatic/correction
B) Protective shield
C) _____
D) _____

11. RINSE MODE

A) Can Paitient dialyize in rinse mode?
B) Can it be "fooled"?
C) How does it work? Does bypass get rinsed?
D) _____
E) _____

12. EXTERIOR

A) Simplicity
B) Breakables
C) Weight
D) Portability
E) Cleaning
F) Electrical leakage?
D) _____
E) _____

13. OPERATOR'S MANUAL

A) Schematics-complete?
B) Understandability?
C) Procedures?
D) Function descriptions?
E) Detail?
F) Service?
G) Cautions/Warnings clear?
H) _____
I) _____

14. DIALYZER ADAPTABILITY

(defined by facility's therapeutic intent & dialyzer type)

A) Ultrafiltration Control?
   i. Principle (Volumetric or Servo-Feed Back
   ii. Accuracy (measured with dialyzers to be used)
   iii. _____
B) Dialysate flow adjustable?
C) _____
D) _____

15. ISOLATED ULTRAFILTRATION

A) P.U.F. capabilities
B) Altering with venous pressure
C) Can ultrafiltration be measured?
D) _____
E) _____

DELIVERY SYSTEM EVALUATION CHECKLIST (cont.)

16. BICARBONATE DIALYSATE

A) What type proportioning system is used? _____ _____ _____
B) Can proportions be altered/programmed? _____ _____ _____
C) High and low limits? _____ _____ _____
D) Can limits be tested? _____ _____ _____
E) What type of readout (monitor) is used (pH)? _____ _____ _____
F) What type of internal monitoring (pH)? _____ _____ _____
G) Will machine bypass if pH probe fails? (if applicable) _____ _____ _____
H) _____ _____ _____ _____
I) _____ _____ _____ _____

17. COMPANY RELIABILITY

A) Service _____ _____ _____
B) Follow through _____ _____ _____
C) Availability _____ _____ _____
D) _____ _____ _____ _____

18. SPARE PARTS

A) Necessary inventory _____ _____ _____
B) Cost _____ _____ _____
C) Availability/delivery time _____ _____ _____
D) _____ _____ _____ _____

19. MAINTENANCE/REPAIRS

A) How often what required for P.M.? _____ _____ _____
B) Special tools required? _____ _____ _____
C) Machine reliability _____ _____ _____
D) Training time/easy for staff/home patients? _____ _____ _____
E) Does company provide training? Cost? _____ _____ _____
F) _____ _____ _____ _____
G) _____ _____ _____ _____

20. OPTIONAL FEATURES

A) Variable/Programable Sodium _____ _____ _____
B) Self-Diagnostics _____ _____ _____
C) Computer Interface (machine data, patient data, etc) _____ _____ _____
D) Blood Pressure Monitoring (patient) _____ _____ _____
E) Auto-disinfect _____ _____ _____
F) _____ _____ _____ _____
G) _____ _____ _____ _____
H) _____ _____ _____ _____
I) _____ _____ _____ _____
J) _____ _____ _____ _____
K) _____ _____ _____ _____

Chapter 5

DIALYSATE AND DIALYSATE CONCENTRATE

CONTENTS

Chapter 5 Dialysate and Dialysate Concentrate

TECHNICAL DESCRIPTION OF DEVICE

Dialysate, or dialysis fluid, is a non-sterile aqueous solution with an electrolyte composition near that of normal extracellular fluid. Its electrolyte composition is designed to correct the metabolic imbalance that occurs as a result of uremia.

Electrolyte content of dialysate includes sodium, potassium, chloride, magnesium, calcium, glucose (optional), and either acetate or bicarbonate as a buffer. Concentration of these electrolytes in dialysate fluid is shown in Table 1. Dialysate contains none of the solutes that are eliminated from the blood during dialysis (urea, creatinine, and other waste products of nitrogen metabolism).

Dialysate concentrate is a preparation of salts which, when diluted with water, yields dialysate for use in dialysis. Dialysate concentrates are manufactured commercially in liquid or powder form.

The chemicals present in the dialysate have access, via the dialyzer, to the bloodstream of patients undergoing the dialysis. Therefore, the proper concentration of all of these chemicals as well as the quality of the concentrate and the water used to dilute the concentrate is critical.

RISKS AND HAZARDS

The literature prior to 1980 contained only one report of patient complications attributed to concentrate: a case of hypermagnesemia due to the use of commercially prepared concentrate with a magnesium concentration ten times greater than specifications.

Incidents reported in the literature and through the Medical Device Reporting program since 1980 are summarized in Appendix A. Of note, 50% of the 18 incidents reported involved problems related to the concentrate when delivered from the manufacturer. The remaining 50% were related to user error or machine malfunctions.

Briefly, the problems related to manufacturers included:

- Microbial growth in liquid bicarbonate concentrate.
- Actual electrolyte content of the concentrate was different than described on the label.
- Foreign matter in liquid bicarbonate concentrate.
- High levels of aluminum contaminating acetate concentrate.

Incidents related to user error, or machine malfunction include:

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

Many of the incidents could have been avoided through fairly simple tests, observations, or quality control procedures implemented in the dialysis facilities. Further, although only a few of these incidents resulted in patient death, almost all had the potential to cause death.

EXISTING GUIDELINES

Guidelines currently available regarding dialysate, or dialysate concentrate, are found in the Association for the Advancement of Medical Instrumentation (AAMI) document, the American National Standards for Hemodialysis Systems (RD5-1981). These standards can be separated into two areas: (1) those related primarily to manufacturers' labeling and literature and manufacturers' specifications for concentrate, and (2) those dealing with microbiological suitability of final, proportioned dialysate.

Table 2 summarizes these standards.

In the absence of federal, local, or other voluntary standards, well accepted "industry" standards, that is, accepted technique for handling of dialysate and dialysate concentrate, are available. In 1983 the Emergency Care Research Institute (ECRI) summarized these and recommended the following steps as the appeared in *Health Devices* (1983):

1. Check the actual pH and conductivity of the dialysate with an external meter.
2. Check the conductivity, pH, and temperature alarm system before each dialysis treatment.
3. Assure that all personnel in the dialysis unit are well informed of the types of concentrates available, even if you presently use only one type.
4. Whenever possible, develop and use a system of labeling, connector types, and matching containers that prevent or minimize cross-connections or use of mismatched concentrates.
5. Store and dispense dialysate concentrates as though they were drugs. Develop a policy for inventory management and storage system that will effectively control the mixing and dispensing of all concentrates. Storing concentrates according to type, composition, and proportioning ratios should reduce the risks of mismatched concentrates. Prohibit access to storage areas and allow only authorized, specially trained personnel to mix and dispense concentrates.
6. Verify and record actual dialysate composition on the patient's records to assure that what is being delivered is appropriate for what has been prescribed by the physician (see Form 1).
7. Do not dispense concentrates from large containers into smaller ones without a "keyed" dispensing system. Such a system should include labeling of the smaller containers as well as color-coded or key-coded (shape) connections between caps of containers and uptake tubing on machines.
8. Always dispose of concentrates remaining 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. Whenever possible, standardize equipment so that only one bicarbonate concentrate system is used.

QUALITY ASSURANCE FOR DIALYSATE AND DIALYSATE CONCENTRATE

Policies and Procedures

Policies and procedures concerning dialysate and dialysate concentrate as it relates to hemodialysis therapy must be developed, written, implemented and evaluated. All standards previously described must be incorporated into these policies and procedures.

Specifically, the policies and procedures should address the different therapeutic prescriptions available in the facility, i.e., high-flux dialysis, high efficiency dialysis, and conventional dialysis. Each of these differing therapeutic modalities may require different types of dialysate; for example, sodium modeling, bicarbonate dialysis, acetate dialysis, ultrafiltration, or individual patient prescription.

Comprehensive policies and procedures must also address the interrelationships of each component of the dialysate as well as the dialysis delivery systems. The risks involved must be clearly identified, considered, and appropriate safety measures and preventative systems developed.

Policies and procedures must also address safe and effective dialysate handling:

- mixing of concentrate additives
- mixing of acid and bicarbonate concentrate
- labeling
- container and delivery system connector systems
- sanitary procedures used in handling and mixing the concentrate, both in large tanks as well as individual containers
- length of time for storing the concentrate after mixing
- frequency of sanitization of the mixing containers and the delivery containers; use of a validated sanitization procedure
- measured microbiological condition of the water used to prepare the bicarbonate concentrate
- monitoring of patient reactions during dialysis and trend analysis.

Staff Training and Continuing Education

Role descriptions should include personnel responsibilities for handling and testing of concentrate, ordering, confirmation of proper labeling, testing and monitoring, and other similar responsibilities. Each responsibility should stem from a specific policy or procedure.

Staff training should be a well-defined and organized process. Content should be clearly defined for the learner and based on behavioral objectives. The behavioral objectives can be used to accurately and objectively measure learning. At the end of the session(s), the instructor should confirm by a written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. Test results should be documented and placed in employee's personnel file.

Comprehension of the purpose and function of dialysate and dialysate concentrate requires a basic understanding of normal physiological concepts, as well as responses associated with uremia and the hemodialysis therapy. Content should include dialysate fluid composition, function, preparation, conductivity and pH, and potential complications with improper mixes of dialysate.

Need for further education, such as inservices or intensive educational sessions, can be determined from the routine quality assurance monitoring process and the ongoing staff performance appraisal process. When problems are identified, all staff should be made aware of the problem and be involved in its solution. This nearly always includes problem specific continuing education.

The medical director of the dialysis facility must ascertain that the individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual review has been performed.

Monitoring and Evaluation

To prevent patient injury associated with the use of improper concentrates, concentrate mix-ups, miscalibrated dialysis delivery systems, and improper function of the dialysate delivery systems proportioning or conductivity circuit, the following monitoring activities are recommended:

A. Daily Monitoring

1. Conductivity of the final dialysate being delivered to the dialyzer should be checked before every treatment. The pH and temperature of the dialysate should also be confirmed before each treatment. Conductivity should be within the manufacturer's stated specifications. If the pH is below 6.5 or above 7.5 dialysis should not be initiated, even if the conductivity is within acceptable limits.

   Conductivity should be checked with a independent reference meter which is known to be properly calibrated. The pH can be checked with a similar meter, or with pH paper.

   Because temperature can alter conductivity reading, the temperature should also be within the manufacturer's specifications. Temperature may be checked with a reference meter or with a reference thermometer.

   All three of these readings should be documented on the patient's daily dialysis record. The actual numerical readings should be recorded, not simply a "check mark" or "o.k." Initials of the person performing the test should also be included (see Form 1 for sample recording format).

2. Before initiating treatment, confirmation that the prescribed concentrate is being used and that all manufacturer's safety devices and features are being employed should be done. This should include reading the label on all concentrate containers, correct use of any color-coding and/or any key-coding, and use of the proper facility-designated concentrate containers. This safety check should be documented on the patient's dialysis treatment record. Dialysis may be initiated when all of these checks correspond to established parameters.

3. If concentrates are mixed from powder in a large container and then distributed into smaller "jugs," each jug should be labeled with the following information (see Form 2 for sample labeling formats):

   - Contents, i.e., A concentrate, B concentrate, acetate concentrate, etc., plus proportioning ratio.
   - Time the solution was mixed and initials of person(s) mixing the solution.
   - Time the solution was dispensed and identification of person(s) performing this procedure.

- Other special additives inserted into the concentrate (i.e., potassium, a potassium "spike," calcium, etc.). This information should also be recorded on the label by the person performing the addition. (Many facilities require that at least two individuals watch this procedure and initial the container.)

4. A monitoring and/or coding system should also be included in the daily monitoring of rinsing, sanitizing, or disinfecting procedures for the bicarbonate mixing tank or "concentrate jugs"; for example:

   - A daily log for sanitization and rinsing of the mixing tank should include time performed and initials of person(s) performing the task.
   - A daily log might also include proper recording of any procedures required on "concentrate jugs". This can more easily be performed if each jug is identified with a serial number (see below for more information on coding of concentrate jugs).
   - The daily log should also include results of any test performed to verify adequate rinsing (absence) of the disinfectant/germicide used so as to prevent any introduction of toxic substances into the patient.

B. Monthly Monitoring

1. On at least a monthly basis, calibration of any reference meters used to perform daily or other conductivity, pH, and other monitoring of dialysate should be performed using a reliable Standard Solution (see Chapter 7 for more information on use of Standard Solution). Manufacturers may recommend more frequent confirmation of proper calibration. Be sure to follow the recommendations of the device manufacturer.

2. On at least a monthly basis, validate the handling and disinfection procedures to prevent microbiological contamination. To do this, the following is recommended:

   - Obtain a sample of the bicarbonate concentrate from any mixing tank. This should be done on a "worse case" basis, i.e., draw the sample after the longest period since the last disinfection/sanitization, and after the longest storage time for concentrate in that container.
   - A random sample of the concentrate from concentrate jugs should also be performed to confirm that the sanitization and handling procedures for these jugs are also valid.
   - A culture sampling of the dialysis delivery systems for dialysate as described in the AAMI American National Standards for Hemodialysis Systems provides an overview of the efficacy of all systems for maintaining microbiological standards.

3. To assess trends, pertinent information, i.e., bacterial levels, conductivity, pH readings, etc., should be logged on a chart across a page so that readings can be examined and compared over an extended period of time. This makes it possible to compare current readings to those taken during the past several days/weeks/months. Any untoward trends thus become immediately obvious (see Form 3 for sample trend chart).

C. Patient Monitoring

The following patient monitoring aspects have relationships to dialysate and dialysate concentrate handling:

1. Routine blood chemistries may provide an indication of improper use of concentrates. These are further explained below.

2. Routine intradialytic monitoring and patient symptoms during the dialysis treatment can also provide indications for improperly used concentrates or dialysates. A few of the primary types of symptoms seen with incorrect use of concentrates are summarized below:

   - **Hyponatremia** induced by low sodium content in the dialysate; may result in hemolysis, nausea and vomiting, and death.
   - **Hypernatremia** induced by improper functioning dialysis proportioning system or too much sodium in the dialysate; may result in nausea and vomiting, seizures, and death.
   - **Acidosis** or **alkalosis** resulting from improperly used, or mix-ups in concentrates; will become apparent by respiratory problems, nausea and vomiting, headaches, seizures, and death.
   - **Hyperkalemia** induced by high potassium content in dialysate; may result in death.

D. Home Dialysis Monitoring

All of the monitoring procedures described above should be performed by the home dialysis patient

and home dialysis support personnel, and reviewed by the medical director as appropriate.

E. Other Monitoring

Other monitoring includes assuring proper use and outcome related to dialysate and dialysate concentrate handling:

1. An incoming materials log should be maintained. Included in this log should be the identification of the product, delivery date, lot number, and person receiving the products. Dialysate should be received, inspected, and released for use only by authorized personnel who are trained in the use and expected specifications of the product. Confirmation that the product is properly labeled as ordered should be performed. Any product with labels that are not intact or that are incorrectly labeled should not be accepted.
2. An annual review of all policies and procedures related to dialysate and dialysate concentrate handling should be performed.
3. All incidents or adverse occurrences related to dialysate or dialysate concentrate handling should be documented and reported at the monthly quality assurance meetings.
4. Quarterly monitoring of actual implementation of dialysate and dialysate concentrate procedures should be performed (see Form 4 for sample dialysate concentrate safety monitor).

F. Prevention

- Follow exactly all of the manufacturer's instructions for use.
- Test conductivity and pH with a properly calibrated independent reference meter before every treatment.
- If final proportioned dialysate is determined to be not of the proper chemical concentration (incorrect conductivity, incorrect pH, particulate contamination, etc.), do not initiate dialysis.
- If a determination is made that the chemical concentration is improper after a patient is connected to a machine, verify that the delivery system is in bypass mode. Troubleshoot the problem with the dialysate hoses disconnected from the dialyzer. Confirm presence or absence of delivery system malfunction. If the equipment malfunction is confirmed, the patient should be immediately disconnected.
- Maintain a well-validated system of sanitization/disinfection of all components of the concentrate and/or dialysate handling system (water treatment system, dialysis delivery system, mixing tank, individual jugs, etc.).

REFERENCES

1. Association for the Advancement of Medical Instrumentation. *American National Standard for Hemodialysis Systems* (AAMI RD5-1981). Arlington, VA (1982).

2. KESHAVIAH, P., LUEHMANN, D., SHAPIRO, F. and COMTY, C. *Investigation of Risks and Hazards Associated with Hemodialysis Systems* (Technical Report, Contract #223-78-5046). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/ Bureau of Medical Devices, Silver Spring, MD (1980).

3. Emergency Care Research Institute. *Improper Dialysate.* Health Devices (October, 1983).

4. FAVERO, M.S. *Dialysis Associated Diseases and Their Control.* Hospital Infections, J.V. Bennet and P.S. Brachman, eds. Little, Brown, & Co., Boston, MA (1985).

5. VLCHEK, D.L. and BURROWS-HUDSON. *Quality Assurance in Bicarbonate Dialysate Handling.* Nephrology News & Issues, 4, 9: 14-15 (1989).

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic.

TABLE 1
TYPICAL RANGES OF DIALYSATE FLUID

	DIALYSATE (mEq/l)
Sodium	135 - 145
Potassium	0 - 4
Calcium	2.5 - 3.5
Magnesium	0.5 - 1.5
Chloride	104 -108
Bicarbonate or Acetate	35 - 40
Glucose (mg%)	0 - 250

TABLE 2

SUMMARY OF AAMI DIALYSATE CONCENTRATE STANDARDS

Manufacturer: Labeling and Documentation

- Name and address of manufacturer
- Date of manufacture
- Lot number (capable of tracing manufactuing history)
- Composition (including metric weight)
- Ratio of water for mixing for proportioning systems; volume for batch systems
- Composition of diluted solution (conductivity, concentration)
- Fill volume of container
- Trade name of product
- For aqueous concentrates:
  - Storage temperature range
  - Instructions for mixing
  - Instructions regarding precipitates
  - Warning regarding damaged containers
  - Warning regarding issues related to bacterial growth
  - System for readily distinguishing between different solutions
- For dry concentrates:
  - Storage temperature range
  - Instructions to keep container tightly sealed until use

Manufacturer: Requirements for Concentrate

- Physical state: either aqueous or dry
- Solute concentration shall be ±5% of stated concentration, except sodium & chlorine which must be ± 2%
- "AAMI Quality water" must be used in manufacture of concentrate
- Fill volume must be within 2% of labeled volume if for use with batch system
- Acidity or alkalinity
  - acetate concentrate: pH range 6.0 to 8.0 and require <1 mEq of acid or base to titrate 1 liter to pH of 7.4
  - bicarbonate concentrate: include directions for proper mixing and prevention of calcium or magnesium precipitation
- Chemical grade must meet current requirements of USP/National Formulary
- Final dialysate arsenic content must not exceed 0.05 mg/l
- Particulates: aqueous concentrate must be filtered through 1.5 μ or finer, non-fiber releasing filter not containing asbestos
- Additives: concentrate must contain no substances other than those listed on label; no indicators or preservatives shall be added
- Containers:
  - shall not interact chemically or physically with contents that would in any way alter strength, purity, or quality
  - shall have closures that prevent contamination or loss of contents
  - shall contain not less than 97% of labeled volume or weight
- Water and chemicals used must be non-pyrogenic

User: Requirements for Dialysate

- Water used to prepare dialysate:
  - total microbial count ≤ 200/ml
  - within AAMI/ANSI maximum chemical contaminant levels
- Dialysate:
  - total microbial count ≤ 2000/ml

FORM 1

PATIENT DAILY DIALYSIS RECORD
XYZ DIALYSIS CENTER

Date _____ **Patient Name** _____

DIALYSIS PRESCRIPTION

Dialyzer	_____	Time on	_____	Dry weight	_____
QB _____	QD _____	Actual time off	_____	Predialysis weight	_____
Heparin Rx:		Rx time off	_____	Desired weight loss	_____
Prime	_____	Rx dialysis length	_____	Postdialysis weight	_____
Infusion	_____	Actual dialysis length	_____	UF rate	_____
Time off	_____	Expected clotting time	_____		
Dialysate Rx	_____	Actual clotting time	_____		

DIALYSATE		**MACHINE CHECKS**		**REUSE**	
Conductivity	_____	Blood leak alarm	_____	Patient ID	_____/_____
pH	_____	Air foam detect (check)	_____	Use number	_____
Temperature	_____	Air foam detect (armed)	_____	Dialyzer structure/aesthetic	_____
Special Rx	_____	UF check	_____	Germicide dwell	_____
Mixed by	_____	Art/Ven press set	_____	Germicide presence	_____
Dispensed by	_____	Machine number	_____	Germicide absence	_____

FORM 2

DIALYSATE CONCENTRATE LABELS

Dialysate Concentrate Tank Label

Date _____ Proportioning Ratio _____

Time Mixed _____ Initials _____

Additives _____ Initials _____

Comments _____

_____

Dialysate Concentrate Jug Label

Date _____ Proportioning Ratio _____

Time Mixed _____ Initials _____

Time Dispensed _____ Initials _____

Additives _____ Initials _____

Comments _____

_____

DIALYSATE CULTURES TREND ANALYSIS

FORM 3

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DATE												
CULTURE SITE												
Machine #1												
Machine #2												
Machine #3												
Machine #4												
Machine #5												
Machine #6												
Machine #7												
Machine #8												
Machine #9												
Machine #10												
MIXING TANK												

PROCEDURE FOR CONCURRENT MONITORING FORM: DIALYSATE CONCENTRATE SAFETY MONITOR (FORM 4)

The purpose of this audit is to monitor technical staff compliance with standard practices and procedures related to the water treatment system. When staff are aware of the importance of the policies and well trained in the procedures, compliance should be very high.

Before the Audit

1. Provide adequate and appropriate inservice to assure total staff awareness and education of all components associated with water treatment for dialysis.
2. Assure staff awareness of all elements of the concurrent audit and how performance will be observed and evaluated.
3. The QA committee specifies the standard (expected percentage compliance) desired for the audit; begin not lower than 85%.
4. Schedule the audit with appropriate personnel (head nurse, charge nurse, chief technician).
5. Make copies of the audit for each auditor/observer.
6. Assign code letters for each staff member to be observed; for example:

   Employee A: Glenn Close
   B: Tom Hanks
   C. William Hurt
   etc.

7. Determine how many staff are to be observed. It is recommend that one auditor should observe no more than three to four staff at one time.
8. Define the length of time for observation. It is recommended that the audit be conducted during peak activity times (daily start-up, shift changeovers, etc.). The time frame should be long enough to observe each staff member completely perform the listed activity.
9. Assign a staff member to perform the audit. Auditor should not be assigned to other responsibilities during the audit.

Perform the Audit

1. On the actual audit sheet, write in the date, auditor's name, patient shift (or time of day), and standard.
2. Read each indicator carefully.
3. Observe staff for actual *performance*. Auditor should not interfere with staff activities, be obtrusive, or preceptibly obvious.
4. Under each staff code letter, write Y for yes if indicator is met, N for no if indicator is not met, or N/A for not applicable, not observed.

   To achieve a Y (yes, indicator was met), staff should be observed with complete compliance for each encounter. For example, for a Y to appear in the "Post-Softener Hardness Done" box, the staff member must perform the test before any patient dialysis is done ***and*** perform the test exactly according to the instructions for use of the test manufacturer ***and*** record the results as per facility policy.
5. Complete all observations within timeframe specified. Assure that each indicator has one response.

After the Audit

1. Under each employee code letter, add total number of Ys and Ns; do not count NAs.
2. For each employee, calculate compliance percentage by dividing the total Ys by the total observations; again, do not count NAs.
3. Calculate total compliance percentage for the audit by dividing total Ys (all employee Ys) by the total observations; do not count NAs.
4. For each indicator, calculate compliance percentage by using the same method as above; again, do not count NAs.
5. Report results to QA committee and clinical management team with additional comments and/or recommendations.

DIALYSATE CONCENTRATE SAFETY MONITOR

FORM 4

Date	Patient Shift	Auditor									
	Station Number	1	2	3	4	5	6	7	8	9	10
	Staff Member (initials)										
PER TREATMENT FUNCTIONS											
Proper concentrate confirmed on patient record											
Proper connectors used (color coded/key coded)											
Conductivity checked/recorded before treatment											
pH checked and recorded before treatment											
Concentrate jug properly labeled											
DAILY/WEEKLY/MONTHLY FUNCTIONS		**Staff Member**								**Y/N**	
Most recent mixing tank sanitzation recorded on log											
Most recent concentrate jugs sanitization recorded on log											
Most recent concentrate jug bacterial culture within limits											
Most recent mixing tank bacterial culture within limits											

Threshold	% Compliant

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

Chapter 6

HEMODIALYZERS

CONTENTS

Chapter 6

Hemodialyzers

Note: Information specific to reuse of hemodialyzers, as well as some other general discussion regarding dialyzers may also be found in Chapter 12, *Hemodialyzer Reuse.*

TECHNICAL DESCRIPTION OF DEVICE

The *hemodialyzer* (dialyzer) is a device that permits electrolyte metabolic and fluid exchange between the blood and the dialysis fluid. A semi-permeable membrane separates two compartments; the patient's blood flows through one and the dialysis fluid, or dialysate, flows through the other.

The solute and fluid removal capabilities of a dialyzer are referred to as *performance characteristics.* Other characteristics such as materials of construction, priming volume and compliance, residual blood volume, fluid dynamic parameters, etc. are referred to as *design characteristics.*

Several of these basic characteristics of the dialyzer are described below:

Mass Transfer. Mass transfer is used to calculate the amount of solute transfer across the semi-permeable membrane. Mass solute transfer is the quantity of a solute transferred from the blood into the dialysis fluid (or vice-versa) per unit of time.

Mass transfer across a semi-permeable membrane includes two basic mechanisms, *diffusion* and *ultrafiltration* .

Diffusion is the passive transfer of solutes across a membrane in the absence of net solvent transfer. The amount of solute crossing a membrane by diffusion depends on three factors: (a) the mean concentration ingredient of the solute on either side of the membrane, (b) the effective dialysis surface area available for diffusion, and (c) the total dialyzer permeability coefficient.

Ultrafiltration is the simultaneous transfer of a solvent, with the small amount of solutes that it contains, across a membrane.

The rate of ultrafiltration depends on the effective surface area and the hydraulic permeability of the membrane, as well as transmembrane hydrostatic pressure.

In practical terms, solute removal (incorporating both diffusion and ultrafiltration) from the blood to the dialysate is most often defined as *clearance* .

Dialysance describes dialyzer efficiency when solute concentration in the dialysate is *not* zero, or the volume of blood cleared of that solute per minute, if the dialysate concentration was zero (see Table 3).

Dialyzer Membranes

There are three basic membrane types:

1. The conventional cellulosic membrane (Cuprophan©, saponified cellulose ester, regenerated cellulose, cuprammonium rayon, etc.)
2. Cellulose acetate, and
3. Non-cellulosic and high flux (polysulfone, polyacrylonitrile, polymethylmethacrylate, polyamide, polycarbonate, etc.)

From a quality assurance perspective, membranes must be evaluated prior to use based on their solute transport characteristics, biocompatibility, water removal, reuse, clotting, and membrane integrity.

Design Characteristics

Dialyzer design characteristics may also influence the facility's selection of a specific dialyzer for a given patient. These characteristics include the priming volume and the compliance of the blood

compartment, blood and dialysate compartment hydraulic pressure drops, the residual blood volume, the uniformity of flow distribution in blood and dialysate compartments, as well as more subjective characteristics such as size, weight, shape, etc.

See Table 1 for a summary description of types of hemodialyzers and their characteristics.

RISKS AND HAZARDS

The literature prior to 1980 contains a large number of reports and patient complications attributed to problems with dialyzers. These include problems with the structural design of the dialyzer, patient allergic responses to the membrane material and/or the chemical used to make or sterilize the membrane, and human errors.

Incidents reported in the literature and through the Medical Device Reporting system since 1980 are summarized in Appendix A.

A total 342 incidents were reported; apparent dialyzer hypersensitivity reactions comprised 205 of these. Of the remaining incidents, many included some component malfunction of the device, due to manufacturer quality control error.

Incidents related to user error or a combination of user error and device malfunction included:

1. Pyrogen reaction and sepsis, indicating bacterial contamination of dialyzer due to poor set-up technique.
2. Dialyzer hypersensitivity reaction when dialyzer was not primed according to manufacturer's recommendations.
3. Extreme blood loss, due to broken blood port on dialyzer, blood line separation, cracked dialyzer header, or fiber rupture with no blood detector alarm.
4. Clotting of extracorporeal circuit, due to improper anticoagulation monitoring.
5. Air embolus, due to improper blood line/dialyzer connection.
6. Inadequate dialyzer clearance, associated with poor priming technique and incomplete removal of air.
7. Dialysate leak at dialysate port, resulting in inadequate dialyzer clearance.
8. Membrane leaks on dialyzers secondary to damaged dialyzer housing, after a case of dialyzers was dropped without being reported.
9. Large plate dialyzer membrane leak secondary to clotting, due to inappropriate anticoagulant administration and monitoring.

Many of the incidents could have been avoided through fairly simple tests, observations, or quality control procedures as specified in the manufacturer's instructions for use. Further, although only a few of these incidents resulted in patient death, almost all had the potential to cause death.

EXISTING GUIDELINES

Guidelines currently relavent to dialyzers are the International Organization for Standardization (ISO) Document 8637, International Standard for Hemodialyzers, Hemofilters, and Hemoconcentrators, and the American National Standard for First Use Hemodialyzers (ANSI/AAMI: RD16—1984) developed by the Association for the Advancement of Medical Instrumentation (AAMI). Both of these documents are, primarily voluntary standards for manufacturers of hemodialyzers.

Table 2 summarizes AAMI's American National Standards for First Use Hemodialyzers.

QUALITY ASSURANCE FOR DIALYZERS

Policies and Procedures

An essential step in designing a facility's quality assurance program is the development, implementation, and evaluation of policies and procedures for hemodialyzers. 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, equipment, disposables, and supplies used in the dialysis facility.

Comprehensive policies and procedures must also address the interrelationship of each component of the hemodialyzer, as well as the various related

components, such as the dialysate, delivery system, blood lines and transducer protectors. The risks involved must be clearly identified and considered, and appropriate safety measures and preventative systems developed.

Policies and procedures must also address the safe and effective handling and use of the hemodialyzer:

1. Storage conditions
2. Inspection of dialyzer before use
3. Priming of blood and dialysate path
4. Intra-dialytic monitoring of blood circuit pressure
5. Intra-dialytic monitoring of dialysate pressure
6. Intra-dialytic monitoring for dialyzer blood leak
7. Technique for termination of dialysis
8. Anticoagulation
9. Management and troubleshooting of complications
10. Patient monitoring.

Staff Training and Continuing Education

Role descriptions should include all personnel responsibilities for general handling and use of the hemodialyzer, treatment safety and record keeping.

Staff training should be a well-defined, organized program with content clearly defined for the learner based on behavioral objectives. The behavioral objectives can be used to accurately and objectively monitor and measure learning. At the end of the session(s), the instructor must confirm by a written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error.

Comprehension of the purpose and function of the hemodialyzer requires a basic understanding of kidney disease, fluids and electrolytes, principles of dialysis, infection control, and complications of the hemodialysis treatment. Content should include dialyzer principles and function, dialyzer related procedures, aseptic technique, parameters of safety, complications management and troubleshooting, patient monitoring, and documentation.

Need for further education such as inservices or intensive educational sessions can be determined from the ongoing quality monitoring process and the continuous staff performance appraisal process. When problems are identified, all staff should be made aware of the problem and be involved in its solution; this nearly always includes problem specific continuing education.

The medical director of the dialysis facility must ascertain that an individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual performance appraisal process has been performed.

Monitoring and Evaluation

The following section provides a summary of recommendations for monitoring that should be performed to enhance safety and reduce the level of risk of patient injury. These recommendations will also ensure that the dialysis being received by the patient is as prescribed by the physician.

A. Daily Monitoring

1. Physical inspection of the dialyzer for appropriate labeling, undamaged packaging, intact caps, and any other obvious defects should be performed.
2. Confirm that the dialyzer prescribed by the physician for the patient's treatment is being used.
3. Confirm that the dialysate flow rate and blood flow rate prescribed by the physician are actual delivery rates. Clarify that equipment settings conform with prescription. Any reduction in blood or dialysate flow rate must be documented with rationale (see Form 1).
4. Confirm that actual dialysis duration is that prescribed by the physician. Any departure from the prescribed treatment time (in minutes) should be explained on the record.
5. Test and document results of all components of the dialysis delivery system, including:
   - the ultrafiltration control system
   - the blood leak detector

- arterial/venous pressure alarms; setting limits
- dialysate

6. Blood flow through the dialyzer as well as dialysate distribution and flow through the dialyzer should be observed at the beginning and throughout the treatment.

7. Monitoring and recording of anticoagulation therapy must be performed to assure that the delivery rate is as prescribed.

8. Special events such as blood leaks, pyrogen reactions, cracked dialyzers or other complications should be recorded on the patient's record.

The performance of the above tests and observations should be recorded on a daily patient dialysis record. The initials of the person performing the test and the specific machine number should appear on that record (see Form 1).

B. Monthly Monitoring

An essential component of assuring adequacy of the dialysis treatment is to confirm that the dialyzers and the way the dialyzers are being used are in compliance with facility expectations and national standards. A well-designed urea kinetics program will enable the facility to monitor adequacy of treatment. The patient should have one or more of the following measured on, at least, a quarterly basis:

- pre/post BUN reduction
- KT/V urea (delivered or actual)
- pre/post creatinine reduction

Individual characterization of the dialyzers may also be performed.

C. Patient Monitoring

1. Routine monitoring of BUN as described above.

2. Routine intradialytic monitoring of the patient's physiological parameters and symptoms can provide indications of improper dialyzer function. A few of the symptoms seen are:

   - Hypotension or hypertension, related to gross dialyzer performance error, especially in the absence of an ultrafiltration controller.
   - Pyrogen reaction (shaking, chills, increase in patient temperature of more than 1°C during treatment) or septicemia (identified through blood cultures), from patient exposure to an improperly sterilized dialyzer or a break in aseptic technique.
   - Acute blood loss, which may be the result of extreme pressures in the blood circuit, causing dialyzer membrane rupture, blood leaking through the actual dialyzer housing, or bloodline separation from the dialyzer.

3. Routine monitoring and evaluation of anticoagulation therapy needs to be conducted for both patient and dialyzer clotting times. Real and/or potential complications related to anticoagulation need to be addressed and documented in the patient record.

4. When treatment delivery is not as prescribed, it is recommended that the patient's vascular access be evaluated for recirculation.

5. First Use Syndrome signs and symptoms include chest pain, anxiety, shortness of breath, and back pain.

   Any case of First Use Syndrome (FUS), or Dialyzer Hypersensitivity Reaction, should be addressed immediately. Signs and symptoms of these reactions include asthmatic reaction, respiratory arrest, pruritis, urticaria, erythema, peripheral and facial edema, hypertension, hypotension, and cardiac arrythmia. The reactions range from very mild to very severe, including death. The following should be done in the case of a suspected FUS reaction:

   - Immediately discontinue dialysis on the patient without returning the contents of the extracorporeal circuit. Provide medical treatment for any resulting symptoms.
   - Many experts recommend that the same dialyzer type not be used on the patient, if possible. If the same dialyzer must be used, be sure to rinse diligently according to the manufacturer's recommendations prior to use.

   Note: A positive history of hypersensitivity reaction is an indication for careful monitoring for such signs and symptoms during dialysis.

D. Home Dialysis Monitoring

All of the monitoring procedures described above should be performed by the home dialysis patient, home dialysis support personnel, and reviewed by the medical director, as appropriate.

E. Other Monitoring

1. Using the prescribed recommendations of the manufacturer, dialysate flow rate, blood pump flow rate and proper calibration of the heparin pump should be tested directly. Actual flow rates should be measured over a prescribed time using precise volume measurements.

2. An annual review of all policies and procedures related to hemodialyzers should be performed. Assure that current standards and/or regulations are incorporated as appropriate.

3. All incidents or adverse occurrences related to hemodialyzers should be documented and reported at the monthly quality assurance meetings. To assess trends that may compromise patient safety, adverse occurrences associated with the dialyzer should be recorded on a "flow chart" so that the information can be examined, analyzed, and compared over an extended period of time by the quality assurance committee. Any trends thus become immediately obvious and appropriate action can be taken. See Form 2 for a sample trend analysis format.

4. Quarterly monitoring of actual implementation of hemodialyzer procedures should be performed. See Form 3 for sample "Dialyzer Use" monitoring instrument.

F. Prevention

1. Each manufacturer provides comprehensive directions for the preventative maintenance of the entire dialysis delivery system. The established schedules and procedures must be followed.

2. Water and dialysate must be tested and evaluated to assure at least minimum compliance with AAMI standards.

G. Purchasing Guidelines

The following is a list of pertinent questions to ask when purchasing hemodialyzers.

- Does the dialyzer meet the facility's definition of adequacy?
- What are the performance characteristics of the dialyzer? How do these performance characteristics fit in with the facility's and physician's therapeutic intent?
- What are the specific equipment needs related to the use of this dialyzer?
- What are the graphic representations of "in-vivo" expectations of performance according to the therapeutic parameters that will be used in the facility?
- Has the specific dialyzer been proven safe, reliable and effective in other facilities?

These questions will enhance the likelihood of selecting a hemodialyzer that best suits the need of the patient. It will also help to assure a treatment that is safe and effective.

REFERENCES

1. Association for the Advancement of Medical Instrumentation. *American National Standard, First Use Hemodialyzers* (AAMI: RD16-1984). Arlington, VA (1984).

2. KESHAVIAH, P., LUEHMANN, D., SHAPIRO, F. and COMTY, C. *Investigation of Risks and Hazards Associated with Hemodialysis Systems* (Technical Report, Contract #223-78-5046). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/Bureau of Medical Devices, Silver Spring, MD (1980).

3. SARGENT, J.A. and GOTCH, F.A. *Principles and Biophysics of Dialysis* in Replacement of Renal Function by Dialysis. William Drukker, Frank M. Parsons and John F. Maher, eds. Martinus Nijhoff, The Hague, The Netherlands (1988).

4. HOENICH, N.A., FROST, T.H. and KERR, D.N.S. *Dialyzers* in Replacement of Renal Function by Dialysis. William Drukker, Frank M. Parsons and John F. Maher, eds. Martinus Nijhoff, The Hague, The Netherlands (1988).

5. SHINABERGER, J.H., MILLER, J.H. and GARDNER, P.W. *Characteristics of Available Dialyzers* in Clinical Dialysis. A .R. Nissenson, R.N. Fine and D.E. Gentile, eds. Appleton-Century-Crofts, Norwalk, CT (1984).

6. DHEW. *Evaluation of Hemodialyzers and Dialysis Membranes* (report of a study group of the Artificial Kidney-Chronic Uremia Program, E. Klein, Chairman. DHEW Pub. No. (NIH)77-1294). U.S. Department of Health, Education and Welfare, Washington, DC (1977).

7. VLCHEK, D.L. and BURROWS-HUDSON S. *Quality Assurance Challenges in Short Dialysis.* Nephrology News & Issues, 5, 1: 12-14 (1990).

8. GOTCH, F. *Kinetic Modeling in hemodialysis.* in Clinical Dialysis. A.R. Nissenson, R.N. Fine and D.E. Gentile, eds. Appleton and Lange, Norwalk, CT (1990).

9. KEEN, M., LANCASTER, C. and BINKLEY, L. *Concept and Principles of Hemodialysis.* in Core Curriculum for Nephrology Nursing. L.E. Lancaster, ed. American Nephrology Nurses' Association, Pitman, NJ (1990).

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic.

TABLE 1
DIALYZER/MEMBRANE CHARACTERISTICS

Membrane Type	Transport	Ultrafiltration	Biocompatibility
Conventional Membrane (Cuprophan, Regenerated Cellulose, SCE, etc.)	+	2.0 to 6.0 ml/hr/mmHg	+
Cellulose Acetate	++	7.0 to 15.0 ml/hr/mmHg	++
Non-Cellulosic and High Flux	+++	20.0 to 70.0 ml/hr/mmHg	+++

Key + = Effective
++ = Very Effective
+++ = Extremely Effective

TABLE 2
AAMI DIALYZER REQUIREMENTS (MANUFACTURER STANDARDS)

LABELING AND DOCUMENTATION

Device Markings

- Manufacturer name and address
- Product trade name and generic name
- Catalog number
- Lot number
- Sterilization date
- Identification of blood and dialysate ports

Unit Container

- Sterilization Date
- Statement regarding "sterile and nonpyrogenic"
- Special conditions of storage and handling
- Statement: "Caution: Federal law restricts device to sale by or on order of a physician"
- A warning that the device must be rinsed before use
- Maximum TMP
- Statement: " Caution: See Directions for Use before using this device"
- Other descriptive information, warnings, etc.
- Warnings regarding flow maldistribution under certain conditions
- Warning if ultrafiltration rate is not linear with relation to TMP

Package Insert/Instructions for Use

- Instructions for priming, operating parameters, monitoring, termination, etc.
- Warranty for first use
- Dialyzer description/specifications
- Indications for use
- Adverse Reactions
- Recommendations regarding anticoagulation
- Contraindications
- Warning regarding conditions for backfiltration
- Method of sterilization
- Any particular features
- Ranges for blood flow rate, dialysate flow rate, TMP, temperature, etc.
- Characteristics (UF coefficient, clearances, pressure drops, blood compartment volume, etc.
- Names of materials in contact with blood or dialysate
- Common chemicals and processes with known adverse effects on dialyzer materials
- Statement that the following is available upon request: detaills of test methodologies, results of clinical performance tests, number of particulates in effluent, results of toxicological tests.

PERFORMANCE REQUIREMENTS

Ultrafiltration Rate

- ±10% of stated

Solute Clearance

- ±10% of stated
- Pressure drop across the hemodialyzer measured
- Blood compartment volume and compliance measured
- Residual blood volume measured

MECHANICAL/STRUCTURAL INTEGRITY REQUIREMENTS

General

- Able to withstand pressure 1.5 x recommended
- Membrane integrity tested
- Packaging integrity to minimize damage during shipping

DEVICE CLEANLINESS/REQUIREMENTS FOR MATERIALS

- Must be sterile and nonpyrogenic
- All materials in contact with blood must be biocompatible
- Residual EtO must be within federal limits

TUBING CONNECTORS

- Blood port shall meet ISO (International Standards Organization) requirements for design
- Dialysate port shall meet ISO requirements for design

TABLE 3

SOME USEFUL FORMULAS IN WORKING WITH DIALYZERS

CLEARANCE

In practical terms, solute removal (incorporating both diffusion and ultrafiltration) from the blood to the dialysate is most often defined as *clearance* (K).

$$= \frac{K_B\ (C_{Bi} - C_{Bo})\ Q_{Bi}}{C_{Bi}} + \frac{Q_f\ C_{Bo}}{C_{Bi}}$$

(for the blood side of the dialyzer)

where:

C_{Bi} is solute concentration entering the dialyzer,
C_{Bo} is solute concentration exiting the dialyzer,
Q_{Bi} is blood flow rate, and,
Q_f is ultrafiltration rate

And, similarly,

(for the dialysate side of the dialyzer)

$$= \frac{K_D\ (C_{Do} - C_{Di})\ Q_{Di}}{C_{Bi}} + \frac{Q_f\ C_{Do}}{C_{Di}}$$

DIALYSANCE

Dialyzer efficiency when solute concentration in the dialysate is not zero (such as recirculating dialysate systems). Dialyzer dialysance (D_B) describes the volume of blood cleared of that solute per minute if the dialysate concentration is zero.

$$D_B = Qb_i\ [(C_{bi} - C_{bo})/C_{bi} - C_{di})] + Qf\ (C_{bo}/C_{bi})$$

FORM 1

PATIENT DAILY DIALYSIS RECORD
XYZ DIALYSIS CENTER

Date _____ **Patient Name** _____

DIALYSIS PRESCRIPTION

Dialyzer	_____	***Time on***	_____	***Dry weight***	_____
QB _____	***QD*** _____	***Actual time off***	_____	***Predialysis weight***	_____
Heparin Rx:		***Rx time off***	_____	***Desired weight loss***	_____
Prime	_____	***Rx dialysis length***	_____	***Postdialysis weight***	_____
Infusion	_____	***Actual dialysis length***	_____	***UF rate***	_____
Time off	_____	***Expected clotting time***	_____		
Dialysate Rx	_____	***Actual clotting time***	_____		

DIALYSATE		MACHINE CHECKS		REUSE	
Conductivity	_____	***Blood leak alarm***	_____	Patient ID	_____/_____
pH	_____	Air foam detect (check)	_____	Use number	_____
Temperature	_____	Air foam detect (armed)	_____	Dialyzer structure/aesthetic	_____
Special Rx	_____	UF check	_____	Germicide dwell	_____
Mixed	_____	Art/Ven press set	_____	Germicide presence	_____
Dispensed	_____	Machine number	_____	Germicide absence	_____

FORM 2

DIALYZER PROBLEMS TREND ANALYSIS

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DATE												
BLOOD LEAKS (MEMBRANE)												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												
BLOOD LEAKS (HOUSING)												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												
UF RATE D *VS* EXPECTED >20%												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												

Other Dialyzer Problems: _____

_____

_____

PROCEDURE FOR CONCURRENT MONITORING FORM: DIALYZER USE MONITOR (FORM 3)

The purpose of this audit is to monitor technical staff compliance with standard practices and procedures related to the water treatment system. When staff are aware of the importance of the policies and well trained in the procedures, compliance should be very high.

Before the Audit

1. Provide adequate and appropriate inservice to assure total staff awareness and education of all components associated with water treatment for dialysis.
2. Assure staff awareness of all elements of the concurrent audit and how performance will be observed and evaluated.
3. The QA committee specifies the standard (expected percentage compliance) desired for the audit; begin not lower than 85%.
4. Schedule the audit with appropriate personnel (head nurse, charge nurse, chief technician).
5. Make copies of the audit for each auditor/ observer.
6. Assign code letters for each staff member to be observed; for example:

   Employee A: Glenn Close
   B: Tom Hanks
   C. William Hurt
   etc.

7. Determine how many staff are to be observed. It is recommend that one auditor should observe no more than three to four staff at one time.
8. Define the length of time for observation. It is recommended that the audit be conducted during peak activity times (daily start-up, shift changeovers, etc.). The time frame should be long enough to observe each staff member completely perform the listed activity.
9. Assign a staff member to perform the audit. Auditor should not be assigned to other responsibilities during the audit.

Perform the Audit

1. On the actual audit sheet, write in the date, auditor's name, patient shift (or time of day), and standard.
2. Read each indicator carefully.
3. Observe staff for actual *performance*. Auditor should not interfere with staff activities, be obtrusive, or preceptibly obvious.
4. Under each staff code letter, write Y for yes if indicator is met, N for no if indicator is not met, or N/A for not applicable, not observed.

   To achieve a Y (yes, indicator was met), staff should be observed with complete compliance for each encounter. For example, for a Y to appear in the "Post-Softener Hardness Done" box, the staff member must perform the test before any patient dialysis is done ***and*** perform the test exactly according to the instructions for use of the test manufacturer ***and*** record the results as per facility policy.
5. Complete all observations within timeframe specified. Assure that each indicator has one response.

After the Audit

1. Under each employee code letter, add total number of Ys and Ns; do not count NAs.
2. For each employee, calculate compliance percentage by dividing the total Ys by the total observations; again, do not count NAs.
3. Calculate total compliance percentage for the audit by dividing total Ys (all employee Ys) by the total observations; do not count NAs.
4. For each indicator, calculate compliance percentage by using the same method as above; again, do not count NAs.
5. Report results to QA committee and clinical management team with additional comments and/or recommendations.

"DIALYZER USE" MONITOR

FORM 3

Date	Patient Shift	Auditor										
Station Number		1	2	3	4	5	6	7	8	9	10	11
Staff Member (initials)												
FUNCTION												
Dialyzer model according to prescription												
Dialyzer setup: Aseptic technique												
Dialyzer prime (blood side and dialysate side)												
Ultrafiltration calculated and set												
Areterial and venous pressure alarms set												
Blood leak detector checked and set												
Blood flow rate according to prescription												
Actual "time on" recorded												
Actual "time off" recorded												
Rx blood flow rate established within 5 min of start												
Rx blood flow rate maintained thruout treatment												
Unusual incidents recorded												
Heparin loading dose properly administered												
Heparin administration as prescribed												

Threshold	% Compliant

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

Chapter 7

ANCILLARY DEVICES AND EQUIPMENT

CONTENTS

Chapter 7

Ancillary Devices and Equipment

TECHNICAL DESCRIPTIONS

Blood Tubing

Blood tubing is the conduit through which blood is taken from the patient, delivered to the dialyzer, and returned to the patient during dialysis therapy. Blood tubing sets include various combinations of special purpose components in addition to the tubing itself. Common components of a blood tubing set may include:

Patient Connectors. Both arterial and venous end pieces of the blood tubing are used to connect the tubing to the fistula needle, catheter, etc. These connectors include both simple luer connectors as well as luer locking connectors.

Dialyzer Connectors. The connection between the arterial and venous blood lines and the dialyzer itself may be a "soft connector" made of pliable plastic or a "rigid luer connector."

Other Connectors. Various other connectors may be attached to the blood tubing including: heparin line, pressure monitoring lines, solution administration lines, and other ports. As with the dialyzer connectors and the patient connectors, these "service line connectors" can either be straight luers or "luer lock connectors."

Injection Sites. Also called "access ports," these are comprised of a "sleeve" around the tubing itself (composed of latex or a similar material) or a small similar port attached to another primary component of the blood tubing, such as a bubble trap/drip chamber. A needle can be directly inserted for the purpose of administering medications, fluids, obtaining a blood sample, or other purposes. Most injection sites are (and should be) equipped with some sort of hard plastic protection device to guard against accidental needle sticks to the patient care staff when inserting needles through the injection site.

Drip Chambers or Bubble Traps. These components are used primarily for removing any air that may have inadvertently entered the extracorporeal circulation. Most dialysis delivery systems also monitor for air and/or foam in the blood at the "venous bubble trap." This is accomplished by ultrasonic or optical sensors which are placed at or near the bottom of the bubble trap to alert the user if bubbles are present.

Bubble traps also serve the purpose of "pressure buffers" in the extracorporeal blood circuit since there always is some air near the top of these components. Wide pressure variations in the extracorporeal circuit due to variability in vascular access, the blood pump, or single needle dialysis can be minimized as compression and expansion of the air at the tops of these bubble traps occurs.

Blood Pump Segment. The blood bump segment is a short piece of the arterial blood tubing that is inserted into the roller section of the blood pump. It is generally made of durable material (most often polyvinyl chloride (PVC) but in some cases silicone) in order to withstand the constant mechanical stress placed upon it.

Clamps. Some blood lines are equipped with their own dedicated clamping devices on the arterial and venous tubing, heparin administration lines, solution administration lines, monitoring service lines, and other areas.

Service Tubing. A variety of "service lines" or "accessory tubing" also appears on most blood tubing sets. These are used for such functions as administration of heparin or heparin infusion, solution administration, pressure monitoring, and other functions.

Blood Tubing. Finally, the tubing itself acts as the primary conduit of the blood from the patient to the dialyzer and back to the patient.

Transducer Protectors

The purpose of these devices is to isolate the interior of the blood tubing and protect the pressure sensor within the dialysis delivery system. Pressure monitoring creates a direct and open channel between the sterile internal surfaces of the blood tubing and the non-sterile components of the dialysis delivery system. An impermeable flexible diaphragm or a submicron filter must be placed at this interface.

Single Needle Devices

"Single needle systems" accomplish hemodialysis with only one venipuncture, the flow through the needle alternating between flow from the patient to the dialyzer (arterial or fill phase) and flow from the dialyzer back to the patient (venous or return phase). While this can also be accomplished with "dual lumen" catheters, the following discussion is limited to single lumen, single needle systems.

Single needle systems are comprised of:

- a single, intermittently operated blood pump and a single clamp (venous) or
- a single, continuously operating blood pump and two clamps (arterial and venous) or
- two intermittently operating blood pumps with no clamps, with pump occlusion providing the necessary clamping action with the pump off.

Conductivity Meter (Independent Reference Test Meter).

Basically, the independent reference conductivity meter operates under the same principle as the conductivity measurement system in the dialysis delivery system. A variety of such meters are currently available in the United States, however, not all of these meters are temperature compensated, which may present measuring problems for the user.

The principle of checking mechanical dilution of concentrate is an indirect one which depends upon the specific conductivity of the total ionic content of the dialysis fluid. Temperature changes influence measurement by about 1.7% per °C in the range of 38°C. Two electrodes are immersed in the dialysis fluid and an alternating current of high frequency pulses through the fluid. When changes in temperature are compensated, the only variable will be the electrical resistance of the dialysis fluid which will cause an alteration in the current passing between the electrodes which may be read on a meter.

Many of these independent reference conductivity meters also enable the user to measure other parameters with relation to the dialysate, including temperature, pressure, and pH.

RISKS AND HAZARDS

Literature prior to 1980 contains a number of reports of patient complications attributed to problems with blood tubing, transducer protectors, single needle devices, and conductivity meters. Problems are usually related to manufacturer's error in product design or manufacturing quality control, inappropriately calibrated equipment, user error in handling the devices, or a combination of user error and design/operation malfunction.

Incidents reported in the literature between 1980 and 1989 are summarized in Appendix A. Many of these incidents could have been avoided by strict adherence to the manufacturer's instructions for use, preventative maintenance, repair protocols, as well as ongoing monitoring and evaluation activities.

EXISTING GUIDELINES

Blood lines. There are three guidelines that address blood lines.

The first two, the Association for the Advancement of Medical Instrumentation (AAMI) American National Standard for Hemodialyzer Blood Tubing (RD17-1984) and the International Organization for Standardization (ISO) Standard for Blood Tubing and Dialyzer Connectors, both are directed to the manufacturers of blood tubing.

A third standard is the HCFA Final Rule: Medicare Program: Protocol for the Reuse of Dialysis Blood Lines (42 CFR Part 405, Federal Register, May 2, 1990, Vol. 55, No. 85, p. 18331-18335). This rule requires that if a facility reuses blood lines, it must reuse only a blood line for which the FDA

has accepted the manufacturer's protocol for reuse of that particular blood line. Additionally, the facility must reuse blood lines only in accordance with that protocol.

In the absence of any other standards of practice or use for dialysis facilities and personnel, we will discuss proper use and handling later in this chapter. Manufacturers' instructions for use serve as the best standard.

Transducer protectors. Manufacturers' instructions for use will serve as the best standard. The Centers for Disease Control and Health Care Financing Administration stipulate that transducer protectors should not be reused.

Single needle control. Single needle control devices are included in the AAMI American National Standard for Hemodialysis Systems as well as in the ISO Standard for Hemodialysis Systems. Manufacturers' instructions for use may serve as the best standard to follow.

Independent reference meters. Two standards refer to conductivity reference standards including: the National Institute of Standards and Technology (N.I.S.T.); and the Organization of Legal Metrology (a European bureau similar to the N.I.S.T.). The standards relate to specific aqueous electrolytic conductance.

QUALITY ASSURANCE

Policies and Procedures

Policies and procedures concerning ancillary equipment and supplies as they relate to the hemodialysis therapy must be developed, written, implemented and evaluated. All standards previously described must be incorporated into these policies and procedures.

Specifically, the policies and procedures should address purpose and function of each device, use, maintenance, safety factors, troubleshooting and repair, and related documentation. The risks involved must be clearly identified and considered, and appropriate safety measures and preventative systems developed. Specifically, the procedures must address storage and inventory control, use/handling, disposal, complication management, and repair.

Staff Training and Continuing Education

Role descriptions should describe all personnel responsibilities for handling and use of ancillary supplies and equipment, ordering, confirmation of proper labeling, testing and monitoring, and other similar responsibilities. Each responsibility should stem from a specific policy or procedure.

Staff training should be a well defined and organized process. Content should be clearly defined for the learner and based on behavioral objectives. The behavioral objectives can be used to accurately and objectively measure learning. At the end of the session(s), the instructor should confirm by a written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. Testing results should be documented and placed in the employee's personnel file.

Comprehension of the purpose and function of each piece of equipment or supply requires a basic understanding of normal physiological concepts, as well as responses associated with uremia and the hemodialysis therapy. Content should include principles of dialysis, patient response to therapy and related complications, aseptic technique and inventory control. The interrelationships of each device and the delivery system, dialysate, dialyzer, etc. must be incorporated into the training process.

Need for further education, such as inservices or intensive educational sessions, can be determined from the routine quality assurance monitoring process and the ongoing staff performance appraisal process. When problems are identified, all staff should be made aware of the problem and be involved in its solution. This nearly always includes problem specific continuing education.

The medical director of the dialysis facility must authorize that the individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual performance evaluation has been performed.

Monitoring and Evaluation

To assure patient safety through the proper use of ancillary equipment and supplies as well as test instruments, the following monitoring activities are recommended.

Blood Tubing

A. Daily Monitoring

On a per-treatment basis, patient care staff should confirm that the blood lines are compatible with the delivery system and dialyzer, and that packaging and all caps on the blood tubing sets are intact, ensuring that the manufacturer's intent for a sterile, non-pyrogenic extracorporeal circuit is maintained.

A physical check of all blood line connectors (dialyzer, accessory ports, heparin syringe, etc.) should be confirmed before attachment to the patient and starting the blood pump. Arterial and venous pressure alarms should be appropriately set to detect excess pressures that could cause line separation.

A visual inspection of the blood tubing and blood tubing connectors for damage, leaks, and whole or partial occlusions, etc., should be performed.

Assure that the air/foam detector is in the proper position and armed.

At the time of setup, all connectors and lines should be inspected by the staff member to ensure absence of kinks, partial occlusions, or other physical damage.

All connections should be double checked for secure fitting.

B. Patient Monitoring

The following should be part of regular intradialytic monitoring and may be related to malfunction or improper use of blood lines:

- Acute blood loss (obvious source of blood spill, shock, vomiting, convulsions) that may be the result of extreme pressures in the blood circuit or poor connections, resulting in disconnection of connectors or other leaking from the blood lines.
- A pyrogen reaction (shaking chills, increase in patient temperature of more than 1°C during treatment) or septicemia (identified through blood cultures) may be the result of an improperly sterilized blood line.
- Air embolism (evidence of air in blood lines and entering patients, chest pain, dyspnea, coughing, cyanosis, visual problems, confusion, coma) that may be the result of the disconnection of specific connectors in the blood line set or air entering through a damaged component.

C. Other Monitoring

An incoming materials log should be maintained. Included in this log should be the identification of the product, delivery date, lot number, and person receiving the products. Confirmation that the product is labeled as ordered should be performed. Any product with labels not intact or incorrectly labeled should not be accepted.

An annual review of all policies and procedures related to blood tubing handling should be performed.

All incidents or adverse occurrences related to blood tubing should be documented and reported at the monthly quality assurance meetings.

D. Prevention

Follow exactly all of the manufacturer's instructions for use.

Transducer Protectors

A. Daily Monitoring

Visually confirm that the packaging and caps are intact before use.

Visually confirm that the transducer protector does not contain water or blood at the beginning of treatment and periodically throughout treatment.

Assure that the transducer protectors are compatible with specific dialysis delivery systems.

Double check that connections of the transducer protector to the dialysis delivery system and to pressure monitoring tubing of the blood tubing set are secure.

Before use, the staff member setting up the system should confirm that the transducer protector does not have occluded ports, cracks, or any other physical damage.

B. Other Monitoring

An incoming materials log should be maintained. This log should include the identification of the product, delivery date, lot number, and person receiving the product. Confirmation that the product is labeled as ordered should be performed. Any products with labels that are not intact or that are incorrectly labeled should not be accepted.

An annual review of all policies and procedures related to transducer protectors should be performed.

All incidents or adverse occurrences related to transducer protectors should be documented and reported at the monthly quality assurance meetings.

C. Prevention

Follow exactly all of the manufacturer's instructions for use.

Single Needle Equipment

A. Daily Monitoring

During setup, check that the blood clamp and/or blood pump occludes tubing and interrupts flow.

Confirmation that pressure alarms are set according to manufacturer's specifications.

Calculate the stroke volume at the beginning of treatment and confirm that the stroke volume fits within the prescription and the manufacturer's recommendations.

B. Monthly Monitoring

An annual review of all policies and procedures related to single needle equipment should be performed.

All incidents or adverse occurrences related to single needle equipment should be documented and reported at the monthly quality assurance meetings.

C. Prevention

All preventative maintenance required by the manufacturer must be performed to assure ongoing function, patient safety, and treatment effectiveness.

Conductivity Meters (Independent Reference Meters)

A. Daily Monitoring

Most conductivity meters include a "self-test" function of electronic circuitry and battery. If the user's meter is equipped with this function, the "self-test" should be performed before every use.

Before using a meter to recalibrate a dialysis delivery system, the conductivity meter should be checked, according to manufacturer's instructions, with a standard conductivity solution. That conductivity should be entered on a regular conductivity meter log (see Form 1 at the end of this chapter).

Manufacturers of some conductivity meters recommend that proper calibration of the meter be confirmed with standard solution daily.

B. Monthly Monitoring

On no less than a monthly basis, conductivity meter calibration should be confirmed using a Standard Conductivity Solution following manufacturer's instructions. That conductivity reading should be entered onto a Conductivity Meter Log (Form 1).

To ensure that all monitoring described above is performed, systems checks should be included on a "Daily Patient Treatment Record" (see Form 2) or a "Daily Dialysis System Checklist" (see Form 3) which requires that the staff members setting up the dialysis delivery system check off all vital functions of the procedure on a specific form before initiation of treatment.

Review all logs and monitoring instruments relating to these pieces of equipment at the monthly quality assurance meeting. Any data outside of acceptable limits must be addressed. Trend analysis (see Form 4) of parameters related to the instruments' function should be a part of this review.

Home Dialysis Monitoring

All of the monitoring procedures described above should be performed by the home dialysis patient, home dialysis support personnel, and reviewed by the medical director, as appropriate.

Form 1
Conductivity Meter Calibration Check Log

Today's Date	Meter Serial Number	Date Last Checked	Standard Solution Conductivity	Meter Conductivity

FORM 2

PATIENT DAILY DIALYSIS RECORD
XYZ DIALYSIS CENTER

Date _____ **Patient Name** _____

DIALYSIS PRESCRIPTION

Dialyzer	_____	Time on	_____	Dry weight	_____
QB _____	QD _____	Actual time off	_____	Predialysis weight	_____
Heparin Rx:		Rx time off	_____	Desired weight loss	_____
Prime	_____	Rx dialysis length	_____	Postdialysis weight	_____
Infusion	_____	Actual dialysis length	_____	UF rate	_____
Time off	_____	Expected clotting time	_____		
Dialysate Rx	_____	Actual clotting time	_____		

DIALYSATE		MACHINE CHECKS		REUSE	
Conductivity	_____	Blood leak alarm	_____	Patient ID	_____/_____
pH	_____	***Air foam detect (check)***	_____	Use number	_____
Temperature	_____	***Air foam detect (armed)***	_____	Dialyzer structure/aesthetic	_____
Special Rx	_____	UF check	_____	Germicide dwell	_____
Mixed	_____	***Art/Ven press set***	_____	Germicide presence	_____
Dispensed	_____	Machine number	_____	Germicide absence	_____

FORM 3
DIALYSIS SYSTEMS CHECKLIST

Pre-Dialysis	
Absence of germicide confirmed	
Dialyzer inspected (structural, etc.)	
Dialyzer primed (no air)	
Correct concentrate (check label)	
Adequate quantity of concentrate in jug	
Correct conductivity confirmed	
Correct pH confirmed (if applicable)	
Dialysate flow confirmed	
Bubble trap levels set	
Blood leak detector checked	
Bypass mode checked	
Air/foam detector checked	
Air/foam detector armed	
Arterial and venous pressure limits set	
UF controller checked (if applicable)	
Weight recorded	
Ultrafiltration calculated and set	
Vital signs done and recorded	
Dialysate temperature	
Post-Dialysis	
Weight recorded	
Vital signs done and recorded	
Unusual events charted	
Machine cleaned and disinfected	

Patient Name _____ Date _____

Machine type _____ Machine No. _____

This checklist is meant as a reminder to the patient care giver to perform the vital functions necessary for safe and effective hemodialysis. It does not replace any ordinary records or charting which should be done (i.e., daily dialysis records/flow sheets, system logs, etc.).

CONDUCTIVITY METER TREND ANALYSIS

FORM 4

DATE	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
CONDUCTIVITY												
Meter #1												
Standard solution conductivity												
Meter conductivity												
Standard solution pH												
Meter pH												
Actual temperature												
Meter temperature												
Recalibration required												
Meter #2												
Standard solution conductivity												
Meter conductivity												
Standard solution pH												
Meter pH												
Actual temperature												
Meter temperature												
Recalibration required												
Meter #3												
Standard solution conductivity												
Meter conductivity												
Standard solution pH												
Meter pH												
Actual temperature												
Meter temperature												
Recalibration required												
INCIDENTS												

Chapter 8

ANTICOAGULATION

CONTENTS

Chapter 8

Anticoagulation

BACKGROUND

Hemodialysis treatment is dependent upon the free flow of blood over the dialysis membrane and through the arterial and venous blood tubing. Blood, however, has a normal tendency to clot when it comes in contact with a foreign surface such as the extracorporeal circuit of the artificial kidney. It is necessary to prevent this clotting during dialysis. The purpose of anticoagulation during hemodialysis is to prevent blood clotting in the extracorporeal circuit.

There are a variety of anticoagulation techniques that are employed for hemodialysis:

Systemic: Systemic heparinization prolongs the patient's clotting time, preventing thrombus formation in the extracorporeal circuit. This is achieved by continuous or intermittent infusion of heparin throughout the dialysis treatment. A heparin loading dose, or bolus, is usually given prior to the initiation of dialysis. During dialysis, heparin is injected into the arterial blood line using either an infusion pump to deliver a continuous amount of heparin throughout the dialysis, or periodic intermittent injections of heparin into the extracorporeal circuit.

Regional Heparinization: This method of anticoagulation is used when the patient is at risk for hemorrhage or where systemic anticoagulation is contraindicated by the patient's condition. Regional heparinization is the continuous infusion of heparin into the the arterial bloodline assuring anticoagulation of the extracorporeal circuit. At the same time, protamine sulfate solution is infused into the venous bloodline. This neutralizes the effect of heparin before the blood is returned to the patient. Disadvantages associated with regional heparinization include the difficulty of simultaneous dosage determination for both heparin and the protamine sulfate as well as the potential for post-therapy heparin-rebound, resulting in hypercoagulability.

Low Dose Heparinization: An alternative to regional heparinization is minimal, controlled, tight or low dose heparinization. The objective is to administer, either continuously or intermittently, just enough heparin systemically to slightly elevate the patient's clotting time so that the dialyzer does not clot. This requires close monitoring by frequent clotting time measurements.

Regional Citrate Anticoagulation: This method of anticoagulation infuses sodium citrate into the arterial bloodline to complex calcium and prevent clotting in the extracorporeal circuit. Calcium is infused into the venous bloodline to restore serum calcium to normal limits. The dialysate used must be calcium-free. The patient must be closely monitored for hypocalcemia and citrate toxicity.

Heparin-free: Using high blood flow rates and intermittent saline flushes of the dialyzer throughout dialysis, dialysis can be achieved using no heparin or other anticoagulant.

There are also a variety of techniques for monitoring anticoagulation. They are:

- Activated clotting time (ACT)
- Lee-White clotting time (LWCT)
- Whole blood activated partial thromboplastin time (WBPTT)
- Plasma partial thromboplastin time (PTT)

To determine an effective anticoagulation regimen for the patient, three key patient parameters must be assessed: normal or baseline clotting time, response and sensitivity to heparin, and elimination rate of heparin.

RISKS AND HAZARDS

The most common complication reported in the literature pertinent to anticoagulation therapy is hemorrhage. The incidence of post dialysis bleed-

ing secondary to dialysis-related heparinization has been reported to be as high as 21%.

The risk of hemorrhage is so significant that heparin infusion is contraindicated in patients with pre-existing bleeding tendencies such as hemophilia, jaundice, post-operative oozing, threatened abortion, bacterial endocarditis, suspected intracranial hemorrhage, inaccessible ulcerative lesions especially of the gastrointestinal tract, heparin hypersensitivity, and shock.

Several factors such as fever, drugs like digitalis and tetracycline, nicotine, and antihistamines affect the activity of heparin. One might even expect that the same patient may react differently at different times to the same dose of heparin. The variables inherent in the drug also effect patient response including commercial source, molecular weight, and potency from lot to lot. The effectiveness of heparin can be altered when in contact with pH levels (dialysate) exceeding a normal range. It has also been reported that heparin tolerance varies not only in different individuals, but in the same individual during surgical procedures.

EXISTING GUIDELINES

The best guidelines to follow must be those of the manufacturer's instructions for use. This includes instructions for use of the drugs as well as the equipment related to drug administration and anticoagulation monitoring. Current literature, including anticoagulation research, must be reviewed and facility policies and procedures updated accordingly.

QUALITY ASSURANCE FOR ANTICOAGULATION

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 hemodialysis anticoagulation. 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, equipment, disposables, and supplies.

Comprehensive policies and procedures must also address the interrelationships of anticoagulation, the patient, and the dialyzer. The risks involved must be clearly identified and considered, and appropriate safety measures and preventative systems developed.

Policies and procedures must also address safe and effective operation of the equipment used to deliver and monitor anticoagulation during dialysis:

- drug inventory, handling, and use
- complication management
- basic technical operation
- set up and use of the equipment and related components
- safety checks
- routine patient monitoring
- preventative maintenance
- cleaning and disinfection
- troubleshooting and repair
- record keeping
- patient education

Staff Training and Continuing Education

Role descriptions should include all personnel responsibilities for handling and use of anticoagulants, infusion pumps, monitoring devices, daily or per-treatment safety and other system checks, recordkeeping pertinent to anticoagulation, and other similar responsibilities.

Staff training should be a well-defined and organized program. Content should be clearly defined for the learner and based on behavioral objectives. The behavioral objectives can be used to accurately and objectively measure learning. At the end of the session(s), the instructor should confirm by a written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. The results of the testing process should be documented and placed in the employee's personnel file.

Comprehension of the purpose and function of anticoagulation requires a basic understanding of normal physiologic concepts, as well as responses associated with uremia and the hemodialysis therapy. Content should include principles of dialysis, patient response to therapy and related complications, aseptic technique, monitoring, care and patient education.

Need for further education such as inservices or intensive educational sessions can be determined from the ongoing quality monitoring process and the continuous staff performance appraisal process. When problems are identified, all staff should be made aware of the problem and be involved in its solution; this nearly always includes problem-specific continuing education.

The medical director of the dialysis facility must authorize that the individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual review has been performed.

Monitoring and Evaluation

The following section provides a summary of recommendations for monitoring that should be performed to enhance safety and reduce the level of risk of patient injury due to incidents related to malfunction and/or improper use of equipment related to anticoagulation:

A. Daily Monitoring

1. Confirm anticoagulation goals as prescribed.
2. Confirm vial contents and strength.
3. Confirm the use of aseptic technique in handling the device.
4. Inspect syringes and connectors for damage, leaks, and whole or partial occlusions. All connections should be double checked for secure fit.
5. Administer the drug within the time frame specified by the manufacturer or as close to syringe preparation as possible. The individual preparing the drug for infusion must administer the drug.
6. Monitor the anticoagulation level until stabilized. After stabilization, monitor as per physician directive or whenever problems are suspected.

B. Monthly Monitoring

1. Confirm proper calibration of the monitoring device using standard provided by the manufacturer.
2. Confirm proper calibration of infusion pumps following the manufacturer's recommendations.
3. Complete monitoring documentation of all preventative maintenance to assure that it is performed within the scheduled timeframe and according to the manufacturer's recommendations.

C. Patient Monitoring

The anticoagulation regimen should be based on the clotting time results, patient's condition, patency of the extracorporeal circuit, and response to previous anticoagulation. The patient should be assessed by reviewing hematocrit, clotting studies, and history of complications per facility policy. Anticoagulant administered and results of monitoring should be documented on the patient's daily dialysis record (see Form 1).

D. Home Dialysis Monitoring

All of the monitoring procedures described above should be performed by the home dialysis patient, home dialysis support personnel, and reviewed by the medical director as appropriate.

E. Other Monitoring

1. Trend monitoring and analysis of various complications, including incidents or adverse occurrences related to anticoagulation should be conducted.
2. Trend monitoring and analysis of monitoring equipment can be documented using Form 2.

F. Prevention

The patient should be advised as to the side effects of heparin therapy and should be encouraged to report any unusual changes prior to the initiation of each dialysis. The patient should also be informed of how to prevent hemorrhaging or bleed-

ing after dialysis and after the patient has left the dialysis unit. The patient should be informed of the rationale for anticoagulation therapy including its purpose, route, dosage, side effects, and monitoring procedures. The patient should understand the signs and symptoms and/or conditions to report regarding complications of coagulation therapy.

REFERENCES

1. KESHAVIAH, P., LUEHMANN, D., SHAPIRO, F. and COMTY, C. *Investigation of Risks and Hazards Associated with Hemodialysis Systems* (Technical Report, Contract #223-78-5046). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/Bureau of Medical Devices, Silver Spring, MD (1980).

2. LINDSAY, R.M. *Practical Use of Anticoagulants.* in Replacement of Renal Function of Dialysis. William Drukker, Frank M. Parsons, and John F. Maher, eds. Martinus Hijhoff, The Hague, The Netherlands (1988).

Note: Additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic .

FORM 1

PATIENT DAILY DIALYSIS RECORD
XYZ DIALYSIS CENTER

Date _____ **Patient Name** _____

DIALYSIS PRESCRIPTION

Dialyzer	_____	Time on	_____	Dry weight	_____
QB _____	QD _____	Actual time off	_____	Predialysis weight	_____
Heparin Rx:		Rx time off	_____	Desired weight loss	_____
Prime	_____	Rx dialysis length	_____	Postdialysis weight	_____
Infusion	_____	Actual dialysis length	_____	UF rate	_____
Time off	_____	***Expected clotting time***	_____		
Dialysate Rx	_____	***Actual clotting time***	_____		

DIALYSATE		**MACHINE CHECKS**		**REUSE**	
Conductivity	_____	Blood leak alarm	_____	Patient ID	_____/_____
pH	_____	Air foam detect (check)	_____	Use number	_____
Temperature	_____	Air foam detect (armed)	_____	Dialyzer structure/aesthetic	_____
Special Rx	_____	UF check	_____	Germicide dwell	_____
Mixed	_____	Art/Ven press set	_____	Germicide presence	_____
Dispensed	_____	Machine number	_____	Germicide absence	_____

FORM 2

ACTIVATED CLOTTING TIME METER CALIBRATION LOG

Date	Meter Serial No.	High Standard ACT	Meter Low ACT	Low Standard ACT	Meter Low ACT

Chapter 9

VASCULAR ACCESS DEVICES

CONTENTS

Chapter 9

Vascular Access

Vascular access, for purposes of hemodialysis, is the patient's life-line. It has been stated that each time there is a real or potential threat to the patient's access, the patient experiences a sense of impending death. (Lundin, 1989). For patients with multiple vascular access problems, this experience can be extraordinarily stressful, limiting the sense of well being, quality of life, and certainly rehabilitation.

TECHNICAL DESCRIPTION OF DEVICES

To perform long-term hemodialysis, reliable access to the blood circulation is required. A fully functional and patent access is imperative. Access can be achieved in a number of ways. For each of the following accesses, there are various modifications, types and brands.

External Arteriovenous Shunt. This consists of two rigid Teflon® tips implanted in an artery and a vein with Silastic® tubing attached to the Teflon tips in the vessels. Each piece of the Silastic tubing is brought to the outside of the skin and connected together for continuous blood flow. When used for hemodialysis, the two Silastic tubings are separated and attached to the two bloodlines leading to and from the dialyzer.

Although not commonly used today, the shunt can be used as a temporary access while the patient is awaiting maturation of an internal fistula, or for acute or reversible renal failure.

Internal Arteriovenous Fistula. The fistula is created with a surgical anastamosis between an artery and a vein. This allows increased blood flow through the vein, causing engorgement and enlargement. When the vein has had an opportunity to mature, large bore needles are inserted into the vein to provide blood access for hemodialysis. The fistula is the ideal access for long-term hemodialysis.

Internal Arteriovenous Graft. This is the surgical implant of a biologic or artificial graft. The ends of the graft are surgically attached to an artery and a vein. Large bore needles are inserted into the graft to provide blood access. The graft can be used for long-term hemodialysis. There are various configurations of the surgical anastomoses.

Temporary Access. A catheter can be used on a short term or temporary basis for vascular access. It is frequently used while a more permanent access can be created or when the patient may be waiting for a different type of renal replacement therapy such as transplantation. Long-term use of the temporary access is not uncommon today. The locations for placement of these catheters are usually the subclavian vein, the femoral vein, and occasionally the jugular vein.

RISKS AND HAZARDS

The literature has reported several problems associated with vascular access types and devices. It has been noted that the primary reason for hospitalization of the hemodialysis patient is related to the vascular access.

The risks and hazards identified in the literature can be classified into the following categories:

Mechanical/technique. These are the incidents which pertain to the cannulation or venipuncture techniques used and the reports regarding performance of the various devices used for access, including flow and long term durability.

Infectious complications. There are numerous incidents related to various microbiological organisms that have resulted in serious infections and are related to surgical techniques, venipuncture or handling techniques.

In the manufacturer's literature and the medical device reporting system, the incidents related to vascular access devices can be divided into three categories:

Mechanical. Reports pertaining to mechanical risks or hazards are related to hubs, lines and/or connectors separating from each other before, during, and after treatment. These unexpected disconnections create numerous problems with bleeding, excess vessel trauma, and even death. Also reported are cracks in connectors or tubing, causing blood loss or air infusion leading to air embolus. Other incidents are reported that pertain to kinking of tubing, faulty packaging, etc.

Infection. There are numerous reports of various organisms that have caused patient morbidity or access failure. These organisms were analyzed and found to be due to improper technique in either the handling or use of the device.

Physiological complications. Incidents include aneurysms, thrombus, hemothorax, pneumothorax, infection and sepsis, fibrin deposition, dermatitis from the device material, excessive bleeding around the access site (during and after dialysis), and injury and loss of access due to inappropriate administration of drugs.

EXISTING GUIDELINES

The best guidelines to follow are the manufacturer's instructions for use. Current research related to each particular vascular access device in use within the facility must be reviewed and evaluated for use as a new or modified facility standard.

QUALITY ASSURANCE FOR VASCULAR ACCESS DEVICES

Policies and Procedures

Policies and procedures concerning vascular access devices and supplies as they relate to the hemodialysis therapy must be developed, written, implemented and evaluated. All standards previously described must be incorporated into these policies and procedures.

The policies and procedures should address the purpose and function, use, safety factors, monitoring, preventive measures, patient education, and related documentation. The risks involved must be clearly identified and considered, and appropriate safety measures and preventative systems developed. Specifically, the procedures must address storage and inventory control, use/handling, complication management, anticoagulation therapy, and care post operatively, as well as before, during and after the dialysis treatment.

Staff Training and Continuing Education

Role descriptions should describe all personnel responsibilities for handling and use of vascular access devices. Each responsibility should stem from a specific policy or procedure.

Staff training should be a well-defined and organized process. Content should be clearly defined for the learner and based on behavioral objectives. The behavioral objectives can be used to accurately and objectively measure learning. At the end of the session(s), the instructor should confirm by written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. Test results should be documented and placed in employee's personnel file.

There needs to be comprehension of the purpose and function of each vascular access device being used within the facility and a basic understanding of normal physiological concepts, as well as responses associated with uremia and the hemodialysis therapy. Content should include principles of dialysis, patient response to therapy and related complications, aseptic technique, and, for each access device type, indications for use, advantages and disadvantages, monitoring, care, complications, anticoagulation, patient education and venipuncture/handling technique. The interrelationships of each device and the delivery system, dialysate, dialyzer, etc. must be incorporated into the training process.

Need for further education such as inservices or intensive educational sessions can be determined

from the routine quality assurance monitoring process and the ongoing staff performance appraisal process. When problems are identified, all staff should be made aware of the problem and be involved in its solution; this nearly always includes problem specific continuing education.

The medical director of the dialysis facility must authorize that the individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual performance evaluation has been performed.

Monitoring and Evaluation

To assure patient safety and device effectiveness, the following monitoring activities are recommended:

A. Daily Monitoring

1. Inspect the device and connectors for damage, leaks, and whole or partial occlusions, etc. All connections should be double checked for secure fitting.
2. Verify access patency and flow direction.
3. Confirm the use of aseptic technique in handling the access device.
4. Monitor anticoagulation therapy until stabilized.
5. Monitor arterial and venous pressures.
6. Monitor blood flow rate.
7. Assess for signs and symptoms of complications.
8. It may become apparent that the prescribed treatment is not being delivered as evidenced by:
   a. Increase in patient's blood chemistries such as BUN, creatinine, potassium, etc.
   b. Percent reduction in urea significantly less than prescribed.
   c. Apparent change in flow and/or pressure.

In such a case the patient's vascular access should be evaluated for recirculation.

Recirculation may be calculated by direct measurement according to the following formula:

$$\% \text{ recirculation} = \frac{P - A}{P - V} \times 100$$

where,

P = peripheral concentration (BUN)

A = sample from arterial blood line (BUN)

V = sample from venous bloodline (BUN)

B. Monthly Monitoring

1. Complications associated with venipuncture.
2. Hospitalizations associated with vascular access infections, revisions, or other related complications.

C. Patient Monitoring

Continuous assessment for signs and symptoms of vascular access complications:

1. Occlusion, mechanical failure
2. Thrombosis
3. Infection
4. Skin erosion
5. Dislodgement
6. Hemorrhage
7. Aneurysm; psuedoaneurysm
8. Arterial insufficiency, steal syndrome

D. Home Dialysis Monitoring

All of the monitoring procedures described above should be performed by the home dialysis patient, home dialysis support personnel, and reviewed by the medical director as appropriate.

E. Other Monitoring

1. Trend monitoring and analysis of various complications, including incidents or adverse occurrences related to venipuncture.
2. Trend monitoring and analysis of hospitalizations due to vascular access devices.
3. Trend monitoring and analysis of the reliability of a vascular access device.

F. Prevention

1. Follow all of the manufacturer's instructions for use and all facility policies and procedures.
2. Conduct and validate patient and staff education.
3. Develop protocols for medication administration using vasucular access devices.

REFERENCES

1. KESHAVIAH, P., LUEHMANN, D., SHAPIRO, F. and COMTY, C. *Investigation of Risks and Hazards Associated with Hemodialysis Systems* (Technical Report, Contract #223-78-5046). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/Bureau of Medical Devices, Silver Spring, MD (1980).

2. BELL, P.R.F. and VEITCH, P.S. *Vascular Access for Hemodialysis* in Clinical Dialysis. A.R. Nissenson, R.N. Fine and D.E. Gentile, eds. Appleton-Century-Crofts, Norwalk, CT (1990).

3. HARTIGAN, M. *Circulatory Access for Hemodialysis* in Core Curriculum for Nephrology Nursing. L.E. Lancaster, ed. American Nephrology Nurses' Association, Pitman, NJ (1990).

4. LUNDIN, P. Personal Communication. 1980.

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic.

Chapter 10

HEMODIALYZER REUSE

CONTENTS

Chapter 10

Hemodialyzer Reuse

TECHNICAL DESCRIPTION OF PROCESS

Hemodialyzer reuse is the practice of using the same dialyzer for multiple dialyses without replacement of membranes or other surfaces in contact with blood. This is accomplished utilizing restoration techniques including cleaning the blood surfaces, followed by disinfection or sterilization.

Dialyzer reprocessing can be performed manually or through use of an automated, commercially available "reprocessing system." Most automated reprocessing systems automatically rinse the dialyzer of residual blood and blood products, perform some manner of "cleaning" process, test the dialyzer for leaks and performance parameters, and fill the dialyzer with an appropriate concentration of a germicide. Some automated systems also provide data storage and labeling functions automatically.

A variety of materials are commonly used in dialyzer reprocessing including cleaning agents, germicidal agents, and purified water used to dilute both of the above. Commonly used cleaning agents include hydrogen peroxide, sodium hypochlorite, reverse ultrafiltration of water from the dialysate compartment into the blood compartment and out through the blood ports, and pressurized water. Germicides used for the high level disinfection required for dialyzer reuse include formaldehyde, peroxyacetic acid (trade name Renalin®), glutaraldehyde (trade names Sporicidin®, Nephrex®, Cidex®) and others.

In 1990 the FDA produced and released a videotape entitled *Reprocessing of Hemodialyzers* which has been distributed to all U.S. dialysis facilities.

RISKS AND HAZARDS

The literature prior to 1980 includes reports of patient complications attributed to problems with dialyzer reuse. The problems were due to user error with an established procedure or the use of an inappropriate procedure. The literature describes patient experiences with pyrogen reactions, boluses of toxic chemicals, decreased adequacy of dialysis, blood loss, and potential immunological problems.

The 20 incidents that have been reported since 1980 are summarized in Appendix A.

- Fifteen incidents were related to pyrogen reactions and/or bacteremia, due to inappropriate water treatment. The causes included use of endotoxin-contaminated water and too low a concentration of germicide used to disinfect the dialyzers.
- Four incidents involved patient reactions to residual germicide.
- One case was related to excessive ultrafiltration rate.

Many of the incidents could have been avoided through simple tests, observations, and/or quality control procedures implemented in the dialysis facilities.

EXISTING GUIDELINES

Unlike many other technical areas of hemodialysis, hemodialyzer reuse has comprehensive standards of practice. The practice is regulated by HCFA according to 42 Part 405.2150. The regulation, incorporating the Association for the Advancement of Medical Instrumentation (AAMI) Recommended Practice for Reuse of Hemodialyzers, contains standards and conditions for safe and effective hemodialyzer reuse and reprocessing, enforceable as conditions of Medicare coverage.

Table 1 reviews the AAMI Recommended Practice for Reuse of Hemodialyzers. The Recommended Practice addresses facility requirements, reuse equipment, cleaning and disinfection methods, labeling, preparation for multiple use, controls, and patient aspects.

Several states, including California, Colorado, Georgia, and Washington DC, also have regulations pertinent to the reuse of hemodialyzers.

QUALITY ASSURANCE FOR HEMODIALYZER REUSE

Policies and Procedures

Policies and procedures concerning the reuse of hemodialyzers must be developed, written, implemented, and evaluated. All standards and regulations previously described must be incorporated into these policies and procedures. Specifically, the policies and procedures must address disposables, equipment, personnel, practice, and the patient.

Comprehensive policies and procedures must also address the interrelationships of reuse, the dialyzer, and the delivery system. The risks involved must be clearly identified and considered, and appropriate safety measures and preventative systems developed and incorporated.

Specifically, policies and procedures must assure the safe and effective operation of a reuse program:

A. Reprocessing Equipment:

- Equipment operation
- Basic technical operation
- Setup and use of the equipment and related components
- Safety checks
- Preventive maintenance
- Cleaning and disinfection
- Troubleshooting and repair

B. Mixing and storage of cleaning agents and germicides.

C. Testing for presence or absence of germicide; effectiveness of germicide.

D. Labeling.

E. Recordkeeping.

F. Storage of reprocessed dialyzers.

G. Preparation of the reprocessed dialyzer for use.

H. Dialyzer performance validation.

I. Patient monitoring.

Staff Training and Continuing Education

Role descriptions should include all personnel responsibilities for the operation, preventative maintenance, repairs of reprocessing equipment, daily safety and/or system checks, appropriate recordkeeping, acceptance of incoming supplies and inventory control, performance and safety checks of reprocessed dialyzers, and other similar responsibilities. Each responsibility should stem from a specific policy or procedure.

Staff training should be a well-defined and organized process. Content should be clearly defined for the learner and based on behavioral objectives. These objectives can be used to accurately and objectively measure learning. At the end of the session(s), the instructor should confirm by written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. Test results should be documented and placed in employee's personnel file.

Comprehension of reuse principles and practices requires a basic understanding of normal physiological concepts, as well as the basic principles of hemodialysis therapy. Content should include the facility's specific reprocessing procedures, documentation requirements, aseptic technique, collection and handling of specimens, risks and hazards of multiple use, consequences of not performing tasks correctly, risks and hazards associated with toxic substances used in the reprocessing procedure, emergency actions, and principles of infection control.

Need for further education such as inservices or intensive educational sessions can be determined from the routine quality assurance monitoring process and the ongoing staff performance appraisal process (see Forms 1, 2, and 3). When need for improvement or problems are identified, all staff should be made aware of the problem and be involved in solution identification and implementation. This nearly always includes problem specific continuing education.

The medical director must approve the written curriculum for training. The medical director of the facility, or his or her designeee, must verify that the individual has successfully completed the initial education and the training program. The medical director is also responsible for assuring that an annual performance appraisal has been performed.

Monitoring and Evaluation

This section provides a summary of recommendations for monitoring and evaluation that should be performed to enhance the safety and reduce the level of risk of patient injury due to incidents related to the reuse of hemodialyzers, and to assure the efficacy of dialyzers that have been reprocessed.

A. Daily Monitoring

1. Dialyzer performance must be validated during the reprocessing procedure by total cell volume (TCV) and/or membrane resistance as determined by in vitro ultrafiltration rate. Alternatively, if the facility performs urea kinetic modeling the "actual dialyzer clearance" data from the kinetic modeling program may be correlated with TCV. Documentation of the information/test results is required (see Form 4).

2. A test of membrane integrity (leak rate) for each dialyzer need be done only if the leak rate of the reprocessed dialyzers is greater than the leak rate of new dialyzers. If the reprocessing equipment includes such a test, it should certainly be a routine monitoring activity (see Form 4).

3. The person performing the dialyzer reprocessing, the staff member setting up a reprocessed dialyzer and, when possible, the patient, should verify that the dialyzer does not appear to be physically damaged, the reuse label on the dialyzer is complete and legible, the headers of the dialyzer do not contain any large quantities of clotted blood or other materials, and that the hollow fibers appear to be relatively free of any blood product (see Forms 4 and 5).

4. A statistically significant number of dialyzers should be checked for concentration of germicide adequate for effective high level disinfection before "rinse out" prior to clinical use (see Form 5).

5. Verify by the time and date the dialyzer was filled with germicide, noted on the dialyzer label, that the "dwell time" for the germicide has been at least the minimum recommended by the manufacturer (see Form 5).

6. Prior to initiating dialysis, staff, and the patient when possible, should confirm that the dialyzer about to be used is the patient's dialyzer. This can be accomplished by comparing patient name and medical record number (or other secondary identification) on the dialyzer label with the same information on the patient's chart (see Form 5).

7. Staff should test that the level of residual germicide (absence of germicide) after "rinse out" and before clinical use of the dialyzer is at or below acceptable levels (see Form 5).

8. Any tests recommended by the manufacturer to confirm proper functioning of the reuse system must be performed (see Form 1).

B. Monthly Monitoring

1. Confirm that all water used in the reprocessing program (dialyzer rinsing and cleaning, dilution of germicides and cleaning chemicals) meets AAMI microbiological requirements. Not more than 200 colony-forming units per ml of water and/or not more than 1 ng/ml bacterial lipopolysaccharide (endotoxin), as measured by Limulus amoebocyte lysate assay (LAL), should be present.

   It should be noted that the choice as to which test (bacterial counts or LAL) to perform is one that should be carefully evaluated. For example, with certain water treatment system configurations, performing only bacterial counts may yield acceptable results, while utilizing concurrent LAL testing would indicate a potential problem. The simpler bacterial count methodology may not always identify a problem, and could place patients at risk.

2. If formaldehyde is used in the dialyzer reprocessing program, formaldehyde vapors should be monitored at least monthly and whenever indicated by discomfort of personnel or patients.

Additionally, OSHA has set mandatory maximum formaldehyde levels:

- 8-hour time weighted average (TWA) exposure limit = 1 ppm

- 15 minute short-term exposure limit (STEL) = 2 ppm
- Action level (AL) = 0.5 ppm in 8 hour TWA

See Chapter 12 for a further dicsucssion on OSHA Regulations.

C. Patient Monitoring

1. Routine blood chemistries may provide an indication of the effectiveness of the reuse procedure and subsequent dialyzer performance.
2. Routine intradialytic monitoring of the patient's physiological parameters and symptomotology during the dialysis treatment can provide indications of adverse events related to reuse. A few of the symptoms seen are:
   a. Hypotension or hypertension, related to improper ultrafiltration due to change in dialyzer performance characteristics.
   b. Pyrogen reaction (shaking chills, increase in patient temperature of more than 1°C during treatment) or septicemia (identified through blood cultures), from improper disinfection of the dialyzer or endotoxin in the dialyzer.
   c. Acute blood loss (obvious source of blood spill, shock, vomiting, convulsions), from membrane damage related to dialyzer reprocessing
   d. Pain around vascular access site, respiratory symptoms, and other indications of toxic or allergic reaction, caused by incomplete removal of the germicide from the dialyzer before use.
   e. Increase in the patient's requirements for anticoagulation, related to excess clotting in reused dialyzers.

D. Home Dialysis Monitoring

When reuse is performed at home, all of the monitoring procedures described above should be performed by the home dialysis patient, home dialysis support personnel, and reviewed by the medical director.

E. Other Monitoring

1. All safety equipment and supplies (protective equipment and clothing, emergency equipment, spill control supplies, etc.) should be inspected to confirm usability and proper condition (see Form 4).
2. Trend analysis, performed by the quality assurance committee, should include patient adverse reactions such as fever, chills, improper ultrafiltration, unexpected changes in BUN and creatinine, incident reports, small molecule clearances, levels of toxic chemicals, other dialyzer failures (leaks, structural damage, etc.), equipment maintenance, and repair logs (see Form 6).
3. Performance appraisal of all personnel participating in the reuse program should be performed.
4. An annual review of facility policies and procedures for applicability to current best practices and current standards and regulations must be completed.

F. Prevention

All equipment must be free of defects that may be a potential hazard to patients or personnel. An established preventative maintenance program must be implemented and evaluated.

Before equipment is placed back in use (following maintenance or repair), confirmation must assure that all aspects of the device are functioning according to manufacturers' specifications and procedures.

Water quality for all aspects of the reuse process must be tested and evaluated to assure compliance with AAMI standard and federal regulation.

All components of the reprocessing equipment must be tested and safety parameters set prior to use.

G. Purchasing Guidelines

Any dialyzer reprocessing system being considered for use should comply with the federal regulations. which incorporate the AAMI Recommended Practice for Reuse of Hemodialyzers. Any state or local regulations which apply for the specific facility should also be met.

1. Equipment

- Complete instructions for use must be available.
- Instructions for preventative maintenance and repair of the equipment are required.
- Training for facility personnel in equipment use is essential.

- The system should be equipped with indicators that show proper function.
- Specifications for utilities must be met, including water pressure, flow rate, chemical quality, bacterial and pyrogenic quality, electrical and drain requirements.
- Design of the reprocessing system should assure ease of disinfection.
- Upon installation and prior to clinical use, validation of dialyzer performance test methods and tests of concentration of germicide must be performed.
- The system should be designed to minimize any exposure to potentially toxic substances, i.e., closed exhaust system for venting toxic fumes, systems to minimize skin or eye contact with toxic liquids, etc.

2. Chemicals

Two types of chemicals are commonly purchased for dialyzer reprocessing, cleaning agents and germicides.

a. Cleaning Agents

- The facility should validate that a specific cleaning agent does not substantially alter the performance or safety characteristics of the dialyzer.
- All cleaning agents must be compatible with the membrane, the potting material, and the casing of the dialyzer, as well as with all components of the automated dialyzer reprocessing system or manual reprocessing system.
- The facility should obtain or establish, for all cleaning agents used, safe handling practices that are included in the Material Safety Data Sheet (MSDS) for the particular chemical.

b. Germicides

- The facility should assure that the germicide, when used according to the manufacturer's instructions, is at least as effective in killing microbial contaminants as 4% formaldehyde with a minimum contact time of 24 hours and a temperature of at least 20°C.
- The germicide used should be shown to be compatible with the dialyzer membrane, the dialyzer potting material, and the casing, as well as all components of the manual or automated dialyzer reprocessing system.
- The manufacturer of the germicide should provide and/or the facility should develop policies and procedures for minimizing risk related to airborne toxicity, as well as direct skin or eye contact. The Material Safety Data Sheet for the chemical should be obtained.
- Instructions should be obtained for inspection of the chemical upon receipt to assure that it is being delivered in a manner that will render it effective for its intended use.
- Storage and environmental requirements should be specified.
- Information regarding compatibility with other chemicals (other germicides, cleaning agents, etc.) should be obtained.
- Appropriate tests or test kits for determining the concentration of the germicide in solution, as well as the relative presence of the germicide and absence of the germicide, should be developed or secured.

REFERENCES

1. Association for the Advancement of Medical Instrumentation. *Recommended Practice: Reuse of Hemodialyzers.* (AAMI ROH-1986). Arlington, VA (1986).

2. KESHAVIAH, P., LUEHMANN, D., SHAPIRO, F. and COMTY, C. *Investigation of Risks and Hazards Associated with Hemodialysis Systems.* (Technical Report, Contract #223-78-5046). U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration/Bureau of Medical Devices, Silver Spring, MD (1980).

3. *Proceedings of the National Workshop on Reuse of Consumables in Hemodialysis.* J.H. Sadler, ed. Kidney Disease Coalition, Washington, DC (1984).

4. *Hemodialyzer Reuse: Issues & Solutions (an AAMI Analysis and Review).* Association for Advancement of Medical Instrumentation, Arlington, VA (1985).

5. *Reprocessing of Hemodialyzers* (Videotape). Food and Drug Administration. (1990).

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic.

TABLE 1

AAMI RECOMMENDED PRACTICE: REUSE OF HEMODIALYZERS

Records
- Master record
- Reprocessing record
- Equipment maintenance and material quality record
- Personnel health monitoring records
- Complaint investigation records
- Quality assurance and quality control records

Personnel Qualifications and Training
- Qualifications (adequate education and background; repairs by qualified technicians)
- Written curriculum
- Documentation of successful completion of training course

Patient Considerations
- Medical issues: written policies and procedures relative to special patient medical conditions
- Legal review of any Informed Consent; if used, Informed Consent belongs in medical record
- Open physician/patient relationship

Equipment
- Appropriate design, construction, and validations

Water Systems
- Meet specifications of reuse equipment operating at peak load
- Proper disinfection
- Water quality testing

Reprocessing Systems
- Utility requirements specified and followed
- Validation testing initially and periodically
- Written preventative maintenance schedule and log
- Repairs by qualified personnel; test equipment function before reinstituting use

Environmental Control and Safety Equipment
- Validation of adequate function initially, periodically, and after any repair
- Written preventative maintenance schedule and log
- Safety equipment inspected and maintained according to manufacturer recommendations

Physical Plant and Environmental Safety Considerations
- Reprocessing area clean and sanitary; ventilation maintains acceptable level of toxicity
- Specific storage area requirements for new and reprocessed dialyzers
- Tests that do not require special facilities may be done in reprocessing or treatment area
- Personnel protection: gloves, protective clothing, eyeprotection, eyewash stations, spill control equipment, etc.
- Environmental safety: evaluate chemicals for safe storage and handling; written procedures; comply with OSHA and other regulatory requirements.

Reprocessing Supplies
- Specifications and testing: certification by supplier or appropriate testing; proper documentation
- Incoming supply control: log results of quality tests
- Inventory control: first in, first out; proper log

Hemodialyzer Labeling
- Use reprocessed dialyzer on same patient; patient's name on label
- Label prior to first use; update with each reprocessing
- Label and markings should withstand reprocessing and dialysis procedures; should not obscure manufacturer's label or disallow inspection of interior of dialyzer
- Required information on label: patient's name, number of previous uses, date of last reprocessing

Reprocessing
- Handle and transport dialyzers in a clean and sanitary manner
- Rinsing and cleaning: written time limits; effective procedures; water quality requirements; cleaning agents must not adversely affect dialyzer
- Both dialysate and blood sides should be free of visible clotted blood except for a few clotted fibers and small clots around periphery of header

Performance Measurements
- In-vitro small molecule clearance should be actual rejection criterion
- Total cell volume is allright, but validation of correlation with clearance (inital and periodic) is required
- In-vitro ultrafiltration should not change ± 20% manufacturer's specifications (initial and periodic validation)
- Blood path integrity should be validated initially and when any changes are made in process
- Leak tests on all dialyzers not required if leak rate is equal to or less than that for new dialyzers

TABLE 1 (cont.)

AAMI RECOMMENDED PRACTICE: REUSE OF HEMODIALYZERS

Germicide

- *Capable of high-level disinfection when tested against highly resistant water microorganisms
- *If formaldehyde is used: 4% for 24hrs at 20°C or demonstrated equivalent
- *Do not mix reactive materials
- *Minimum water quality (microbiological) requirements for dilutent
- *Dialyzer should be filled with disinfectant until effluent is within 10% of original concentration
- *Use disinfected or new caps
- *Testing of concentration of germicide
- *Exterior of dialyzer: clean and use low-level germicide

Inspection

- Dialyzer jacket free of visible blood or foreign material
- *No leaks or cracks
- *No more than a few clotted fibers
- *Headers free of all but a few small peripheral clots
- *Blood and dialysate ports capped with no leakage
- *Label properly filled-out and legible

Disposition of Rejected Dialyzers

- *Policies
- *Proper contamination prevention (of blood-borne pathogens) procedures

Storage

- *If greater than one month, validation of safety and effectivess of dialyzer

Preparation for Dialysis and Testing for Potentially Toxic Residues

- *Visual inspection of dialyzer and label for safety and efficacy
- *Verification of patient identification (two people)
- *Testing for presence of germicide on at least random sample
- *Validation of proper germicide concentration (initially and periodically)
- *Priming procedure and elution of germicide (documented procedure)
- *Testing for residual germicide: written procedure; assure level is below maximum recommended level
- *Rinsing should prevent rebound to inappropriate level (validate)
- *Set-up procedures: maximum waiting time to prevent bacterial problems; verification of germicide dwell time
- *Validated and documented test of residual germicide
- Monitor patient and dialyzer for complications during dialysis; record any problems

Symptoms

- *Measure temperature before and after dialysis; evaluate reprocessing if patient shows fever, chills
- *Evaluate reprocessing if other sypmtoms such as pain in access arm or other unexplained symptoms
- *"Special Incident Report" if problems
- *Dialyzer failures (leaks, excessive deviations from expected performance, etc.) should be documented, investigated, and placed in complaint file

Quality Assurance and Quality Control
QA personnel should:

- *Review and audit master record at least annually
- *Audit complaint invesitgation file and perform trend analysis at least quarterly
- Audit job descriptions, training materials, and documentation of training at least annually
- *Audit compliance with informed consent policy at least annually.
- *Be involved in equipment and supplies specifications and purchases
- *Audit written policies and procedures at least annually, and whenever problems
- *Audit written maintenance and repair policies at least annually
- *Audit physical plant and environmental safety parameters at least quarterly
- *Audit parameters related to reprocessing supplies at least semiannually
- Audit parameters related to hemodialyzer labeling at least quarterly
- *Audit compliance with actual reprocessing technique at least monthly initially, and at least semiannually later; trend analysis should be performed at least quarterly.
- *Audit written procedures regarding QA and QC and verify their implementation at least quarterly
- *Audit results of performance validation

PROCEDURE FOR CONCURRENT MONITORING FORMS:

REUSE LABELING AND RECORDKEEPING (FORM 1)

REUSED DIALYZER PREPARATION FOR USE (FORM 2)

REUSE PHYSICAL PLANT AND ENVIRONMENTAL SAFETY MONITOR (FORM 3)

The purpose of this audit is to monitor technical staff compliance with standard practices and procedures related to the water treatment system. When staff are aware of the importance of the policies and well trained in the procedures, compliance should be very high.

Before the Audit

1. Provide adequate and appropriate inservice to assure total staff awareness and education of all components associated with water treatment for dialysis.
2. Assure staff awareness of all elements of the concurrent audit and how performance will be observed and evaluated.
3. The QA committee specifies the standard (expected percentage compliance) desired for the audit; begin not lower than 85%.
4. Schedule the audit with appropriate personnel (head nurse, charge nurse, chief technician).
5. Make copies of the audit for each auditor/observer.
6. Assign code letters for each staff member to be observed; for example:

   Employee A: Glenn Close
   B: Tom Hanks
   C. William Hurt
   etc.

7. Determine how many staff are to be observed. It is recommend that one auditor should observe no more than three to four staff at one time.
8. Define the length of time for observation. It is recommended that the audit be conducted during peak activity times (daily start-up, shift changeovers, etc.). The time frame should be long enough to observe each staff member completely perform the listed activity.
9. Assign a staff member to perform the audit. Auditor should not be assigned to other responsibilities during the audit.

Perform the Audit

1. On the actual audit sheet, write in the date, auditor's name, patient shift (or time of day), and standard.
2. Read each indicator carefully.
3. Observe staff for actual *performance*. Auditor should not interfere with staff activities, be obtrusive, or preceptibly obvious.
4. Under each staff code letter, write Y for yes if indicator is met, N for no if indicator is not met, or N/A for not applicable, not observed.

   To achieve a Y (yes, indicator was met), staff should be observed with complete compliance for each encounter. For example, for a Y to appear in the "Post-Softener Hardness Done" box, the staff member must perform the test before any patient dialysis is done ***and*** perform the test exactly according to the instructions for use of the test manufacturer ***and*** record the results as per facility policy.
5. Complete all observations within timeframe specified. Assure that each indicator has one response.

After the Audit

1. Under each employee code letter, add total number of Ys and Ns; do not count NAs.
2. For each employee, calculate compliance percentage by dividing the total Ys by the total observations; again, do not count NAs.
3. Calculate total compliance percentage for the audit by dividing total Ys (all employee Ys) by the total observations; do not count NAs.
4. For each indicator, calculate compliance percentage by using the same method as above; again, do not count NAs.
5. Report results to QA committee and clinical management team with additional comments and/or recommendations.

REUSE LABELING AND RECORDKEEPING MONITOR

FORM 1

Date	**Auditor**									
	Station Number	1	2	3	4	5	6	7	8	9	10
	Staff Member (initials)										
FUNCTION											
Reuse machine diagnostics checked and recorded											
Log record completed											
Dialyzers properly labeled											
Dialyzers properly stored											
Predialysis dialyzer check done and recorded											
Predialysis TBV check done and recorded											

Threshold	% Compliant

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

REUSED DIALYZER PREPARATION FOR USE MONITOR

FORM 2

Date	Auditor										
	Station Number	1	2	3	4	5	6	7	8	9	10
	Staff Member (initials)										
FUNCTION											
Verification of patient identification (two people)											
Presence of germicide tested and recorded (observe)											
Aesthetic and structural criteria confirmed											
Proper germicide dwell time confirmed											
Facility germicide rinseout procedure followed											
Absence of germicide tested and recorded (observe)											

Threshold	% Compliant

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

REUSE PHYSICAL PLANT AND ENVIRONMENTAL SAFETY MONITOR

FORM 3

Date	Patient Shift	Auditor									
	Station Number	1	2	3	4	5	6	7	8	9	10
	Staff Member (initials)										
INDICATOR											
Reprocessing area clean and sanitary											
Supplies & devices stored to minimize breakage/contam.											
Separate storage for new versus reused dialyzers											
Storage compliant with fire safety considerations											
Eyewash station available and provides adequate flow											
MSDS for toxic substances posted											
Spill control procedures posted											
Spill control materials available											
Exhaust fan operating during reprocessing											
Environmental testing meets OSHA standard											

Threshold	% Compliant

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

DIALYZER REPROCESSING LOG

FORM 4

Patient Name	Med Rec #	Date	Use #	Dialyzer	New FBV	Test FBV	Clearance	Leak	Time	Initials	Comments	Audit

FORM 5

PATIENT DAILY DIALYSIS RECORD
XYZ DIALYSIS CENTER

Date _____ **Patient Name** _____

DIALYSIS PRESCRIPTION

Dialyzer	_____	Time on	_____	Dry weight	_____
QB _____	QD _____	Actual time off	_____	Predialysis weight	_____
Heparin Rx:		Rx time off	_____	Desired weight loss	_____
Prime	_____	Rx dialysis length	_____	Postdialysis weight	_____
Infusion	_____	Actual dialysis length	_____	UF rate	_____
Time off	_____	Expected clotting time	_____		
Dialysate Rx	_____	Actual clotting time	_____		

DIALYSATE		**MACHINE CHECKS**		**REUSE**	
Conductivity	_____	Blood leak alarm	_____	***Patient ID***	_____/_____
pH	_____	Air foam detect (check)	_____	***Use number***	_____
Temperature	_____	Air foam detect (armed)	_____	***Dialyzer structure/aesthetic***	_____
Special Rx	_____	UF check	_____	***Germicide dwell***	_____
Mixed	_____	Art/Ven press set	_____	***Germicide presence***	_____
Dispensed	_____	Machine number	_____	***Germicide absence***	_____

REUSE PROBLEMS TREND ANALYSIS

FORM 6

DATE	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
BLOOD LEAKS (MEMBRANE)												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												
PYROGEN REACTIONS												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												
AVERAGE NUMBER USES												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												
CLEARANCE D >10%												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												
OTHER INCIDENTS/COMPLAINTS*												
Model #1												
Model #2												
Model #3												
Model #4												
Model #5												
Model #6												

* Attach summary of incident/complaint

Chapter 11

INFECTION CONTROL

CONTENTS

Chapter 11

Infection Control

BACKGROUND

Infection control is a mechanism by which the adherence, colonization, or invasion of an infectious organism is prevented. Infection control is used in dialysis units to prevent patients from acquiring infections specific to the dialysis unit. The purpose of infection control is to ensure the prevention of infections through appropriately applied policies and procedures. Continuous surveillance and other monitoring and evaluation activities assist in identifying factors that may influence the occurrence of infections.

Although the risk to patients and staff in a hemodialysis unit for contact with viral and bacterial infections is quite high, the use and monitoring of carefully developed procedures can significantly limit the degree of risk involved. The Center for Disease Control (CDC) has reported that from 1980 to 1985 attention to infection control has systematically decreased the incidence of Hepatitis B among dialysis patients and staff alike. Infection control procedures in hemodialysis today require isolation of HBV patients. The CDC notes that isolation of HIV patients is not necessary.

Further, the CDC has noted that infections due to contaminated water, dialysate, and/or dialyzers have been significantly reduced as a result of appropriately applied surveillance and control efforts. Infection control-oriented procedures for vascular access venipuncture and other direct invasions to the patient's circulatory system have been shown to successfully protect the patient from exposure to infection.

Each manufacturer describes the infection control strategies that are to be employed for their particular medical device in the directions for use. Within this manual, infection control is addressed for each of these devices in the respective chapters. This particular chapter will focus on the control of blood-borne infections.

In December of 1989 the FDA produced and released a videotape entitled *Infection Control for Hemodialysis* which has been distributed to all dialysis facilities in the United States.

EXISTING GUIDELINES

Throughout the years the CDC has issued and updated blood-borne infection control strategies and precautions (including universal precautions) for the renal dialysis community as well as other health care agencies. The dialysis community has complied with the CDC recommendations over the years as a voluntary standard. Now the Occupational Safety and Health Administration (OSHA) has regulations that would enforce the use of universal precautions as well as other infection control strategies for all of health care.

Federal OSHA Regulation, Subpart Z of 29CFR Part 1910.1030, addresses control of blood-borne pathogens. The regulation specifies facility infection control strategies as follows.

1. Written Plan

It is expected that each employer having employees whose anticipated duties may result in occupational exposure to infectious agents shall establish a written infection control plan designed to minimize or eliminate employee exposure. The plan shall include a determination of that exposure, and the schedule for and method of implementation for each of the following requirements. The plan shall be reviewed and updated as necessary to reflect significant changes in tasks or procedures. The plan shall be made available for inspection by federal and state surveyors.

a. Universal precautions shall be followed.

b. Certain control measures shall be examined and maintained or replaced on a regular schedule to ensure effectiveness. For example, employees shall wash their hands immediately or as soon as possible after the removal of gloves or other personal protective equipment and after hand contact with blood.

c. All personal protective equipment and clothing shall be removed immediately upon leaving the work area and shall be disposed in an appropriately designated area or container for storage, washing, decontamination or disposal.

d. Used needles and other sharps shall not be sheared, bent, broken, recapped or re-sheathed by hand. These needles shall not be removed from the disposable syringes and they shall be discarded in puncture-proof and color-coded containers.

e. Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in the work area.

f. Food and drink shall not be stored in refrigerators, freezers, or cabinets where blood or other potentially infectious materials are stored.

g. All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying and aerosolization of these substances.

2. Personal Protective Equipment

a. When there is a potential for occupational exposure, the employer shall provide and ensure that employees use appropriate personal protective equipment such as but not limited to gloves, gowns, fluid-proof aprons, laboratory coats, face shields or masks and eye protection.

b. The employer shall assure that the appropriate personal protective equipment in the appropriate sizes is readily accessible at the work site or issued to employees. Hypo-allergenic gloves shall be readily accessible to employees who are allergic to gloves normally provided.

c. The employer shall provide for the cleaning, laundering, or disposal of personal protective equipment.

d. The employer shall repair or replace required personal protective equipment as needed to maintain its effectiveness.

e. Gloves shall be worn when the employee has the potential for hands to have direct skin contact with blood or other blood products, mucous membranes, non-intact skin and when handling items or surfaces soiled with blood. Gloves shall be replaced as soon as possible when visibly soiled, torn, or punctured. They shall not be washed or disinfected for reuse. Utility gloves may be disinfected for reuse if the integrity of the glove is not compromised.

f. Masks, eye protection and face shields shall be worn whenever splashes, sprays, droplets or aerosol of blood or other potentially infectious materials may be generated and there is a potential for eye, ear, nose or mouth contamination. Gowns, aprons, and other body clothing shall be worn when the employee has a potential for occupational exposure. The gowns, coats or aprons shall be worn if there is a potential for soiling of clothes with blood or other infectious materials. Fluid-resistant clothing shall be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials.

3. Housekeeping

a. Employers shall ensure that the work site is maintained in a clean and sanitary condition. There will be a written schedule for cleaning and methods of disinfection based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks and procedures being performed.

b. All equipment and environmental and working surfaces shall be properly cleaned and disinfected after contact with blood or other potentially infectious materials. Work surfaces shall be decontaminated with an appropriate disinfectant when surfaces are overtly contaminated after completion of procedures or immediately after any spill of blood and at the end of the work shift. Equipment that may become contaminated with blood or other potentially infectious materials shall be checked routinely and prior to servicing or shipping and shall be decontaminated as necessary. All bins, pails, cans and similar receptacles intended for reuse that have a potential for becoming contaminated with blood shall be inspected, cleaned and disinfected on a regularly scheduled basis. If the contamination is evident they should be cleaned and disinfected immediately. Broken glassware shall not be picked up by hands. It shall be cleaned up using mechanical means. Specimens of blood or other potentially infectious materials shall be placed in a closable, leak-proof container, labeled and/or color-coded accordingly.

4. Infectious Waste Disposal

All infectious waste destined for disposal shall be placed in closable, leak-proof containers or bags that are color-coded or labeled as required. If outside contamination of the container or bag is likely to occur, then a second leak-proof container or bag which is closeable and labeled or color coded shall be placed over the outside of the first and closed to prevent leakage during handling, storage and transport.

All disposal of infectious waste shall be in accordance with applicable federal, state and local regulations. Immediately after use, sharps shall be disposed of in closeable puncture-resistant disposable containers which are leak-proof on the sides and bottom and are labeled or color-coded accordingly. These containers shall be easily accessible to personnel and located in the immediate area of use. They shall be replaced routinely, not allowed to overfill, nor be reused.

5. Laundry

Laundry that is contaminated with blood shall handled as little as possible with a minimum of agitation. Contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in patient care areas. Contaminated laundry shall be placed and transported in bags that are labeled and color coded. The employer shall ensure that laundry workers wear protective gloves and other appropriate personal protective equipment to prevent occupational exposure.

6. Training Program

The training program of the employee shall be provided at the time of initial employment or within ninety days after being hired. At least annually thereafter the employer shall ensure that all employees with occupational exposure participate in the training program. The material should be appropriate in content and vocabulary to the educational level, literacy and language background of the employees The training program shall contain the following elements:

a. a copy of the OSHA regulations and an explanation of its contents;

b. general explanation of the epidemiology and symptoms of blood-borne diseases;

c. an explanation of the modes of transmission of blood-borne pathogens;

d. an explanation of the employer's infection control program;

e. an explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

f. an explanation of the use and limitations of practices that will prevent or reduce exposure to blood borne pathogens including appropriate engineering controls, work practices and personal protective equipment;

g. information on the types, proper use, location, removal, handling, decontamination and/or disposal of personal protective equipment;

h. an explanation of the basis for selection of personal protective equipment;

i. information on the Hepatitis B vaccine including information on its efficacy, safety, hazards (potential side effects), and the benefits of being vaccinated;

j. information on the appropriate actions to take and persons to contact in an emergency;

k. an explanation of the procedures to follow if an exposure incident occurs including the method of reporting the incident and the medical follow-up that will be made available;

l. information on the medical counseling that the employer is providing for exposed individuals and an explanation of the signs and labels and/or color coding required by the various standards within thisregulation.

m. A copy of the facility's universal precautions procedure.

7. Medical Records

The employer shall establish and maintain an accurate record for each employee. The record shall include the name and social security number of the employee, a copy of the employee's Hepatitis B vaccination records and medical records relative to the employee's ability to receive vaccine or the circumstances of an exposure incident. A copy of all results of physical examinations, medical testing and followup procedures as they relate to the employee's ability to receive vaccination or to post-exposure evaluation following an exposure incident should also be included in the medical record.

The employer's copy of the physician's written opinion and a copy of the information provided to the physician as required by the various standards in this regulation are to be included in the medical record. The employer shall assure that the employee medical records are kept confidential and are not disclosed or reported to any person within or outside the work place except as required by law. The employer shall maintain this record for at least the duration of the employment plus thirty years in accordance with Federal Regulation 29CFR 1910.20.

8. Training records

Training records shall include the following information: the dates of the training sessions, the contents or a summary of the training session; the names of persons conducting the training; and the names of all persons attending the training sessions. These records shall be maintained for five years.

The employer shall assure that all records required to be maintained by this section shall be made available upon request. The employee training records required shall be provided upon request for examination and copying to employees, employee representatives, and any state or federal surveyors.

QUALITY ASSURANCE

Policies and Procedures

Policies and procedures pertaining to infection control must be developed, written, implemented, and evaluated. All standards and regulations previously described must be incorporated into the policies and procedures.

Comprehensive policies and procedures must address the interrelationships of the equipment, the people involved and the environment. The risks must be clearly defined and considered, and preventative systems developed and incorporated.

Policies and procedures must assure safe and effective practices:

- Universal precautions
- Housekeeping practices
- Infectious waste disposal
- Laundry disposition
- Medical recordkeeping
- Employee records

Staff Training and Continuing Education

Role descriptions should describe all personnel responsibilities for infection control practices. Each responsibility should stem from a specific policy or procedure.

Staff training should be a well-defined and organized process. Content should be clearly defined for the learner and based on behavioral objectives. The objectives can be used to accurately and objectively measure learning. At the end of the session(s), the instructor should confirm by a written test and/or return demonstration that learning has occurred and that the learner is able to perform the procedure(s) independently without error. Test results should be documented and placed in personnel file.

Comprehension of the purpose and function of infection control principles and procedures requires a basic understanding of normal physiological concepts, as well as responses associated with uremia and the hemodialysis therapy. Content should include the specific areas spelled out in the OSHA regulation previously described.

Need for further education such as inservices or intensive educational sessions can be determined from the routine quality assurance monitoring process and the ongoing staff performance appraisal process. When problems are identified, all staff should be made aware of the problem and be involved in its solution; this nearly always includes problem specific continuing education.

The medical director of the dialysis facility must verify that the individual has successfully completed the initial education and training program. The medical director is also responsible for assuring that an annual review has been performed.

Monitoring and Evaluation

On a periodic basis, quality assurance monitoring of facility personnel's compliance with policies and procedures should be performed. A concurrent monitoring instrument may be used for this purpose (see Form 1).

All policies and procedures must be reviewed and updated annually to reflect changes in regulations and/or standards.

Trend analysis, performed by the quality assurance committee, should include incident reports and surveillance monitoring results.

REFERENCES

1. Centers for Disease Control. *Recommendations for Prevention of HIV Transmission in Health Care Settings.* MMWR, 36 (Supplement no. 25), pp. 144-185 (1987).

2. Occupational Safety and Health Administration. *Occupational Exposure to Blood Borne Pathogens HIV and HBV Notice of Proposed Rule Making,* 29 CFR Part 1920, Federal Register, May 30, 1989.

3. *Infection Control for Hemodialysis* (VideoTape). Food and Drug Administration. (1989).

4. Centers for Disease Control. *Protection Against Viral Hepatitis.* MMWR, 39 (1990).

5. ALTER, M.J. and FAVERO, M.S. *National Surveillance of Dialysis-Associated Diseases in the United States, 1987.* Centers for Disease Control, Atlanta, GA (1988).

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation for the purpose of training or research on this topic.

PROCEDURE FOR CONCURRENT AUDIT:

UNIVERSAL PRECAUTIONS MONITOR (FORM 1)

The purpose of this audit is to monitor technical staff compliance with standard practices and procedures related to the water treatment system. When staff are aware of the importance of the policies and well trained in the procedures, compliance should be very high.

Before the Audit

1. Provide adequate and appropriate inservice to assure total staff awareness and education of all components associated with water treatment for dialysis.
2. Assure staff awareness of all elements of the concurrent audit and how performance will be observed and evaluated.
3. The QA committee specifies the standard (expected percentage compliance) desired for the audit; begin not lower than 85%.
4. Schedule the audit with appropriate personnel (head nurse, charge nurse, chief technician).
5. Make copies of the audit for each auditor/ observer.
6. Assign code letters for each staff member to be observed; for example:

   Employee A: Glenn Close
   B: Tom Hanks
   C. William Hurt
   etc.

7. Determine how many staff are to be observed. It is recommend that one auditor should observe no more than three to four staff at one time.
8. Define the length of time for observation. It is recommended that the audit be conducted during peak activity times (daily start-up, shift changeovers, etc.). The time frame should be long enough to observe each staff member completely perform the listed activity.
9. Assign a staff member to perform the audit. Auditor should not be assigned to other responsibilities during the audit.

Perform the Audit

1. On the actual audit sheet, write in the date, auditor's name, patient shift (or time of day), and standard.
2. Read each indicator carefully.
3. Observe staff for actual *performance*. Auditor should not interfere with staff activities, be obtrusive, or preceptibly obvious.
4. Under each staff code letter, write Y for yes if indicator is met, N for no if indicator is not met, or N/A for not applicable, not observed.

   To achieve a Y (yes, indicator was met), staff should be observed with complete compliance for each encounter. For example, for a Y to appear in the "Post-Softener Hardness Done" box, the staff member must perform the test before any patient dialysis is done ***and*** perform the test exactly according to the instructions for use of the test manufacturer ***and*** record the results as per facility policy.
5. Complete all observations within timeframe specified. Assure that each indicator has one response.

After the Audit

1. Under each employee code letter, add total number of Ys and Ns; do not count NAs.
2. For each employee, calculate compliance percentage by dividing the total Ys by the total observations; again, do not count NAs.
3. Calculate total compliance percentage for the audit by dividing total Ys (all employee Ys) by the total observations; do not count NAs.
4. For each indicator, calculate compliance percentage by using the same method as above; again, do not count NAs.
5. Report results to QA committee and clinical management team with additional comments and/or recommendations.

UNIVERSAL PRECAUTIONS MONITOR

FORM 1

Date	Patient Shift	Auditor									
	Station Number	1	2	3	4	5	6	7	8	9	10
	Staff Member (initials)										
INDICATOR											
Wears gloves, mask, eye protection and protective clothing when initiating dialysis											
Wears gloves, mask, eye protection, and protective clothing when discontinuing dialysis											
Changes gloves between patients (observe staff with four patients)											
Washes hands between patients (non-glove situations)											
Places uncapped needles in puncture-proof container											
Wears gloves and protective clothing when tearing down/cleaning equipment											
Surface cleans all dialysis equipment with disinfectant between each patient											
Removes protective clothing before leaving dialysis unit											
# YES											
# NO											
% COMPLIANT											

Threshold	% Compliant

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

Chapter 12

HANDLING OF TOXIC CHEMICALS

CONTENTS

Chapter 12

Handling of Toxic Chemicals

BACKGROUND

The average dialysis unit has a number of toxic or hazardous chemicals present. They are used as cleaning and disinfecting agents, janitorial supplies, and for other purposes. A list of the common chemicals present in a dialysis facility include, but are not limited to:

Acids
Bases/Caustics
Cleaning Agents
Degreasing Agents
Disinfectants
Flammables
Greases
Paints
Solvents
Surfactants
Water Treatment Agents
Sterilants
Bactericidal Agents
Janitorial Supplies

Although it is impossible to avoid all risk associated with use of these toxic chemicals, the facility can significantly reduce that risk by following some practical quality assurance measures. The first step is to be aware of the chemicals found in the unit. A chemical that meets the criteria of a *hazardous substance* may be: corrosive to living tissues; carcinogenic; toxic when administered orally, cutaneously, or through inhalation; irritant; sensitizer; toxic to target organs including the liver, kidney, central nervous system, blood, lung, reproductive system, or eyes. Some of the chemicals that meet this definition that are commonly found in the dialysis facility include:

Acetic Acid
Peracetic Acid
Chlorine Dioxide
Formaldehyde
Glutaraldehyde
Sodium Hypochlorite (Bleach)
Hydrogen Peroxide
Povidone Iodine Solution
Chlorhexidine Gluconate
Hexachlorophene
Ethyl Alcohol
Ethyl Chloride
Benzalkonium Chloride

EXISTING STANDARDS

Three Occupational Safety and Health Administration (OSHA) standards are especially relevant to the dialysis community and must be incorporated into policies and procedures and clinical practice:

1. hazard communication
2. occupational exposure to formaldehyde, and
3. occupational exposure to blood borne pathogens.

A separate chapter in this manual, Chapter 11, entitled *Infection Control*, discusses the occupational exposure to blood-borne pathogens standard.

Hazard Communication Standard

This standard requires employers to provide information to their employees about the hazardous chemicals used in the work place through the development and the implementation of a "hazard communication program."

Compliance with this rule can be achieved through a four step process as described below.

Step 1. List the hazardous chemicals in the facility. In general, these chemicals will have a label warning of a potential hazard such as eye irritation.

Step 2. Obtain the Material Safety Data Sheets (MSDS) for all chemicals identified. The MSDS, prepared and supplied by the manufacturer of the chemical, contains information including:

- identification (trade name, chemical name, chemical family, formula);
- hazardous ingredients (components, specific chemical identity, common name);
- physical/chemical characteristics (boiling point, vapor pressure, vapor density, solubility in water, appearance and odor, specific gravity, melting point, evaporation rate);
- fire and explosion hazard data (flash point, extinguishing media; special fire fighting procedures, flammable limits, unusual fire and explosion hazards);
- reactivity data (stability, conditions to avoid, incompatibilities, materials to avoid);
- hazardous decomposition or bioproducts (hazardous polymerization); health hazard data (routes of entry: inhalation, skin, ingestion);
- health hazards (acute and chronic) carcinogenicity, signs and symptoms of hazardous exposure, medical conditions generally aggravated by hazardous exposure, and emergency first aid procedures;
- precautions for safe handling and use (steps to be taken in case the material is released or spilled, waste disposal method, precautions to be taken in handling and storing, other precautions);
- control measures (respiratory protection), ventilation (total exhaust, special, etc.), protective gloves, eye protection, other protective clothing or equipment, and work/hygienic practices.

The MSDS for specific chemicals should be posted in any area where that chemical is used. This is done to assure the staff direct access to information about the risks involved with the chemicals, proper handling procedures, and information required in case of an emergency.

Additionally, a list of all toxic chemicals used in the facility and all of the MSDS's should be in one file. This file must be available to all employees. Finally, the facility is required to provide a copy of a MSDS upon the request of any employee, designated representatives of employees, emergency personnel, and to OSHA.

Step 3. All toxic chemical containers must be appropriately labeled. The label must contain the product name, as well as appropriate warnings regarding use. Upon delivery of these chemicals, proper labeling should be confirmed and employees should be instructed not to remove labels under any circumstances. Empty containers from toxic chemicals should be immediately discarded and not reused for other purposes.

Step 4. A written hazard communications program must be developed and implemented. Such a program should be included in the initial training of all staff members, and during annual review. The program should include at least the following.

- Discussion of the contents of all regulations related to handling of hazardous chemicals.
- Discussion of the contents on Material Safety Data Sheets of all hazardous chemicals in the facility.
- Description of any medical surveillance programs related to hazardous chemicals available in the facility.
- Description of potential health hazards related to exposure of any hazardous chemicals and description of signs and symptoms of that exposure.
- Instruction to immediately report any adverse signs or symptoms that the employee suspects are attributable to hazardous chemical exposure.
- Description of all operations within the facility or procedures where potential exposure to a hazardous chemical is present.
- Purpose for, proper use of, and limitations of all personal protective clothing and equipment related to hazardous chemical use.
- Instructions for handling of spills, emergencies, and clean-up procedures.

- An explanation of the importance of any engineering and/or work practice controls for employee protection and necessary instruction in the use of these controls.
- A review of emergency procedures including specific duties or assignments of each employee in the event of a hazardous chemical emergency.

Whenever a new hazardous chemical is introduced, training must be understaken and completed.

Upon completion of the training program, the employer should verify and document employee comprehension. This should be repeated on an annual basis and be incorporated into the performance appraisal process. It is recommended that documentation of successful completion of the program be included in the employee's personnel file.

The facility should also have written policies regarding hazard communication for any outside contractors. Should any outside contractor bring hazardous materials into the dialysis facility, that contractor should provide the facility with an MSDS along with written procedures as to how the material will be used, monitored, and eliminated. An example may be a water treatment vendor bringing materials to disinfect or clean water treatment system components.

The facility is required to complete and maintain OSHA Form 200 reporting all occupational injuries and illness. The form must be recorded within six months of occurrence. A copy of the total number of occupational injuries and illnesses must be posted in each facility in a place where employee notices are posted on an annual basis.

To obtain a copy of the OSHA hazard communication standard, specify Federal Register 52 (163): 31852-31886, August 4, 1987.

Certain states and territories have "approved" programs that meet the requirements of the federal regulation but also have additional laws and regulations. These states and territories include:

Alaska	New Mexico
Arizona	New York
California	North Carolina
Connecticut	Puerto Rico
Hawaii	South Carolina
Indiana	Tennessee
Iowa	Utah
Kentucky	Vermont
Maryland	Virgin Islands
Michigan	Virginia
Minnesota	Washington
Nevada	Wyoming

If your facility is located in a state with a OSHA-approved plan, you must comply with the Hazards Communications Requirements of that state.

Occupational Exposure to Formaldehyde

The OSHA standard for Occupational Exposure to Formaldehyde stipulates:

A. Exposure Limits

1. Permissible exposure limit: the employer shall ensure that no employee is exposed to an airborne concentration of formaldehyde that exceeds one part formaldehyde per million parts of air (1 ppm), as an 8 hour time-weighted average (TWA).
2. Short term exposure limit: the employer shall ensure that no employee is exposed to an air borne concentration of formaldehyde which exceeds two parts formaldehyde per million parts air as a 15 minute short term exposure limit (STEL).
3. Action level equals 0.5 parts per million (ppm) in a 8 hour time-weighted average (TWA).

B. Required Monitoring

1. Initial monitoring shall identify all employees who may be exposed at or above the action level or above the short term exposure limit and accurately determine the exposure of each employee so identified.
2. Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job clas-

sification of each work shift. The purpose of this is to correctly characterize and not underestimate the exposure of any employee within each exposure group.

3. The initial monitoring process shall be repeated each time there is a change in production, the equipment process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

C. Periodic Monitoring

1. The employer shall periodically measure and accurately determine exposure to formaldehyde for employees shown by initial monitoring to be exposed at or above the action level or at or above the short term exposure limit.
2. If the last monitoring results reveal employees exposure at or above the action level, the employer shall repeat monitoring of the employees at least every six months.
3. If the last monitoring results reveal employee exposure at or above the short term exposure limit, the employer shall repeat monitoring of the employees at least once a year under worst conditions.

D. Termination of Monitoring

The employer may discontinue periodic monitoring for employees if results from two consecutive samples, taken at least seven days apart, demonstrate that the employee exposure is below the action level and the short term exposure limits. This must be a statistically significant sample.

E. Other Monitoring Information

1. Monitoring shall be accurate at the 95% confidence level to within plus or minus 25% of airborne formaldehyde concentration at time-weighted exposure and short term exposure limits and to within plus or minus 35% for action level.
2. Monitored employees must receive the results of the monitoring within 15 days.
3. If employee exposure exceeds the 8 hour time weighted average or the short term exposure limit, the employer shall develop and implement a written plan to reduce employee exposure to or below either (both) and give written notice to employees.
4. Employees have the right to observe monitoring procedures.

F. Regulated Areas

These are areas where airborne formaldehyde exceeds 8 hour time weighted average or short term exposure limit.

In these areas:

1. A notice regarding the danger and hazard must be posted.
2. Access to these areas must be restricted to authorized personnel who have been trained as described earlier.
3. Respiratory protection must be provided (permanently) if engineering or workplace practice cannot reduce employee exposure to acceptable limits, or temporarily in the interval until feasible engineering or workplace practice changes are made to correct exposure levels.
4. Protective clothing must be worn and work practices performed.
5. Employee training programs in hazards and proper handling must be provided.
6. Proper housekeeping (preventative maintenance, proper storage, spill contingency plans) must be implemented and practiced.

G. Emergency Procedures

For all areas where there is a possibility of an emergency involving formaldehyde, the facility must assure that appropriate procedures are adopted to minimize injury. Appropriate procedures must be implemented in the event of any such emergency.

H. Medical Surveillance

The facility must institute a medical surveillance program for all employees exposed to formaldehyde at concentrations equal to, or exceeding, the action level. Also medical surveillance must be performed when concentrations exceed the short term exposure limits, as well as for any employee developing signs or symptoms of formaldehyde overexposure. Such surveillance and any examinations must be performed by or under the supervision of a physician and provided without cost, loss of pay, and at a reasonable time and place.

The facility must also administer a medical disease questionnaire to any employee prior to being assigned to a job where formaldehyde exposure is at or above the action level or above the short term exposure limit including: work history, smoking history, any evidence of eye, nose or throat irritation, chronic airway problems, hydroactive airway disease, allergic skin conditions, dermatitis, respiratory problems. This questionnaire must be administered annually. It should also be given to employees experiencing signs and symptoms indicative of possible over exposure to formaldehyde. Assuming that the facility has already instituted all possible engineering control measures, the physician must determine on the basis of this questionnaire, his examination, and other information whether the employees are required to wear respirators to reduce exposure to formaldehyde.

I. Medical Examinations

Medical examinations are to be given to any employee if the physician feels, based on information in the medical disease questionnaire, the employee may be at risk from hazardous exposure to formaldehyde. This requirement for physical examination also pertains to employees exposed during an emergency situation. The physician's opinion must be documented.

J. Employee Training and Information

1. Training must be provided to all employees assigned to work places with a health hazard.
2. Training must be provided at the time of initial assignment and whenever new hazards from formaldehyde are introduced into the work place.
3. Training must be provided at least annually for all employees at or above the action level or the short term exposure limit.
4. The training program shall be conducted in a manner that all employees are able to understand and must include:
   - Contents of the regulation and of the MSDS
   - Medical surveillance program purpose and description
   - Potential health hazards (how to identify and what to do)
   - Proper formaldehyde handling
   - Proper use of protective equipment
   - Spill contingency plans
   - Use of engineering environmental controls
   - Emergency procedures
   - Proper use of each type of eyewash station in facility.
5. All employees must be informed of the location of the written training materials. These must be available to the employees at no cost.

K. Recordkeeping

Recordkeeping must include:

1. Results of all scheduled and unscheduled airborne formaldehyde exposure measurements.
2. Objective documentation if the employer has determined that no measurements are necessary (no employee is exposed to formaldehyde at or above the action level).
3. An accurate record of each employee who is subject to medical surveillance under this standard.
4. Records regarding fit testing of all respirators.
5. All records must be retained for 30 years after employment ends and all records must be available for OSHA inspection (Federal Register, December 4, 1987, 29 CFR Parts 1910 and 1926, Volume 52, Number 233, Pages 46168 to 46312).

MONITORING AND EVALUATION

The following are recommendations for monitoring that should be performed to enhance the safety and reduce the level of risk to patients or staff. These recommendations are in addition to those previously described.

Daily Monitoring

A. Test for the absence of clinically significant levels of germicide or cleaning agents (toxic

chemicals) in clean/sanitized/disinfected dialysis delivery systems.

B. Test for the absence of clinically significant levels of germicide or cleaning agents (toxic chemicals) in clean/sanitized/disinfected water treatment systems.

C. Test for the absence of clinically significant levels of germicide or cleaning agents (toxic chemicals) in clean/sanitized/disinfected reprocessed dialyzers before clinical use.

Monthly Monitoring

A. If formaldehyde is used as the disinfectant in reuse of hemodialyzers, the AAMI Recommended Practice for Reuse of Hemodialyzers states that "formaldehyde vapors should be monitored at least monthly, and whenever indicated by the discomfort of personnel."

B. Incident reports related to use of toxic chemicals should be reviewed and analyzed by the quality assurance committee.

Other Monitoring

A. Emergency equipment should be inspected for proper function/condition according to the manufacturer's instructions or facility policy.

B. A trend analysis of incidents and/or regular monitoring pertaining to use of toxic chemicals should be performed. Performance appraisal of all personnel responsible for handling toxic chemicals should also be performed (see Form 1).

C. All incoming supplies and records should be inspected periodically for completeness.

D. All policies and procedures related to handling of toxic chemicals must be reviewed annually.

E. Performance appraisal process for all personnel responsible for handling toxic chemicals and facility review should be completed annually (see Form 2).

REFERENCES

1. Occupational Safety and Health Administration (OSHA) Standard. *Hazard Communication Standard.* Federal Register, 52 (163): 31852-31886, August 4, 1987.

2. Occupational Safety and Health Administration (OSHA) Standard. *Occupational Exposure to Formaldehyde.* Federal Register, 52 (233): 46168-46312, December 4, 1987.

3. BEDNAR, B. *Meeting OSHA Hazard Communication Standards.* Nephrology News & Issues. 4, 6: 14-15, 1989.

Note: A list of additional references on this topic can be found in Appendix E at the end of this manual. These additional references are included to enable the reader to pursue further investigation on this topic for the purpose of training or research.

FORM 1

TOXIC CHEMICALS HANDLING TREND ANALYSIS

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
DATE												
MONITORING: AIRBORNE LEVELS												
Location #1												
Location #2												
Location #3												
Location #4												
Location #5												
Location #6												
Location #7												
Location #8												
SPILLS												
Location #1												
Location #2												
Location #3												
Location #4												
ACCIDENTAL EYE CONTACT, ETC.												
Location #1												
Location #2												
Location #3												
Location #4												

Other: _____

_____

_____

PROCEDURE FOR CONCURRENT MONITORING FORM: TOXIC CHEMICAL HANDLING (FORM 2)

The purpose of this audit is to monitor technical staff compliance with standard practices and procedures related to the water treatment system. When staff are aware of the importance of the policies and well trained in the procedures, compliance should be very high.

Before the Audit

1. Provide adequate and appropriate inservice to assure total staff awareness and education of all components associated with water treatment for dialysis.
2. Assure staff awareness of all elements of the concurrent audit and how performance will be observed and evaluated.
3. The QA committee specifies the standard (expected percentage compliance) desired for the audit; begin not lower than 85%.
4. Schedule the audit with appropriate personnel (head nurse, charge nurse, chief technician).
5. Make copies of the audit for each auditor/observer.
6. Assign code letters for each staff member to be observed; for example:

   Employee A: Glenn Close
   B: Tom Hanks
   C. William Hurt
   etc.

7. Determine how many staff are to be observed. It is recommend that one auditor should observe no more than three to four staff at one time.
8. Define the length of time for observation. It is recommended that the audit be conducted during peak activity times (daily start-up, shift changeovers, etc.). The time frame should be long enough to observe each staff member completely perform the listed activity.
9. Assign a staff member to perform the audit. Auditor should not be assigned to other responsibilities during the audit.

Perform the Audit

1. On the actual audit sheet, write in the date, auditor's name, patient shift (or time of day), and standard.
2. Read each indicator carefully.
3. Observe staff for actual *performance*. Auditor should not interfere with staff activities, be obtrusive, or preceptibly obvious.
4. Under each staff code letter, write Y for yes if indicator is met, N for no if indicator is not met, or N/A for not applicable, not observed.

   To achieve a Y (yes, indicator was met), staff should be observed with complete compliance for each encounter. For example, for a Y to appear in the "Post-Softener Hardness Done" box, the staff member must perform the test before any patient dialysis is done ***and*** perform the test exactly according to the instructions for use of the test manufacturer ***and*** record the results as per facility policy.
5. Complete all observations within timeframe specified. Assure that each indicator has one response.

After the Audit

1. Under each employee code letter, add total number of Ys and Ns; do not count NAs.
2. For each employee, calculate compliance percentage by dividing the total Ys by the total observations; again, do not count NAs.
3. Calculate total compliance percentage for the audit by dividing total Ys (all employee Ys) by the total observations; do not count NAs.
4. For each indicator, calculate compliance percentage by using the same method as above; again, do not count NAs.
5. Report results to QA committee and clinical management team with additional comments and/or recommendations.

TOXIC CHEMICAL HANDLING MONITOR

FORM 2

Date	Patient Shift	Auditor									
	Station Number	1	2	3	4	5	6	7	8	9	10
	Staff Member (initials)										
PERSONNEL											
Knows location of MSDS											
Knows location of spill contingency materials											
Knows location of spill contingency procedures											
Wears protectective clothing and equipment when handling toxic materials											

Threshold	% Compliant

FACILITY	**Y/N**
MSDS on file for all toxic chemicals used	
Eyewash stations at appropriate locations and properly maintained	
Spill contingency materials on hand	
Spill contingency procedures current and posted	
Airborne levels monitored as per facility policy (check back one year)	
All toxic chemicals labeled and stored as per facility policy	

Threshold	% Compliant

Q.A. Committee Recommended Action: _____

_____

_____

_____

_____

Chapter 13

MEDICAL DEVICE REPORTING

CONTENTS

Chapter 13

Medical Device Reporting

In Appendix A the reader will find a complete analysis of all Medical Device Reporting (MDR) files pertaining to hemodialysis devices for the period from January 1, 1980 through December 31, 1989.

BACKGROUND

As has been noted elsewhere in this manual, a large number of these incidents are related to user error or to inappropriate or inadequate maintenance and repair of the devices. Other incidents may have been less severe had the user acted in accordance with the manufacturer's instructions. Another large segment of these incidents involves some degree of device or equipment malfunction.

The primary protection that providers and patients have to ensure that unsafe or ineffective devices do not remain on the market is provided by the Food and Drug Administration (FDA). The FDA performs routine inspections of manufacturers' facilities and recordkeeping systems to ensure compliance with "Good Manufacturing Practices."

Another method by which safety is maintained is by the FDA's investigation of problems reported in the use of the devices. Thus, the absolute importance of all users reporting any problems/incidents related to use of the devices is underscored. Essentially, if dialysis personnel do not inform the FDA of problems related to devices, it may take longer to become aware that a device may be unsafe or ineffective.

PROBLEM REPORTING MECHANISMS

There are basically four mechanisms by which problems related to hemodialysis can be reported:

1. The "Medical Device and Laboratory Problem Reporting Program,"
2. The "Medical Device Reporting" regulation,
3. The Medical Device Amendments of 1976, as amended by the Safe Medical Devices Act of 1990, and
4. Manufacturers' Complaint investigation files.

Medical Device and Laboratory Problem Reporting Program

The Problem Reporting Program, or PRP, is funded by the Food and Drug Administration, Center for Devices and Radiological Health, and coordinated by the United States Pharmacopeia (USP). One of the USP's objectives is to improve product quality and to inform industry and government about the health hazards caused by medical devices. The PRP provides healthcare practitioners and other medical device users with an effective and expedient way to report problems related to the safety and efficacy of medical devices.

A. Guidelines for Reporting

The PRP encourages users to report incidents of:

- Death,
- Serious injury, or
- Malfunctions that could result in hazards or injuries.

Problems with medical devices, in-vitro diagnostic equipment, and radiological health products should also be reported:

- When there is user error. It is important to determine if the design of the device contributes to user error or if incomplete labeling may have contributed to the event.
- When a decision is made to no longer use a piece of equipment due to a malfunction which has occurred or recurred. It is better to report the event rather than just discard the

device, place it in storage, or return it to the manufacturer.

- When repeated repairs do not solve the problem.
- When a manufacturer's design or repair changes to the product adversely affect the performance, safety, or efficacy in the opinion of the practitioner.
- When the problem indicates poor quality control by the manufacturer.
- When a problem of incompatibility between devices of different manufacturers results in a serious hazard or injury.
- When a malfunction results in medical treatment, hospitalization, repeat surgical procedures, or readmission.

Even when a problem has occurred only once, if the practitioner believes that the possibility for recurrence may exist, the problem should be reported. The USP informs both the manufacturer and the FDA. Analyses of other "isolated incidents" that may have occurred and a trend analysis are then performed. It is possible that a single problem reported from one facility may be seen to fit into a pattern of incidents reported by many facilities and therefore be more significant than might first appear.

B. Guidelines for Not Reporting

If the device involved does not have the potential to cause or contribute to a death or serious injury, it probably should not be reported. These include:

- Changes to a product that are only cosmetic in nature and do not affect, or have the potential to affect, the performance, safety, or efficacy of the device. This includes personal preference for a device.
- Normal wear and tear of a device or routine service complaints where no performance problems exist such as consumer service complaints, nonresponsiveness of the firm, unavailable service manuals, or parts and replacements not readily supplied.
- Isolated occurrences where the problems occur only once, the chance of recurrence is, in the practitioner's opinion, either zero or highly unlikely, and there is no potential for death or injury. If interested in determining if others are experiencing the same problem, contacting the facility's centralized reporting area, such as the Biomedical Engineering, Purchasing, or Risk Management departments, may be helpful before deciding not to report an isolated occurrence.

C. Required Information for Reporting

Reporters are encouraged to supply as much information as possible when reporting. A copy of the Product Problem Reporting Program Form is included at the end of this chapter. The report can be submitted in writing or by telephoning a toll-free number: 1-800-638-6725 (in Maryland call collect 301-881-0256).

When reporting, it would be helpful to include the following:

- Identification numbers (lot number, model number, serial number, etc.). These numbers can help to identify if problems are recurring in one particular lot or involve one particular model and enable the FDA and the manufacturer to rapidly solve the problems.
- Complete name of the device and the manufacturer name that appears on the label.
- Whether the same firm or another firm is identified as the distributor and/or manufacturer.
- Whether it is a disposable device that has been reused.
- If the directions for use were properly followed; if not, could the directions have been improved.
- Indicate whether a sample of the device(s) has been retained. If possible and practical, it is important to retain a sample of the device, as well as other devices that may have been related to the particular problem.
- Identify the location of the event (i.e., hospital, clinic, home, transport, etc.).
- Include the title or practice specialty of the practitioner (physician, nurse, technician, etc.) who was using the device when the problem occurred.
- Include a complete description of the problem including any actual or potential adverse effects upon the patient or practitioner. Include any results of physical examinations or

laboratory tests performed in conjunction with the problem in assistance or treatment of diagnosis or that can otherwise assist in understanding the problem.

D. How the Program Works

USP is an independent, nongovernmental body composed of approximately 300 representatives from associations and colleges of pharmacy, nursing and medicine. Once the PRP is notified by submitting the problem on the reporting form or by calling the toll-free telephone number, copies of the report are forwarded to the FDA on the day that it is received. The USP also sends a copy to the manufacturer so that it is aware of the problem and your concern. The USP will acknowledge receipt of the report and provide additional reporting materials for future use.

Reports submitted to the USP are subject to the Privacy Act. The USP will delete the reporter's name on the manufacturer and/or FDA copy of the report if requested. However, it should be noted that the manufacturer and the FDA may be limited in the amount of follow-up that can be done if the reporter's name is not available. In addition, FDA will delete the hospital, patient, and physician names (or any other data that can be used to identify them) prior to public release of a report under the Freedom of Information Act.

If a name is given, the reporter may be contacted by the FDA, the manufacturer, or both for additional information or to inform the reporter about their evaluation of the report. Manufacturers have other responsibilities regarding the investigation, evaluation, and reporting of device-related problems ("complaint investigations" according to Good Manufacturing Practices, Medical Device Reporting regulations, etc.).

Although the primary purpose of the PRP system is to improve the products utilized in healthcare, it is also a vital means of quickly bringing health hazards to the attention of officials in government and industry. In this way, appropriate action may be taken, either in the form of product improvements or recalls.

This system is not designed to replace any reporting requirements that the institution may already have. Remember to also use any normal facility reporting procedures such as incident reports.

The PRP form (see Form 2) at the end of this chapter summarizes actions for the problem reporting program. It is recommended that this form be photocopied and posted in a prominent place in the dialysis center, head nurse's office, medical director's office, and chief technician's office.

Medical Device Reporting Regulation

Note: The following information on the Medical Device Reporting rule applies to manufacturers of medical devices only. It is included in this manual solely for informational purposes.

The Medical Device Reporting (MDR) final rule, dated December 13, 1984, requires manufacturers to report information to the FDA when one of their devices may have caused or contributed to a death or serious injury or when a malfunction may contribute to death or serious injury. The MDR regulation is intended to ensure that the FDA is informed promptly of all serious or potentially serious problems associated with marketed medical devices.

Under the Good Manufacturing Practices (GMP) regulations, a manufacturer is required to review, evaluate, investigate, and maintain a failure record of its devices.

The MDR regulation requires the manufacturer to notify the FDA as follows:

- In case of a death, the manufacturer must submit the report to the FDA by telephone as soon as possible, but no later than five calendar days of receipt of the information and must file a written report within 15 days of receipt of the information.
- In the case of serious injury or a malfunction that is likely to cause or contribute to a serious injury or death if it recurs, a report should be made to the FDA as soon as the necessary information for making the report is obtained, but no later than 15 working days after initial receipt of the information. The manufacturer must report to the FDA each time it becomes aware of a reportable event or malfunction.

Safe Medical Devices Act of 1990

On November 28, 1990, President Bush signed into law the "Safe Medical Devices Act of 1990," which amends the Federal Food, Drug, and Cosmetic Act. Several of the provisions of this new legislation have an impact on the requirements of reporting medical device problems. The new law will impose reporting requirements on users for the first time. Certain device user facilities, including hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities that are not physician's offices, will be required to report deaths related to medical devices to the FDA. They are also required to submit reports of serious illnesses or injuries related to devices to the manufacturer or to the FDA if the manufacturer is not known. These provisions of the law will go into effect upon publication of the final regulations or 12 months from the date of enactment (November 28, 1991), whichever is earlier.

Other provisions of this law include that distributors of medical devices will be required to provide copies of MDR reports to the manufacturer of the device and that manufacturers, importers, and distributors who make MDR reports will be required to certify the number of reports submitted to the FDA in a year. Also, manufacturers of permanently implantable or life-sustaining and life-supporting devices **used outside a device user facility** and that are reasonably likely to have serious adverse health consequences will be required to establish tracking systems for these devices.

A FACILITY'S RESPONSIBILITY FOR REPORTING

In the event of a death or serious injury related to the use of a medical device or in the event of a malfunction of a medical device that is likely to cause or contribute to death or serious injury if it recurs the facility may report to the manufacturer as well as the PRP. Once the new law goes into effect (no later than November 28, 1991), facilities will be **required** to report deaths to the FDA and serious injury/serious illness to the manufacturer or the FDA if the manufacturer is not known. These are important reporting mechanisms for the surveillance of products by both the manufacturer and the FDA. It is only through such reporting that serious product defects or other problems can be discovered, investigated, and resolved.

Reportable events also include improper labeling, defective components, performance that does not meet the specifications of the product, poor packaging, incomplete or confusing instructions, and erroneous information. This information may be filed as a complaint with the manufacturer as well as with the PRP.

All facility staff members should be trained in the problem reporting process. This should be a component of the initial training of new employees and reviewed annually.

FORM 1

Medical Device & Laboratory Product Problem Reporting Program

Form Approved; OMB No. 0910-0143

DATE RECEIVED

ACCESS NO

1. PRODUCT IDENTIFICATION:

Name of Product and Type of Device
(Include sizes or other identifying characteristics and attach labeling, if available)

Manufacturer's Name

Manufacturer's City, State, Zip Code

Is this a disposable item? YES ☐ NO ☐

Lot Number(s) and Expiration Date(s) (if applicable)

Serial Number(s)

Manufacturer's Product Number and/or Model Number

2. REPORTER INFORMATION:

Your Name Today's Date

Title and Department

Facility's Name

Street Address

City State Zip Phone ( ) Ext:

3. PROBLEM INFORMATION:

Date event occurred

This event has been reported to: Manufacturer ☐ FDA ☐

Please indicate how you want your identity publicly disclosed:

Other

No public disclosure ☐

To the manufacturer/distributor ☐

To the manufacturer/distributor and to anyone who requests a copy of the report from the FDA ☐

If requested, will the actual product involved in the event be available for evaluation by the manufacturer or FDA? YES ☐ NO ☐

Problem noted or suspected (Describe the event in as much detail as necessary. Attach additional pages if required. Include how and where the product was used. Include other equipment or products that were involved. Sketches may be helpful in describing problem areas.)

RETURN TO
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852
Attention: Dr. Joseph G. Valentino

OR

CALL TOLL FREE ANYTIME
800-638-6725*
IN THE CONTINENTAL UNITED STATES
*In Maryland, call collect (301) 881-0256 between 9:00 AM and 4:30 PM

FORM FDA 2519f (3/85)

FORM 2

PROBLEM REPORTING PROGRAM

1. WHAT TO REPORT?

   Anything you consider to be a problem with a device:

   - When a device problem causes serious hazard, injury, or death (*even if user error was involved*)
   - Repeated device repairs are required and problem is not solved
   - Incompatibility in two products could or did create a hazard and you were not warned of this possibility by the manufacturer
   - Improper labeling
   - Defective components
   - Performance failures
   - Poor packaging
   - Incomplete or confusing instructions
   - Erroneous information
   - Again, anything you consider to be a problem with a device!

2. WHAT TO HAVE READY WHEN YOU MAKE THE CALL OR FILL OUT THE FORM:

   - Your name and title
   - Facility name, address, telephone number
   - Product name
   - Lot number, model number, serial number, product expiration date
   - Manufacturer's name and address (also Distributor's if notes both)
   - Problem noted:

     Was a disposable device reused?

     Were instructions for use followed (could they be improved?)

     Has a sample of the device been retained?

     Identify location of the event

     Identify title/practice specialty of person using device at time of problem occurence

     Include complete description of problem including any actual or potential adverse effects upon the patient or practitioner

3. **MAKE THE CALL!** (OR FILL OUT THE FORM AND SEND IT)

CALL TOLL FREE ANYTIME
800-638-6725

(In Maryland call collect (301) 881-0256 between 9:00AM and 4:30PM)

4. **PERFORM ANY OTHER REGULAR REPORTING PROCEDURES REQUIRED BY FACILITY POLICY.**

Appendix A

Summary of Incidents/Problems

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Air Foam Detector	11/6/81	Guide pin on connection may bend	Will not detect air	Check pins; replace bent ones
Air Foam Detector	12/2/85	PC Board failure	Will not detect air	Perform pre-dialysis functional check
Air Foam Detector	12/31/87	Did not detect foam	Will not detect air	No malfunction found;
Air Foam Detector	5/21/89	Connector may not seat on machine	Will not detect air	Check connection; make sure power light is on
Bld Line Clamp	8/10/85	Clamp doesn't occlude completely	Air to patient	Inspect for proper clamping
Bld Line Clamp	10/15/85	Clamp doesn't occlude completely	Air to patient	Inspect for proper clamping
Bld Line Clamp	6/4/86	Stop pin in clamp adulterated	Clamp doesn't work	Replace pin in clamp
Bld Line Clamp	3/2/87	Clamp cut blood line; pin bent; staff altered clips	Blood loss; hypotension; sepsis	Inspect for proper clamping; do not alter device
Bld Line Clamp-SN	2/19/85	Clamp fatigued blood line; line leaked	Blood loss; hypotension; sepsis	Inspect blood lines and clamps calibration
Bld Line Clamp-SN	12/9/85	Clamp fatigued blood line; line leaked	Blood loss; hypotension; sepsis	Inspect blood lines and clamps calibration
Bld Line Clamp-SN	2/6/86	Clamp fatigued blood line; line leaked	Blood loss; hypotension; sepsis	Inspect blood lines and clamps calibration
Bld Line Clamp-SN	9/16/88	Clamp operated without guide clips; tub. shifted	Air embolus	Do not remove guide clips; inspect device before use
Del Sys-Central	12/28/84	Machine malf causes hypertonic dialysate; no alarm; leak in valve	Hypernatremia; nausvom; seizure; death	Follow mfrs safety/mtnc prcdrs; check cond before dialysis
Del Sys-Central	12/28/84	System operated with no conch bypass mode; patient expired	Hyponatremia; nausvom; hemolysis	Mech alarm check; follow mfr's safety/mtnc prcdrs; check cond before dialysis
Del Sys-Central	1/11/85	Machine malf causes hypertonic dialysate; no alarm	Hypernatremia; nausvom; seizure; death	Follow mfrs safety/mtnc prcdrs; check cond before dialysis
Del Sys-Central	1/30/85	Improper sodium conc (low); improper set up by user	Hyponatremia; nausvom; hemolysis	Follow mfrs procedures; check conductivity before dialysis
Del Sys-Central	6/21/85	Machine malf causes hypotonic dialysate; incorrect servicing of machine	Hyponatremia; nausvom; hemolysis	Follow mfrs service prcdrs; check cond before dialysis
Del Sys-Central	7/19/85	Machine malf causes hypertonic dialysate; no alarm	Hypernatremia; nausvom; seizure; death	Follow mfrs safety/mtnc prcdrs; check cond before dialysis
Del Sys-Central	8/7/85	Machine malf allowed air to partially pass air detector	Air embolus; death	Follow manufr safety checks; manuf action
Del Sys-Central	10/22/85	8 patients exposed to formaldehyde disinfectant	Toxic reaction; death	Proper disinfect/rinse out prcdr; check for formaldehyde before dialysis
Del Sys-Central	10/18/88	Backflow of drain line contaminates dialysate mix tank; bact contam.	Pyrogen reactions; sepsis	Manuf action; bacterial monitoring
Del Sys-Central	11/3/88	Pyrogen reaction; user cont (bacteria) pH probe with contam. sol	Pyrogen reactions; sepsis	Follow mfr's procedures; proper sys sanitization; bact monitoring
Del Sys-Central	11/3/88	PL adverse rxn due to improper pH; poor user mtnc; alarm set wrong	Alkylosis/addosis; death	Follow mfrs mtnc procedures; check pH before dialysis; proper alarm set
Del Sys-Central	12/20/88	Alkylosis x2; add pump stopped and no pH alarm; suspect user disabled alarm	Alkylosis/addosis; death	Follow mfrs mtnc prcdr; check pH before dialysis; set alarms properly
Del Sys-Central	2/8/89	Addosis/Alkylosis x18; proportioning pump malf and no pH alarm	Alkylosis/addosis; death	Follow mfrs mtnc procedures; check pH before dialysis; mfr action
Del Sys-Central	3/3/89	Improper sodium concentration (low); cond levels improperly set	Hyponatremia; nausvom; hemolysis	Follow mfrs safety procd; check cond before dialysis
Del Sys-Central	3/14/89	Improper calcium conc (high); concentrate mixed improperly	Nausea vomiting; muscle weakness	Follow manufr safety procedures;
Del Sys-Central	9/1/89	Machine malf causes improper dialysate pH	alkylosis/addosis; death	Manuf action; check pH before dialysis
Del Sys-Sngl Pt	5/1/82	Overheated elec components (smoke and melting); component failure	Fire; machine malfunction	Manuf. action; electical inspection
Del Sys-Sngl Pt	5/12/82	Overheated elec components (smoke and melting); component failure	Fire; machine malfunction	Manuf. action; electical inspection

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Del Sys-Sngl Pt	5/21/82	Air embolus; patient expired; air detector not in activated mode	Air embolus; death	Proper safety check before dialysis
Del Sys-Sngl Pt	8/6/82	Overheated elec components (smoke and melting); component failure	Fire; machine malfunction	Manuf. action; electical inspection
Del Sys-Sngl Pt	8/25/82	Overheated elec components (smoke and melting); component failure	Fire; machine malfunction	Manuf. action; electical inspection
Del Sys-Sngl Pt	3/9/84	Pump operated at max speed (700) despite setting; control malfunction	Excessive blood flow	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	12/10/84	Severe metabolic acidosis with sorbent system; incorrect use	Acidosis; death	Follow manufacturer's procedures
Del Sys-Sngl Pt	12/18/84	High positive dialysate pressure due to clogged check valve (home patient)	Improper UF; hypervolemia	Proper water treatment; proper machine mtnc
Del Sys-Sngl Pt	12/18/84	Pt fluid gain poss 2° to high positive dialysate pressure	Improper UF; hypervolemia	Proper machine maintenance
Del Sys-Sngl Pt	12/21/84	Patient exposed to low sodium dialysate; machine malfunction; no alarm	Hyponatremia; naus/vom/t; hemolysis	Manuf action ; check conductivity before dialysis
Del Sys-Sngl Pt	1/7/85	Improper sodium concentration (high); equipment malfunction	Hypernatremia; naus/vom; seizure; death	Mfr action; check cond before dialysis; proper mtnc procd
Del Sys-Sngl Pt	1/7/85	Dialysate conductivity exceeds acceptable limits; details unknown	Hypernatremia; naus/vom; seizure; death	Manuf action ; check conductivity before dialysis
Del Sys-Sngl Pt	1/21/85	Formaldehyde backsiphoned from one machine to others being used; pt expired	Toxic reaction; death	Proper procedures; antisiphon valve needed in water piping
Del Sys-Sngl Pt	2/14/85	Conductivity control grossly misadjusted; formaldehyde exposure; pt expired	Hypernatremia; toxic rxn; death	Follow mfr's repair procd; check cond & formaldehyde resid before dial
Del Sys-Sngl Pt	2/21/85	Pump operated at maximum speed (700) despite setting; control malfunction	Excessive blood flow	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	2/26/85	Excess UF due to equipment malfunction	Hypovolemia; hypotension	Manuf action
Del Sys-Sngl Pt	2/27/85	High sodium (180); system did alarm; pt. expired; details unknown	Hypernatremia; naus/vom; seizures; death	Check cond before dialysis; proper procedures; mfr action (?)
Del Sys-Sngl Pt	2/28/85	Pump operated at accelerated speed despite setting; control malfunction	Excessive blood flow	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	3/6/85	Low sodium (123) concurrent with staff overiding alarm	Hyponatremia; naus/vom; hemolysis	Proper procedures; check conductivity before dialysis
Del Sys-Sngl Pt	3/12/85	Air in blood circuit does not stop blood pump	Air embolus; death	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	3/29/85	Machine malfunction causes concentrate drawn into dialyzer	Hypernatremia; naus/vom; seizure; death	Manuf action; check conductivity before dialysis
Del Sys-Sngl Pt	4/9/85	Flow through dialysate circuit despite temp alarms or "rinse" setting	Hyponatremia; naus/vom; hemolysis	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	4/18/85	User used acetate concentrate for bicarbonate dialysis; pt expired	Acidosis; death	Facil treat conc as drug (procd); pH and cond check before dialysis
Del Sys-Sngl Pt	4/29/85	High sodium; details unknown	Hypernatremia; naus/vom; seizures; death	Check conductivity before dialysis; proper procedures; mfr action (?)
Del Sys-Sngl Pt	5/1/85	Excess UF due to equipment malfunction	Hypovolemia; hypotension	Manuf action
Del Sys-Sngl Pt	5/17/85	High dialysate sodium (248); reversed plumbing inside of machine	Hypernatremia; naus/vom; seizures; death	Check cond before dialysis; proper mtnc/repair procd; mfr action (?)
Del Sys-Sngl Pt	6/28/85	Air embolus; air detector not armed	Air embolus; death	Facility pre-dialysis checks
Del Sys-Sngl Pt	7/17/85	Air embolus; air detector did not activated; details unknown	Air embolus; death	Facility pre-dialysis checks; ? manuf action
Del Sys-Sngl Pt	7/30/85	Pump operated at max speed (700) despite setting; control malf	Excessive blood flow	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	8/9/85	Low sodium dialysate (possibly no dialysate)	Hyponatremia; naus/vom; hemolysis	Proper procedures; check conductivity before dialysis
Del Sys-Sngl Pt	9/4/85	Low sodium dialysate; improper machine calibration by facility	Hyponatremia; naus/vom; hemolysis	Proper mtnc/repair procd; check dialysate cond before dialysis
Del Sys-Sngl Pt	9/13/85	Put machine in bypass during dialysis/water into dialyzer/pt. hemolysis	Hemolysis; severe hemolytic anemia	Proper facility procedures; conductivity check before dialysis
Del Sys-Sngl Pt	10/3/85	Dialysate at 42° instead of 37° as set; no alarm	Hemolysis	Proper mtnc/repair procd; check T° before dialysis; mfr action
Del Sys-Sngl Pt	11/12/85	Low conductivity alarm but machine did not bypass; blood pump did stop	Hyponatremia; naus/vom/t; hemolysis	Proper mtnc/repair procd; check cond before dialysis; mfr action
Del Sys-Sngl Pt	12/3/85	Excess UF due to ? equipment malfunction	Hypovolemia; hypotension	Manuf action
Del Sys-Sngl Pt	12/11/85	Excess heparinization due to poor hep. pump mtnc (clamps clogged with blood)	Over-anticoagulation; bleeding	Proper facility mtnc procd; anticoagulation monitoring
Del Sys-Sngl Pt	12/19/85	Acidosis due to low bicarb/pH; cause unknown	Acidosis; death	Facil treat conc as drug (procedures); pH & cond check before dialysis
Del Sys-Sngl Pt	2/7/86	Dialysate at 46°; simultaneous failure of 2 components	Hemolysis	Proper mtnc/repair procedures; check T° before dialysis; mfr action

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Del Sys-Sngl Pt	2/18/86	Air embolus; details unknown; suspect air detector not armed	Air embolus; death	Facility pre-dialysis checks;
Del Sys-Sngl Pt	3/21/86	High sodium; pt sodium=187; alarms maladjusted by facility	Hypernatremia; naus/vom; seizures; death	Check conductivity before dialysis; proper mtnc/repair/QC procedures
Del Sys-Sngl Pt	4/10/86	Excess UF due to ? equipment malfunction; possible user error	Hypovolemia; hypotension	Facility follow manuf instructions; Manuf action ?
Del Sys-Sngl Pt	4/18/86	Acidosis due to low bicarb/pH; improper concentrate used	Acidosis; death	Facility treat conc as drug (procd); pH and cond check before dialysis
Del Sys-Sngl Pt	4/22/86	Hemolysis due to empty concentrate jug; no alarm	Hyponatremia; naus/vom; hemolysis	Proper procedures; manuf action
Del Sys-Sngl Pt	4/28/86	Pyrogen reactions 2° to gross machine bacterial contamination	Pyrogen reactions; sepsis	Proper disinfection procedures, water treatment, bacterial monitoring
Del Sys-Sngl Pt	4/28/86	Pyrogen reactions 2° to gross water system bacterial contamination	Pyrogen reactions; sepsis	Proper disinfection procedures, water treatment, bacterial monitoring
Del Sys-Sngl Pt	4/29/86	Potential air embolus; details unknown; suspect user error	Air embolus; death	Facility pre-dialysis checks;
Del Sys-Sngl Pt	5/5/86	Heater overheated due to dirt in water	Hemolysis	Proper water treatment; proper machine maintenance
Del Sys-Sngl Pt	7/18/86	High dialysate sodium(234); alarms and proportioning maladjusted by facility	Hypernatremia; naus/vom; seizures; death	Check conductivity before dialysis; proper mtnc/repair/QC procedures
Del Sys-Sngl Pt	8/5/86	High dialysate sodium; details unknown	Hypernatremia; naus/vom; seizures; death	Check conductivity before dialysis; proper mtnc/repair/QC procedures
Del Sys-Sngl Pt	8/13/86	Appar. pyrogen rxn; Renalin;poor water treatment; poss. backfilter (high flux)	Pyrogen reaction; sepsis	Proper water trtmt design & disinfect; proper microbiol monitor & germicide dilution
Del Sys-Sngl Pt	9/19/86	Blood pump stopped working during dialysis; also did predialysis (ignored)	Ineffective dialysis; potential of clotting	Manuf action; proper machine maintenance/pre-dialysis checks
Del Sys-Sngl Pt	11/17/86	Excess UF due to ? equipment malfunction	Hypovolemia; hypotension	Manuf action
Del Sys-Sngl Pt	1/6/87	Excess UF due to ? equip malfunction; user bypassed calib requirerment	Hypovolemia; hypotension	Facility follow manuf instructions;
Del Sys-Sngl Pt	2/11/87	Pump operated at max speed (700) despite setting; control malfunction	Excessive blood flow	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	2/12/87	Excess UF due to equipment malfunction	Hypovolemia; hypotension	Manuf action
Del Sys-Sngl Pt	2/18/87	Pt gained weight ? 2° to positive dialysate press; no predialysis mach checks	Hypervolemia; hypertension	Proper facility procedures; manuf action
Del Sys-Sngl Pt	3/2/87	Pump operated at accelerated speed despite setting; control malfunction	Excessive blood flow	Manuf action; facility pre-dialysis checks
Del Sys-Sngl Pt	3/9/87	Staff used machine despite knowledge of conductivity problem; high sodium	Hypernatremia; naus/vom; seizures; death	Check cond before dialysis; proper mtnc/repair/QC procedures
Del Sys-Sngl Pt	4/13/87	Pump operated at accelerated speed despite setting; control malfunction	Excessive blood flow	Manufacturer action; facility pre-dialysis checks
Del Sys-Sngl Pt	4/24/87	Patient received small electrical shock due to wiring problem	Electricution	Proper mtnc/repair procedures; elec checks; QC procedures
Del Sys-Sngl Pt	4/29/87	Potential air embolus: bld pump continued to run & no clamp despite air alarm	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	4/30/87	Potential air embolus: bld pump continued to run & no clamp despite air alarm	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	5/1/87	Potential air embolus: bld pump continued to run & no clamp despite air alarm	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	5/1/87	Potential air embolus: bld pump continued to run & no clamp despite air alarm	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	6/12/87	Air embolus; malfunction of reset switch disabled alarm	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	6/23/87	Formaldeyde exposure due to backsiphon from upstream machine	Toxic rxn; death	Anti siphon valves; proper procedures
Del Sys-Sngl Pt	6/25/87	Excess UF due to equip malf; user did not follow mfr's procedures	Hypovolemia; hypotension	Facility follow mfr instructions;
Del Sys-Sngl Pt	6/25/87	Pot. air embolus: bld pump cont to run & no clamp despite air alarm; improp repair	Air embolus; death	Facility pre-dialysis checks; follow mfr's repair/mtnc procd; QC
Del Sys-Sngl Pt	6/30/87	Air embolus; air detector stuck in reset position	Air embolus; death	Facility pre-dialysis check; mfr action
Del Sys-Sngl Pt	7/1/87	Pot. air embolus: bld pump cont to run & no clamp despite air alarm; poor mtnc	Air embolus; death	Facility pre-dialysis checks; follow mfr's repair/mtnc procd; QC
Del Sys-Sngl Pt	7/16/87	Art & ven pressure alarm but no blood pump stop;	Problems assoc with excess pressure	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	7/17/87	Excessive UF caused dialzr memb rupture; malf due to poor facility equip mtnc	Blood loss; hypotension; sepsis	Proper maintenance/repair procedures; QC procedures
Del Sys-Sngl Pt	7/31/87	Excess UF due to equipment malfunction	Hypovolemia; hypotension	Manufacturer action
Del Sys-Sngl Pt	8/11/87	Pump operated at accel speed despite setting; control malfunction	Excessive blood flow	Manufacturer action; facility pre-dialysis checks

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Del Sys-Sngl Pt	8/14/87	Overheated elec components (smoke, flames, and melting); component failure	Fire; machine malfunction	Manufacturer action; electical inspection
Del Sys-Sngl Pt	9/17/87	Dialyzer bld leak but no mach alarm; facil did not check bld leak calib before dialysis	Blood loss; hypotension; sepsis	Follow manufacturer's pre-dialysis checks
Del Sys-Sngl Pt	9/21/87	Acidosis due to improper concentrate (acid instead of acetate) used	Acidosis; death	Facil treat conc as drug (procedures); pH and cond check before dialysis
Del Sys-Sngl Pt	10/23/87	Air embolus; details unknown	Air embolus; death	Facility pre-dialysis checks; manufacturer action
Del Sys-Sngl Pt	11/9/87	Formaldeyde exposure; facil did not check for resid formaldehyde aft disinfec	Toxic rxn; death	Proper procedures; predialysis formaldehyde check
Del Sys-Sngl Pt	11/11/87	Excess UF due to equip malf; user didn't follow mfr's cleaning or pre-dial check prcd	Hypovolemia; hypotension	Facility follow manufacturer's instructions;
Del Sys-Sngl Pt	11/16/87	Air embolus; details unknown	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	11/23/87	Potential air embolus; details unknown	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	11/24/87	Air embolus: bld pump continued to run,no clamp, no alarm	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	11/24/87	Low sodium dialysate; high T°; alarms func properly but patient hemolysis occurred	Hyponatremia; naus/vom; hemolysis	Proper mtnc/repair procd; check dialysate cond & T° before dial; mfr action
Del Sys-Sngl Pt	12/17/87	Pt. gained weight ? 2° UF cntrl malf; facil did not perform mfr's recom pre-check	Hypervolemia; hypertension	Proper facility procedures; pre-dialysis check
Del Sys-Sngl Pt	12/23/87	Overheated electrical components (smoke and melting); component failure	Fire; machine malfunction	Manufacturer action; electrical inspection
Del Sys-Sngl Pt	1/6/88	Air embolus due to microbubbles; no alarm; blood tubing collapse	Air embolus; death	Facility pre-dialysis check; mfr action
Del Sys-Sngl Pt	1/12/88	Low Na dialysate; improp propor; conduct alarm malf; no indpndnt conduct check	Hyponatremia; naus/vom; hemolysis	Check dialysate conduct before dialysis; manuf action
Del Sys-Sngl Pt	1/18/88	Air embolus: bld pump continued to run,no clamp, no alarm	Air embolus; death	Facility pre-dialysis checks; mfr action
Del Sys-Sngl Pt	1/18/88	Clotting 2° to bld pump rollers becoming inoperative	Blood loss; hypotension; sepsis	Manu action; proper facility mtnc, pre-checks, QC
Del Sys-Sngl Pt	1/25/88	Overheated electrical components (smoke and melting); component failure	Fire; machine malfunction	Manufacturer action; electrical inspection
Del Sys-Sngl Pt	1/26/88	Air embolus due to microbubbles; no alarm	Air embolus; death	Facility pre-dialysis check; mfr action; proper machine mtnc
Del Sys-Sngl Pt	1/27/88	Disinfectant exposure due to backsiphon from upstream machine	Toxic rxn; death	Antisiphon valves; proper procd; remove disinfec from all lines before trmt
Del Sys-Sngl Pt	2/15/88	Low dialysate cond vis alarm but no aud or bypass—facil contd dialysis; hemolysis	Hyponatremia; naus/vom; hemolysis	Pre-dialysis alarm checks; follow mfr's procd for alarm condition
Del Sys-Sngl Pt	2/19/88	Pt gained weight ? 2° UF cntrl malf; no pre-check by facility; improper mtnc	Hypervolemia; hypertension	Proper facility maintenance procedures; pre-dialysis check
Del Sys-Sngl Pt	2/20/88	High dialysate sodium (180); no predialysis conductivity check	Hypernatremia; naus/vom; seizures; death	Check cond before dialysis; proper mtnc/repair procd; mfr action (?)
Del Sys-Sngl Pt	2/24/88	Low Na dialysate; improp propor; conductivity alarm malf; no pre-dialysis cond check	Hyponatremia; naus/vom; hemolysis	Check dialysate cond before dialysis; mfr action
Del Sys-Sngl Pt	3/2/88	Overheated heater (smoke, flames, and melting); 2° to mach oper without water	Fire; machine malfunction	Follow mfr's procedures
Del Sys-Sngl Pt	3/2/88	Overheated heater (smoke, flames, and melting); 2° to mach oper without water	Fire; machine malfunction	Follow manufacturer's procedures
Del Sys-Sngl Pt	3/7/88	Excessive infusate rate; malfunctioning drip chamber		Manufacturer repairs and recalls
Del Sys-Sngl Pt	3/15/88	Excessive UF; machine malfunction	Hypotension; hypovolemia	Manufacturer action;
Del Sys-Sngl Pt	3/15/88	Excessive UF; machine malf due to improper calibration (user caused)	Hypotension; hypovolemia	Patient care staff must report broken components; follow mfr's procd
Del Sys-Sngl Pt	3/17/88	Inadequate UF 2° to malfunction of dialysate pressure gauge	Hypertension; hypervolemia	Proper facility mtnc and QC; mfr action
Del Sys-Sngl Pt	3/25/88	Malfunction of TMP controller resulting in dialyzer membrane rupture	Blood loss; hypotension; sepsis	Manufacturer action; proper facility maintenance and QC
Del Sys-Sngl Pt	4/18/88	Dialzr bld leak but no mach alarm; pt sepsis; pt death; needle resis prvds presssure	Blood loss; hypotension; sepsis	Follow mfr's pre-dialysis checks
Del Sys-Sngl Pt	4/18/88	Excess UF; home pt; user did not set TMP alarms	Hypertension; hypervolemia	Follow mfr's procedures
Del Sys-Sngl Pt	4/26/88	Dialysate conductivity exceeds acceptable limits; bypass malfunction	Hypernatremia; naus/vom; seizure; death	
Del Sys-Sngl Pt	5/3/88	No alarm when venous needle pulled out; pt expired; needle resis prvds pressure	Hypotension; blood loss	Facility's procedures
Del Sys-Sngl Pt	5/6/88	Excess UF due to equip malfunction	Hypovolemia; hypotension	Manufacturer's action
Del Sys-Sngl Pt	5/12/88	Air embolus; patient expired; details unknown	Air embolus; death	Facility pre-dialysis check; manufacturer's action

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Del Sys-Sngl Pt	5/13/88	Air embolus; pt expired; details unknown	Air embolus; death	Facility pre-dialysis checks; manufacturer's action
Del Sys-Sngl Pt	5/16/88	Air embolus; details unknown	Air embolus; death	Facility pre-dialysis checks; manufacturer's action
Del Sys-Sngl Pt	5/25/88	Acidosis due to improper concentrate (acid instead of acetate) used	Acidosis; death	Facil treat conc as drug (procd); pH and cond check before dialysis
Del Sys-Sngl Pt	6/3/88	Excess UF due to equip malfunction	Hypovolemia; hypotension	Manufacturer's action
Del Sys-Sngl Pt	6/9/88	Clotting 2° to improper bld pump occlusion	Blood loss; hypotension	Proper equipment maintenance; manufacturer's action
Del Sys-Sngl Pt	6/9/88	Clotting 2° to improper bld pump occlusion	Blood loss; hypotension	Proper equipment maintenance; manufacturer's action
Del Sys-Sngl Pt	6/9/88	Clotting 2° to improper bld pump occlusion	Blood loss; hypotension	Proper equipment maintenance;manufacturer's action
Del Sys-Sngl Pt	6/13/88	Acidosis due to improp conc (acid & buffered used with mach in acetate mode)	Acidosis; death	Facil treat conc as drug (procedures); pH and cond check before dialysis
Del Sys-Sngl Pt	6/20/88	Dialyzer blood leak but no alarm	Blood loss; hypotension; sepsis	Manufacturer's action; proper machine maintenance
Del Sys-Sngl Pt	6/20/88	Low Na dialysate (80); improp propor; conduct alarm malf; no predial cond check	Hyponatremia; naus/vom; hemolysis	Check dialysate cond before dialysis; manufacturer's action
Del Sys-Sngl Pt	6/21/88	No alarm when venous needle pulled out; needle resis provides enough pressure	Hypotension; blood loss	Facility's procedures
Del Sys-Sngl Pt	7/8/88	No dialysate flow due to dirt in water clogging filter	Ineffective dialysis	Proper water treatment; proper machine maintenance
Del Sys-Sngl Pt	7/11/88	Low dialysate Na 2° to malf valve; severe hemolysis; no predial cond check	Hyponatremia; naus/vom; hemolysis	Check dialysate conduct before dialysis; manufacturer's action
Del Sys-Sngl Pt	7/14/88	Excess UF due to equip malf; improper user procedures after equip malf	Hypovolemia; hypotension	Manufacturer's action; follow manuf procedures
Del Sys-Sngl Pt	7/22/88	Excess UF due to equip malfunction x 5	Hypovolemia; hypotension	Manufacturer's action
Del Sys-Sngl Pt	8/1/88	Heparin pump asmbly broke during tx causing discon & bld loss; user misuse	Blood loss; hypotension; sepsis	Follow manuf's procedures;
Del Sys-Sngl Pt	8/9/88	Conductivity of dialysate improperly proportioned because ref meter calib off	Hypernatremia/hyponatremia	Calibrate mach with properly calib ref meter (checked with std SLN)
Del Sys-Sngl Pt	8/9/88	Conductivity of dialysate improperly proportioned because ref meter calib off	Hypernatremia/hyponatremia	Calibrate machines with properly calib ref meter (checked with std SLN)
Del Sys-Sngl Pt	8/15/88	Conductivity of dialysate improperly proportioned because ref meter calib off	Hypernatremia/hyponatremia	Calibrate machines with properly calib ref meter (checked with std SLN)
Del Sys-Sngl Pt	9/13/88	Pot air embolus: bld pump contd to run & no clamp desp visual (no aud) air alarm	Air embolus; death	Facility pre-dialysis checks; manufacturer's action
Del Sys-Sngl Pt	9/15/88	Low cond with no bypass caused failure in proportioning and cond alarm systems	Hyponatremia; naus/vom; hemolysis	Check dialysate conduct before dialysis; manufacturer's action
Del Sys-Sngl Pt	9/19/88	Dialyzer blood leak but no machine alarm;	Blood loss; hypotension; sepsis	Follow manuf's pre-dialysis checks; manufacturer's action
Del Sys-Sngl Pt	9/23/88	Blood pump stops working during dialysis	Ineffective dialysis; pot of clotting	Manufacturer's action; proper machine mtnc/pre-dialysis checks
Del Sys-Sngl Pt	10/14/88	Home pt ran out of conc & mach when to rinse instead of bypass; concntr replaced	Hyponatgremia; Naus/vom; sepsis	Manufacturer's action; proper procedures
Del Sys-Sngl Pt	10/17/88	Excess neg press due to equip malfunction	Hypovolemia; hypotension	Manufacturer's action
Del Sys-Sngl Pt	10/26/88	No alarm when venous needle pulled out; needle resis provides pressure	Hypotension; blood loss	Facility's procedures
Del Sys-Sngl Pt	10/26/88	Low dialysate cond (10) 2° to improper facil calib; no pre-dialysis cond check	Hyponatremia; naus/vom; hemolysis	Check dialysate cond before dialysis; follow mfr's mtnc/repair/QC procd
Del Sys-Sngl Pt	12/22/88	Excess UF due to equip malf; improper user pre-dialysis check	Hypovolemia; hypotension	Manufacturer's action; follow mfr procedures
Del Sys-Sngl Pt	1/30/89	Excess UF ? due to equip malfunction; details unknown	Hypovolemia; hypotension	Manufacturer's action ?
Del Sys-Sngl Pt	2/15/89	Inad UF due to equip malf; facil didn't perform predial check/follow other procd	Hypovolemia; hypotension	Pre-dialysis checks; follow mfr's instructions for use
Del Sys-Sngl Pt	2/16/89	Excess UF due to equip malf; facil did not stop trmt even though alarms	Hypovolemia; hypotension	Follow mfr's instructions re: response to alarms
Del Sys-Sngl Pt	3/3/89	Formaldehyde exposure due inad rinse 2° to alarm during rinse procd	Toxic rxn; death	Proper rinsing procd/resid testing; change in mfr's recomm procd
Del Sys-Sngl Pt	3/24/89	Cond of dialysate improperly propor; no predialysis cond check done	Hypernatremia/hyponatremia	Predialysis conductivity check

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialysate	7/10/81	Improper sodium conc (low); improper dilution of concentrate by user	Hyponatremia; naus/vom; hemolysis	Manufacturer's action; check conductivity before dialysis
Dialysate	1/9/84	Improper sodium concentration (low)	Hyponatremia; naus/vom; hemolysis	Follow manufacturer's procedures; check cond before dialysis
Dialysate	8/7/84	Improper potassium content (low and high)	Nausea/vomiting; cardiac problems	Manufacturer's action
Dialysate	11/8/84	pH of acid concentrate too high	Alkylosis; cardiac problems	Manufacturer's action; check pH before dialysis
Dialysate	5/1/85	Improper sodium conc (high); ? facility equip calib	Hypernatremia; naus/vom; seizure; death	Manufacturer's action; check conductivity before dialysis
Dialysate	8/9/85	Improper Potassium content; facility staff misread label	Nausea/vomiting; cardiac problems	Manuf color-code labels; facil treat conc as drug (procedures)
Dialysate	10/4/85	High aluminum levels in concentrate	Aluminemia; bone/brain problems	Manufacturer's action
Dialysate	3/21/86	Improper potassium content; home patient misread label	Nausea/vomiting; cardiac problems	Manuf color-code labels; facil treat conc as drug (procedures)
Dialysate	8/7/86	Microbial growth in liquid concentrate; recall	Pyrogen reactions; sepsis	Manufacturer's action; facility microbiological monitoring
Dialysate	10/14/86	Microbial growth in liquid concentrate; recall	Pyrogen reactions; sepsis	Manufacturer's action; facility microbiological monitoring
Dialysate	10/29/86	Microbial growth in liquid concentrate; recall	Pyrogen reactions; sepsis	Manufacturer's action; facility microbiological monitoring
Dialysate	11/5/86	Microbial growth in liquid concentrate; recall	Pyrogen reactions; sepsis	Manufacturer's action; facility microbiological monitoring
Dialysate	3/16/87	Used improper conc; pt required medical intervention	Hypernatremia; naus/vom; seizure; death	Mfr color-code labels; facil treat conc as drug (procd); √ cond/pH before dial
Dialysate	7/21/87	Sodium content on label was wrong (off by 100%)	Hypernatremia; naus/vom; seizure; death	Manufacturer's action; check conductivity before dialysis
Dialysate	6/23/88	Concentrate contains dirt	Pyrogen reactions; sepsis	Mfr action; facil microbiolog monitoring; visual inspection at facility
Dialysate	8/20/88	Microbial growth in liquid concentrate; recall;	Pyrogen reactions; sepsis	Manufacturer's action; facility microbiological monitoring
Dialysate	9/12/88	Improper Potassium content; facility staff misread label	Nausea/vomiting; cardiac problems	Manuf color-code labels; facility treat concentrate as drug (procedures)
Dialysate	5/23/89	23 pts dialzd with acid instd of acetate conc on acetate mach; staff error	Acidosis; death	Facility treat conc as drug (procedures); check cond/pH before dialysis

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	1/14/80	Blood leaking out of cracked dialyzer	Blood loss; hypotension; sepsis	Inspect dialyzer; manufacturer recalls
Dialyzer-HF	1/21/80	Cracked header resulting in blood loss	Blood loss; hypotension; sepsis	Inspect dialyzer; manufacturer Δ product
Dialyzer-HF	3/4/80	Fiber rupture btd leak; visual obsrv (no blood leak detector)	Blood loss; hypotension; sepsis	Proper functioning blood leak detector
Dialyzer-HF	6/30/80	Patient symptoms indicating bact contam of dialyzer	Pyrogen reaction; sepsis	Sterile technique for set up; proper system disinfection
Dialyzer-HF	2/27/81	Fiber rupture blood leak; visual obsrv (no blood leak detector)	Blood loss; hypotension; sepsis	Proper functioning blood leak detector
Dialyzer-HF	3/2/81	Fiber rupture blood leak; visual obsrv (no blood leak detector)	Blood loss; hypotension; sepsis	Proper functioning blood leak detector
Dialyzer-HF	3/6/81	Fiber rupture blood leak; visual obsrv (no blood leak detector)	Blood loss; hypotension; sepsis	Proper functioning blood leak detector
Dialyzer-HF	3/11/81	Fiber rupture blood leak; visual obsrv (no blood leak detector)	Blood loss; hypotension; sepsis	Proper functioning blood leak detector
Dialyzer-HF	4/22/81	Fiber rupture blood leak; visual obsrv (no blood leak detector)	Blood loss; hypotension; sepsis	Proper functioning blood leak detector
Dialyzer-HF	6/18/81	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/30/81	External lood leak at blood port connector	Blood loss; hypotension; sepsis	Inspect dialyzer; manufacturer Δ product; use leur lock
Dialyzer-HF	12/8/81	External lood leak at blood port connector	Blood loss; hypotension; sepsis	Inspect dialyzer; manufacturer Δ product; use leur lock
Dialyzer-HF	12/9/81	Broken blood port	Blood loss; hypotension; sepsis	Inspect dialyzer; be careful of manual stress
Dialyzer-HF	3/15/82	Apparent Hypersensitivity reaction during 6% of treatments	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/28/83	Apparent Hypersensitivity reaction (fibers alcohol washed by mfr)	Anaphylaxis; death	FUS measures; manufacturer Δ alcohol wash technique
Dialyzer-HF	2/4/83	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/4/83	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/4/83	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/3/83	? Pyrogen Reaction	Pyrogen reaction; sepsis	Proper facility disinfection and microbiological monitoring
Dialyzer-HF	5/31/83	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/28/83	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/28/83	Apparent Hypersensitivity reaction ; no reaction on plate dialyzer	Anaphylaxis; death	FUS measures; Δ dialyzer
Dialyzer-HF	11/10/83	Metal shavings found in blood compartment	Unknown	Inspect dialyzer before use; manufacturer action
Dialyzer-HF	4/30/84	Apparent Hypersensitivity reactio	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/4/84	Highly variable UF coefficient	Hypotension; improp fluid removal	Characterize new dialyzers; UF control; manufacturer action
Dialyzer-HF	7/11/84	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	8/13/84	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	8/22/84	Membrane Blood Leak	Blood loss; hypotension; sepsis	Use blood leak detector; manufacturer action
Dialyzer-HF	11/8/84	Apparent Hypersensitivity reaction; patient expired	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/2/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/9/85	Possible patient injury due to excessive UF rate (out of specs)	Hypotension; excessive fluid loss	Characterize dialyzer before use; UF control; manufacturer action
Dialyzer-HF	1/10/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/18/85	Possible pyrogenic reaction on second use of dialyzer	Pyrogen reaction; sepsis	Proper facility disinfection and microbiological monitoring
Dialyzer-HF	1/23/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/31/85	Apparent Hypersensitivity reac; did not follow mfr's priming procd	Anaphylaxis; death	FUS measures; follow manufacturer's rinsing procedures
Dialyzer-HF	2/8/85	Clotting of extracorporeal circuit; cuase unknown	Blood loss; hypotension; sepsis	Unknown; proper anticoagulation monitoring

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	2/8/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/11/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/14/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/14/85	Apparent Hypersensitivity reac; none on other dialyzer if bicarb dialysate	Anaphylaxis; death	FUS measures; change dialyzer and use bicarbonate dialysate
Dialyzer-HF	2/14/85	Apparent Hypersensitivity reaction; none with reused dialyzer	Anaphylaxis; death	FUS measures; use reused dialyzer
Dialyzer-HF	3/13/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/21/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/29/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/29/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/3/85	Apparent Hypersensitivity reaction; no reac on plate dialyzer	Anaphylaxis; death	FUS measures; change to plate dialyzer
Dialyzer-HF	4/4/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/5/85	Apparent Hypersensitivity reaction; no reac on same dialyzer next time	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/5/85	Apparent Hypersensitivity reaction; no reac on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	4/5/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/11/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/12/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/1/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/3/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/13/85	Apparent Hypersensitivity reaction; no reac on alt dialyzer	Anaphylaxis; death	FUS measures; A dialyzer
Dialyzer-HF	5/14/85	Large extrnl blood leak (red transfus 2 units) due to cracked header	Blood loss; hypotension; sepsis	Inspect dialyzer before use; proper handling
Dialyzer-HF	5/14/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/14/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/14/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/22/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/6/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/17/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/17/85	Apparent Hypersensitivity reaction; did not follow mfr's priming procd	Anaphylaxis; death	FUS measures; follow manufacturer's rinsing procedures
Dialyzer-HF	6/28/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/28/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	7/2/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	7/16/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	8/2/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	8/14/85	Apparent Hypersensitivity reaction; mfr rinse procd not followed	Anaphylaxis; death	FUS measures; follow manufacturer's rinsing procedures
Dialyzer-HF	8/15/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	9/6/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	9/10/85	Apparent Hypersensitivity reaction ; no reac with dfr dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	9/16/85	Apparent Hypersensitivity reaction ; no reac with dfr dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	10/7/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/13/85	Apparent Hypersensitivity reaction ; no reac with dfr dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	10/23/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/25/85	Apparent Hypersensitivity reaction ; no reac with dfr dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	11/1 1/85	Apparent Hypersensitivity reaction; patient expired	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/1 1/85	Apparent Hypersensitivity reaction ; no reac with dfr dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	11/19/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/20/85	Apparent Hypersensitivity reaction x 3	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/28/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/3/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/13/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/13/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/18/85	Apparent Hypersensitivity reaction x 2	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/20/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/26/85	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/26/85	Possible excessive UF coefficient (out of mfr spec); no patient injury	Excess fluid removal; hypotension	Characterize new dialyzers; manufacturer action; UF control
Dialyzer-HF	1/16/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/16/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/17/86	Blood line (ERIK) separates from dialyzer	Blood loss; hypotension; sepsis	Staff attention to connection; luer lock
Dialyzer-HF	2/11/86	Cracked header resulting in blood leak-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	2/21/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/25/86	Blood leaks at header connection	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	3/12/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/1/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/2/86	Possible excessive UF coef (out of mfr spec); no patient injury	Excess fluid removal; hypotension	Characterize new dialyzers; manufacturer action; UF control
Dialyzer-HF	4/15/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/16/86	Apparent Hypersensitivity reaction x 3	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/16/86	Possible excessive UF coef (out of mfr spec); no patient injury	Excess fluid removal; hypotension	Characterize new dialyzers; manufacturer action; UF control
Dialyzer-HF	4/16/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/28/86	Apparent Hypersensitivity reaction; patient expired	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/28/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/28/86	Apparent Hypersensitivity reaction ; no reac with dfr dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	4/28/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/28/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	4/28/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/28/86	Apparent Hypersensitivity reaction ; no reaction with plate dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	4/29/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/29/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/15/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/24/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/30/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/30/86	Sepsis	Pyrogen reaction; sepsis	Proper aseptic technique; proper disinfection and microbial monitoring
Dialyzer-HF	7/1/86	Blood leak at header after dot entered dialyzer-no patient injury	Blood loss; hypotension	Proper anticoagulation monitoring
Dialyzer-HF	7/3/86	Apparent Hypersensitivity reaction ; no reaction with plate dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	7/17/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	7/24/86	Blood leak at header connection	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	8/4/86	Apparent Hypersensitivity reaction; none with longer pre-rinse	Anaphylaxis; death	FUS measures; longer prerinse
Dialyzer-HF	8/5/86	Blood leak at header connection-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	8/22/86	Blood leak at header connection-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	8/25/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	8/27/86	Apparent Hypersensitivity reaction ; no reac with dit dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	9/3/86	Apparent Hypersensitivity reaction ; no reac with dit dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	9/10/86	Possible excessive UF coef (out of rnr spec); no patient injury	Excess fluid removal; hypotension	Characterize new dialyzers; manufacturer action; UF control
Dialyzer-HF	9/12/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	9/15/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	9/16/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	9/18/86	Apparent Hypersensitivity reaction; patient expired	Anaphylaxis; death	FUS measures
Dialyzer-HF	9/19/86	Apparent Hypersensitivity reaction; no reaction with dit dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	9/26/86	Apparent Hypersensitivity reaction; patient expired	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/13/86	Blood leak at header connection-no patient injury; dialyzer reused	Blood loss; hypotension; sepsis	Check dialyzer before use;
Dialyzer-HF	10/16/86	Apparent Hypersensitivity reaction x 2	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/16/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/16/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/17/86	External lood leak at blood port/blood line connector x 3	Blood loss; hypotension	Staff improve tachnique of attaching lines; use laur lock
Dialyzer-HF	10/24/86	Blood leak at header-no pt injury (blood loss apr x 1 unit)	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/28/86	Blood leak at header-no patient injury x 5	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/28/86	Apparent Hypersensitivity reaction x 2	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/28/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/7/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/14/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	11/14/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/26/86	Apparent Hypersensitivity reaction; no reac on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	11/26/86	Apparent Hypersensitivity reaction; no reac on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	11/26/86	Apparent Hypersensitivity reaction; no reac on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	11/26/86	Apparent Hypersensitivity reaction; no reac on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	11/26/86	Apparent Hypersensitivity reaction; no reac on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	12/3/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/4/86	Possible pyrogen reaction; reprocessed dialyzer	Pyrogen reaction; sepsis	Proper disinfection and microbiol monitoring
Dialyzer-HF	12/8/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/10/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/19/86	Possible excessive UF coef (out of mfr spec); no patient injury	Excess fluid removal; hypotension	Characterize new dialyzers; manufacturer action; UF control
Dialyzer-HF	1/15/87	External lood leak due to broken blood port x 2	Blood loss; hypotension	Inspect dialyzer before use
Dialyzer-HF	1/26/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/2/87	Blood leak at header-no patient injury x 3	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	2/2/87	Blood leak at header-no patient injury x 5	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	3/12/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/12/87	Blood leak at header-no patient injury x 5	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	3/13/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/16/87	Blood leak at header-no patient injury x 4	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	3/19/87	Apparent Hypersensitivity reaction; pt expired	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/19/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/19/87	Fiber leak requiring transfusion of one unit of blood	Blood loss; hypotension; sepsis	
Dialyzer-HF	3/19/87	Fiber leak requiring transfusion of one unit of blood	Blood loss; hypotension; sepsis	
Dialyzer-HF	4/2/87	Clotting of arterial header	Blood loss; hypotension; sepsis	Proper anticoagulation monitoring
Dialyzer-HF	3/19/87	Apparent Hypersensitivity reaction x 2	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/19/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	3/26/87	Apparent Hypersensitivity reaction x 5	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/2/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/27/87	Apparent Hypersensitivity reaction; no reac with dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	4/28/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures; will switch to CAPD
Dialyzer-HF	4/28/87	Blood leak at header-no patient injury x 3	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	5/11/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/15/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/26/87	Blood leak at header-no patient injury x 2	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	5/26/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	6/18/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	6/30/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	8/6/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use.; manufacturer action
Dialyzer-HF	8/10/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use.; manufacturer action
Dialyzer-HF	8/10/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use.; manufacturer action
Dialyzer-HF	8/12/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures; will reuse dialyzer
Dialyzer-HF	8/27/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use.;manufacturer action
Dialyzer-HF	8/28/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measure
Dialyzer-HF	9/14/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measure
Dialyzer-HF	9/14/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measure
Dialyzer-HF	9/15/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measure
Dialyzer-HF	9/16/87	Apparent Hypersensitivity reaction; did not follow mfr printing procedures	Anaphylaxis; death	FUS measures; follow manufacturer's printing procedures
Dialyzer-HF	9/22/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	9/22/87	Blood leak at header-no patient injury x 2	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	9/23/87	Apparent Hypersensitivity reaction x 3	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/2/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/22/87	Blood leak at header; apparently resulted in cardiac arrest	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/23/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	10/27/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/28/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/30/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/30/87	Header leak-no pt injury x 3: 1st, 2nd, 8th use; air leaked into dialysate	Erratic UF; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	11/2/87	Blood leak at header-no patient injury x 2	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	11/2/87	Blood leak at header-no patient injury x 3	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	11/20/87	Blood leak at header-no pt injury x 6: (4 - 1st use; 1 ea 2nd and 6th use)	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	11/20/87	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/24/87	Apparent Hypersensitivity reaction ; no reaction on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	12/8/87	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use.; manufacturer action
Dialyzer-HF	12/22/87	Blood leak at btd port/btd line connection; broken dialyzer blood port	Blood loss; hypotension; sepsis	Check dialyzer before use; mfr action; avoid stress on blood port
Dialyzer-HF	12/30/87	Apparent Hypersensitivity reaction; ? not primed acrd to mfr recomm	Anaphylaxis; death	FUS measures; prime according to mfr's rinse procd
Dialyzer-HF	1/5/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/8/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	1/15/88	Blood leak at blood port/blood line connection; broken dialyzer blood port	Blood loss; hypotension; sepsis	Check dialyzer before use; mfr action; avoid stress on blood port
Dialyzer-HF	1/29/88	Apparent Hypersensitivity reaction (new dial); no reaction on reused dialyzer	Anaphylaxis; death	FUS measures; use reused dialyzer
Dialyzer-HF	1/29/88	Apparent Hypersensitivity reaction; no reaction on different dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	2/4/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	2/4/88	Blood leak at blood port/blood line connection; broken dialyzer blood port	Blood loss; hypotension; sepsis	Check dialyzer before use; mfr action; avoid stress on blood port

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	2/19/88	Blood leak at header-no pt injury	Blood loss; hypotension; sepsis	Check dialyzer before use; mfr action
Dialyzer-HF	2/26/88	Apparent Hypersensitivity reaction; no reaction on different dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	2/26/88	Apparent Hypersensitivity reaction; no reaction on different dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	3/28/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/5/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/7/88	Blood leak at header associated with dotted dialyzer	Blood loss; hypotension; sepsis	Check dialyzer before use; proper antiocag monitoring; mfr action
Dialyzer-HF	4/7/88	Blood leak at header associated with dotted dialyzer	Blood loss; hypotension; sepsis	Check dialyzer before use; proper antiocag monitoring; mfr action
Dialyzer-HF	4/11/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	4/11/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	4/19/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/21/88	Blood line separated from dialyzer arterial blood port; no pt injury	Blood loss; hypotension; sepsis	Check dialyzer before use; proper set up technique; luer lock
Dialyzer-HF	4/21/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	4/22/88	Air embolus; unknown patient injury (no death)	Cardiac arrest; death	Check dialyzer before use; proper set up technique; luer lock
Dialyzer-HF	4/22/88	Air embolus; unknown patient injury (no death)	Cardiac arrest; death	Check dialyzer before use; proper set up technique; luer lock
Dialyzer-HF	4/22/88	Air embolus resulting in cardiac arrest (no death)	Cardiac arrest; death	Check dialyzer before use; proper set up technique; luer lock
Dialyzer-HF	4/22/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	4/25/88	Febrile reactions during dialysis	Pyrogen reaction; sepsis	Mfr action; proper facility disinfect and mirorbiol monitoring
Dialyzer-HF	5/2/88	Febrile reaction during dialysis x 4	Pyrogen reaction; sepsis	Mfr action; proper facility disinfect and mirorbiol monitoring
Dialyzer-HF	5/3/88	Apparent Hypersensitivity reaction on 15th use of dialyzer	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/3/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/19/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/24/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/27/88	Blood leak at cracked header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	6/9/88	Blood leak at cracked header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	6/24/88	Apparent Hypersensitivity reaction x 2; no reaction on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	6/25/88	Broken header caps & blood ports; possible 2° to manuf or reuse	Blood loss; sepsis	Manuf Δ product; inspect after reprocessing
Dialyzer-HF	6/29/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manuf action
Dialyzer-HF	6/30/88	Inadequate clearance associated with reuse technique	Inadequate treatment; uremia	Use proper reuse technique; use proper dialyzer pfmnc monitoring
Dialyzer-HF	7/1/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	7/1/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	7/7/88	Apparent Hypersensitivity reaction on gamma steril dialyzer; pt expired	Anaphylaxis; death	FUS measures
Dialyzer-HF	7/11/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	7/12/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	7/26/88	Apparent pyrogen reaction associated with cracked dialyzer housing	Pyrogen reaction; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	7/29/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	8/10/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	8/18/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	8/18/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	8/26/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	9/21/88	Apparent Hypersensitivity reaction; no reaction with dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	9/27/88	Dialysate leak at dialysate port	Unknown	Inspect dialyzer before use
Dialyzer-HF	10/17/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	10/25/88	Apparent Hypersensitivity reaction; improper priming procedure	Anaphylaxis; death	FUS measures; follow mfr's priming procedures
Dialyzer-HF	11/3/88	Apparent Hypersensitivity reaction; no reaction with dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	11/11/88	Blood leak at header x 2-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	11/21/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	11/23/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/29/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	11/29/88	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	12/7/88	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	12/21/88	Apparent Hypersensitivity reaction; improper priming procedure	Anaphylaxis; death	FUS measures; follow mfr's priming procedures
Dialyzer-HF	1/4/89	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	1/4/89	Blood leak at header x 2-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	1/4/89	Blood line separated from dialyzer arterial blood port x 2; no pt injury	Blood loss; hypotension; sepsis	Check dialyzer before use; proper set up technique; luer lock
Dialyzer-HF	1/9/89	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	1/9/89	Blood leak at header x 2-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	1/22/89	Blood leak at header x 4-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	1/27/89	Blood leak at header x 2-no pt injury; dialyzer may have been dropped	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	1/27/89	Blood leak at header-no pt injury; extended storage	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	1/27/89	Hemolysis-unknown cause	Decrease in hct; death	Since cause is unknown action is difficult to access
Dialyzer-HF	1/31/89	Blood leak at header x 2-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	3/17/89	Blood leak at header possible due to clotting-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; proper anticoag monitoring; mfr action
Dialyzer-HF	4/10/89	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/11/89	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	4/11/89	Apparent Hypersensitivity reaction x 2; no reaction on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	4/11/89	Apparent Hypersensitivity reaction; no reaction on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	4/11/89	Apparent Hypersensitivity reaction; no reaction on dif dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-HF	5/4/89	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	5/10/89	Blood leak at header x 5-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	5/11/89	Fiber rupture blood leak; visual observation (no blood leak detector)	Blood loss; hypotension	Proper functioning blood leak detector
Dialyzer-HF	5/19/89	Blood leak between dialyzer blood port and blood line; no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; proper set up; mfr action; luer lock
Dialyzer-HF	5/19/89	Blood line separated from dial blood port(luer lock adapter); no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; proper set up technique; mfr action

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HF	6/2/89	Blood line separated from arterial blood port (luer lock adapter); no pt injury	Blood loss; hypotension; sepsis	Check dialyzer before use; proper set up technique; mfr action
Dialyzer-HF	6/2/89	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	6/2/89	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	6/30/89	Blood line separated from dialyzer blood port; no pt injury	Blood loss; hypotension; sepsis	Check dialyzer before use; proper set up; mfr action; luer lock
Dialyzer-HF	7/5/89	Blood leak into dialysate compartment at header-no pt injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	8/2/89	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	9/14/89	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	9/14/89	Blood leak at header-no patient injury	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Dialyzer-HF	9/14/89	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HF	9/17/89	Blood leak at header; possible pyrogen reaction (possibly related)	Blood loss; hypotension; sepsis	Check dialyzer before use; manufacturer action
Note: Successful FUS treatment includes: stopping treatment, continuing treatment with meds, slowing down BP, changing dialyzers to another of same kind, changing to a different dialyzer. No single tactic appears more preferable from review of MDR reports. Symptoms reported include: back pain, shaking, "hot feeling", respiratory distress, wheezing, itching, chest pain, nausea, shortness of breath, "asthma-like symptoms", pain radiating from spine, vomiting, nasal congestion, coughing, diaphoresis, "funny taste in mouth", swollen tongue, agitation, respiratory arrest, anxiety, flushing, tachycardia, laryngeal, facial, or neck edema, cyanosis, seizure, abdominal pain, diarrhea, rash. In cases of febrile reaction it is important to save "everything", including dialyzer, blood lines, solution admin set, heparin bottle, saline bags, etc.				
CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-HiPerm	6/17/85	Apparent Hypersensitivity reaction; ? inadequate rinse; no reaction on dff dial	Anaphylaxis; death	FUS measures; follow mfr procedures; change dialyzer
Dialyzer-HiPerm	6/17/85	Apparent Hypersensitivity reaction; ? inadequate rinse; no reaction on dff dial	Anaphylaxis; death	FUS measures; follow mfr procedures; change dialyzer
Dialyzer-HiPerm	6/17/85	Apparent Hypersensitivity reaction; ? inadequate rinse; no reaction on dff dial	Anaphylaxis; death	FUS measures; follow mfr procedures; change dialyzer
Dialyzer-HiPerm	9/17/85	Apparent Hypersensitivity reaction; pt. expired; 1st exposure to this dialyzer	Anaphylaxis; death	FUS measures; follow mfr procedures; change dialyzer
Dialyzer-HiPerm	10/2/85	Possible excessive UF coefficient (out of Manuf spec); no patient injury	Excess fluid removal; hypotension	Characterize new dialyzers; mfr action; UF control
Dialyzer-HiPerm	1/3/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HiPerm	1/27/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HiPerm	8/5/86	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HiPerm	11/24/86	Apparent pyrogen reaction x 6; details unknown	Pyrogen reaction; sepsis	Proper water treatment design, disinfection, microbiol monitoring
Dialyzer-HiPerm	3/17/89	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Dialyzer-HiPerm	3/20/89	Apparent Hypersensitivity reaction	Anaphylaxis; death	FUS measures
Note: FUS treatment that has been successful includes: stopping treatment, continuing treatment with meds, continuing without meds, slowing down BP, changing dialyzers to another of same kind, changing to a different dialyzer. No single tactic appears more preferaeble from the review of the MDR reports. Symptoms reported include: backpain, shaking, "hot feeling", respiratory distress, wheezing, itching, chest pain, nausea, shortness of breath, "asthma-like symptoms", pain radiating form spine, vomiting,nasal congestion, coughing, diaphoresis, "funny taste in mouth", swollen tongue, agitation, respiratory arrest, anxiety, flushing, tachycardia, laryngeal, facial, or neck edema, cyanosis, seizure, abdominal pain, diarrhea, rash. In the case of febrile reactions it is important to save "everything", including" dialyzer, blood lines, solution admin set, heparin bottle, saline bags, etc.				

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-Plate	5/2/83	? Allergic reaction to dialyzer (?FUS)	Anaphylaxis; death	None suggested
Dialyzer-Plate	6/6/83	Blood leaking out of plate dialyzer housing	Blood Loss; sepsis	Inspect dialyzer; mfr recalls
Dialyzer-Plate	7/26/83	"Asthma type reaction" on plate dialyzer; ? inadequate rinse	Anaphylaxis; death	Rinse dialyzer better; other FUS measures
Dialyzer-Plate	1/14/85	Large blood leak out of dialyzer (250 ml); pressure plate separated	Blood loss; hypotension; sepsis	Inspect dialyzer; mfr ; pressure plate separated product
Dialyzer-Plate	1/18/85	Large blood leak out of dialyzer (300 ml); pressure plate separated	Blood loss; hypotension; sepsis	Inspect dialyzer; manufacturer Δ product
Dialyzer-Plate	1/25/85	Large blood leak out of dialyzer; pressure plate separated	Blood loss; hypotension; sepsis	Inspect dialyzer; manufacturer Δ product
Dialyzer-Plate	2/12/85	Severe anaphylactic reaction	Anaphylaxis; death	Switch to plate dialyzer; other FUS measures
Dialyzer-Plate	10/4/85	Large blood leak (500ml) on plate dialyzer; user employed excessive pressure	Blood loss; hypotension; sepsis	Use pressures only within manufacturer's specs
Dialyzer-Plate	3/27/86	Apparent Hypersensitivity reaction (x2) on plate dialyzer	Anaphylaxis; death	None suggested; FUS measures
Dialyzer-Plate	4/28/86	? Hypersensitivity reaction; ? pyrogenic reaction	Anaphylaxis; death	FUS measures; check endotoxin levels
Dialyzer-Plate	6/2/86	Blood leak out of dialyzer and membrane rupture due to ? excess pressure	Blood loss; sepsis	Monitor pressure accurately
Dialyzer-Plate	9/8/86	Several large membrane blood leaks on plate dialyzer (? damaged case)	Blood loss;hypotension; sepsis	Inspect dialyzer and packaging; mfr Δ prod
Dialyzer-Plate	11/21/86	Apparent Hypersensitivity reaction on plate dialyzer	Anaphylaxis; death	None suggested; FUS measures
Dialyzer-Plate	11/21/86	Apparent Hypersensitivity reaction on plate dialyzer	Anaphylaxis; death	None suggested; FUS measures
Dialyzer-Plate	1/14/86	Apparent Hypersensitivity reaction on plate dialyzer; no rxn on hollow fiber	Anaphylaxis; death	FUS measures; change dialyzer
Dialyzer-Plate	2/13/87	Apparent Hypersensitivity reaction on plate dialyzer	Anaphylaxis; death	None suggested; FUS measures
Dialyzer-Plate	2/13/87	Apparent Hypersensitivity reaction on plate dialyzer; ? inadequate rinse	Anaphylaxis; death	FUS measures; rinse dialyzer more completely
Dialyzer-Plate	5/22/87	Large blood leak out of dialyzer (250 ml); also membrane rupture	Blood loss; hypotension; sepsis	Inspect dialyzer; manufactureΔ product
Dialyzer-Plate	9/21/87	Large blood leak out of dialyzer; 2° to clotting	Blood loss; hypotension; sepsis	Inspect dialyzer; proper anticoag monitoring
Dialyzer-Plate	10/30/87	Apparent Hypersensitivity reaction on plate dialyzer	Anaphylaxis; death	FUS measures; Δ dialyzer
Dialyzer-Plate	11/13/87	Apparent Hypersensitivity reaction on plate dialyzer; no reaction on hollow fiber	Anaphylaxis; death	FUS measures; rinse dialyzer more completely
Dialyzer-Plate	11/23/87	Apparent Hypersensitivity reaction on plate dialyzer; ? inadequate rinse	Anaphylaxis; death	FUS measures; rinse dialyzer more completely
Dialyzer-Plate	12/4/87	Blood leaking out of plate dialyzer housing	Blood Loss; sepsis	Inspect dialyzer; manufacturer recalls
Dialyzer-Plate	12/8/87	Blood line separation from dialyzer due to excessive pressure 2° to clotting	Blood loss; hypotension	Proper anticoagulation monitor; luer lock connector
Dialyzer-Plate	2/22/88	Membrane blood leak during dialysis; failure of pressure test before dialysis	Blood loss; sepsis	Ascertain membrane integrity with new dialyzers
Dialyzer-Plate	4/22/88	Large blood leak out of dialyzer	Blood loss; hypotension	Inspect dialyzer; manufactureΔ product
Dialyzer-Plate	5/27/88	Apparent Hypersensitivity reaction on plate dialyzer	Anaphylaxis; death	FUS measures
Dialyzer-Plate	6/29/89	Large blood leak out of dialyzer 2° to internal dialyzer clotting	Blood loss; hypotension; sepsis	Adequate anticoagulation monitoring
Dialyzer-Plate	7/3/89	Small blood leak out of dialyzer; possible damage in shipment	Blood loss; sepsis	Inspect dialyzer and packaging; mfr Δ product
Dialyzer-Plate	7/3/89	Small blood leak out of dialyzer; possible damage in shipment	Blood loss; sepsis	Inspect dialyzer and packaging; mfr Δ product
Dialyzer-Plate	7/3/89	Small blood leak out of dialyzer; possible damage in shipment	Blood loss; sepsis	Inspect dialyzer and packaging; mfr Δ product
Dialyzer-Plate	2/29/89	Apparent Hypersensitivity reaction; no reaction on another dialyzer	Anaphylaxis; death	FUS measures; change dialyzer
Note: FUS treatment that has been successful includes: stopping treatment, continuing treatment with meds, continuing without meds, slowing down BP, changing dialyzers to another of same kind, changing to a different dialyzer.				
No single tactic appears more prefereable from the review of the MDR reports. Symptoms reported include: backpain, shaking, "hot feeling", respiratory distress, wheezing, itching, chest pain, nausea, shortness of breath,				
"asthma-like symptoms", pain radiating form spine, vomiting,nasal congestion, coughing, diaphoresis, "funny taste in mouth", swollen tongue, agitation, respiratory arrest, anxiety, flushing, tachycardia, laryngeal, facial, or neck				
edema, cyanosis, seizure, abdominal pain, diarrhea, rash. In the case of febrile reactions it is important to save "everything", including" dialyzer, blood lines, solution admin set, heparin bottle, saline bags, etc.				

CATEGORY	DATE	DESCRIPTION	POTENTIAL HAZARD/RISK	ACTION REQUIRED
Dialyzer-Spedal	2/5/87	Severe hemolytic anemia after treatment with Alu Kart	Severe hemolytic anemia	*Unknown*
Dialyzer-Spedal	5/16/88	Severe hemolytic anemia after treatment with Alu Kart	Severe hemolytic anemia	Unknown
Germicide	8/12/85	Patient had burning sensation and SOB 2° to improper dilution of Renalin (too high)	Unknown	Proper dilution of germicide & QC check; check for absence of gmcd before use
Germicide	5/9/86	4 cases of pseudomonas with ReNew-D reused dialyzers	Pyrogen Reaction; Sepsis	Stop using ReNew-D as germicide in reuse
Germicide	7/9/86	Pyrogen reactions and bacteremia with reused dialyzers (ReNew-D)	Pyrogen Reaction;Sepsis	Stop using ReNew-D as germicide in reuse
Reuse	4/3/86	Apparent pyrogen reaction on reused dialyzer (ReNew-D)	Pyrogen reaction; sepsis	Stop using this disinfectant
Reuse	5/23/86	Apparent pyrogen reaction on reused dialyzer (ReNew-D); improper procedure	Pyrogen reaction; sepsis	Stop using this disinfectant; follow proper prcd for product use
Reuse	5/30/86	Pseudomonas bacteremia with reuse.? contam. dialysate; low germicide conc	Pyrogen reaction; sepsis	Proper facility disinfection and mtrcdcl monitoring; confirm germicide conc
Reuse	6/10/86	Patient bacteremia on reused dialyzer (ReNew-D); patient recovered	Pyrogen reaction; sepsis	Stop using this disinfectant
Reuse	6/10/86	Patient bacteremia on reused dialyzer (ReNew-D); patient recovered	Pyrogen reaction; sepsis	Stop using this disinfectant
Reuse	6/10/86	Patient bacteremia on reused dialyzer (ReNew-D);patient recovered	Pyrogen reaction; sepsis	Stop using this disinfectant
Reuse	6/10/86	Patient bacteremia on reused dialyzer (ReNew-D); patient recovered	Pyrogen reaction; sepsis	Stop using this disinfectant
Reuse	6/26/86	Apparent pyrogen reaction; Renalin; suspect endotoxin contam water	Pyrogen reaction; sepsis	Proper water trmt design & disinfect; mtrcdcl monitor; proper germicide dilution
Reuse	7/15/86	Apparent pyrogen reaction; Renalin; bacteremia; suspect contam water	Pyrogen reaction; sepsis	Proper water trmt design & disinfect; mtrcdcl monitor; proper germicide dilution
Reuse	8/22/86	Apparent pyrogen reaction; Renalin; improper automated reprocessing	Pyrogen reaction; sepsis	Proper water trmt design & disinfect; *mtrcdcl monitor; proper germicide dilution*
Reuse	2/7/87	Container labeled formaldehyde did not contain formaldehde	Pyrogen reaction; sepsis	Check disinfectant (chemtically) before use; proper mtrcdcl monitoring
Reuse	5/11/87	App pyrogen rxn/bacteremia; Renalin; poor reuse technique; poor water qual	Pyrogen reaction; sepsis	Proper water trmt design & disinfect; mtrcdcl monitor; proper germicide dilution
Reuse	5/4/87	Excessive UF *rate; reused dialyzers*	Hypotension; hypovolemia	Proper reuse performance monitoring
Reuse	7/2/87	Apparent hypersensitivity reaction related to formaldehyde reuse	Anaphylaxis; death	Stop reuse on this patient; change germicide
Reuse	7/17/87	Apparent pyrogen reaction; Renalin; poor water quality	Pyrogen reaction; sepsis	Proper water trmt design & disinfect; mtrcdcl monitor; proper germicide dilution
Reuse	12/23/87	Apparent hypersensitivity rxn; improper mixing of Renalin (high conc)	Pyrogen reaction; sepsis	Follow manufacturer's instruction for use
Reuse	1/12/88	Apparent pyrogen rxn/bacteremia; Renalin; broken Renatron; no check for germicide	Pyrogen reaction; sepsis	Follow mfr's instruc for use; do not use broken equip; check germicide presence
Reuse	1/20/88	Apparent pyrogen rxn.; Renalin; on hemofilters only; suspect backfiltration	Pyrogen reaction; sepsis	Proper water trmt design and disinfect; proper mtrcdcl monitor
Reuse	10/5/88	Bacteremia associated with reuse (Renalin); low blood side germicide conc	Pyrogen reactions; sepsis	Check disinfect concentration before next use; proper mixing technique
Water Treatment	2/9/84	Backsiphon of formaldehyde from pipes due to improper design	Toxic reaction; death	Install backsiphon valve; eliminate piping dead space
Water Treatment	10/26/84	Backsiphon of formaldehyde from pipes due to improper design	Toxic reaction; death	Install backsiphon valve
Water Treatment	4/28/86	Dialyzer hypersensitivity-like reactions; dialyzer clotting; pH=4.5	Heparin inactivation; toxic reaction	Proper water treatment
Water Treatment	8/22/86	Bacterial growth in water pipes and deliv. sys; Renalin; poor plumbing (dead ends)	Pyrogen reaction; sepsis	Proper water trtmt design;
Water Treatment	4/15/87	Reduction in Hct due to bypassed carbon filter at home; chloramine hemolysis	Lower hematocrit	Proper water treatment
Water Treatment	5/11/87	Septicemia (x2) + pyrogen reaction; bacteria in water system	Pyrogen reactions; sepsis	Proper water treatment design, disinfection, microbial monitoring
Water Treatment	10/6/87	Chloramine induced hemolysis; inadequate carbon treatment/monitoring	Hemolytic anemia	Proper water treatment design; proper chloramine monitoring

Appendix B

Trend Analysis

Recommendations that trend analysis be performed on various aspects of technical data have been included in several sections throughout this manual. Trend analyses can be performed in a variety of different ways, using many formats. To assist the reader in understanding how to perform and use trend analysis as a quality assurance tool the following case history is presented.

It is recommended that all hemodialysis facilities perform certain bacteriological monitoring on a monthly basis. These should include at least water bacterial levels and dialysate bacterial levels to confirm compliance with AAMI Standards.

Most hemodialysis facilities draw cultures monthly; and, when results are received back from the laboratory, many stack the actual lab reports in a three-ring binder or drawer after checking that the results are within AAMI limits.

Although such a practice gives the facility some assurance that the water and dialysate are microbiologically acceptable for dialysis, a few additional actions will provide more helpful information. They may also prevent problems, long before they occur.

In addition to simply looking at the laboratory report form and filing it, the facility should also record the results on a spreadsheet.

Sample Case History

Trend Analysis of Delivery System Dialysate Bacterial Levels

An anecdote about an actual occurence reported in a hemodialysis facility indicates the value of such a recordkeeping system. The name and location of the facility has been changed.

Mt. Evans Dialysis Facility in Conifer, Colorado contacted the authors in November 1989 complaining that two of their patients were experiencing pyrogen reactions. Upon interview with facility personnel, it was found that one delivery system's bacterial culture results showed > 30,000 colonies/ml in October.

The facility had not been charting bacterial levels, but simply filing the lab slips in a manner similar to that described above. To investigate and solve the problem, the initial step taken was to array all culture results obtained in 1989, for all six of the facility's machines on one spreadsheet. The results are presented in Figure 1.

Using a line chart further enhances the visibility of trends. In Figure 2 the constantly increasing level of bacterial colonization in machine #2 is obvious.

A simple rule of thumb is that any value which shows three consecutive increases or decreases in such a line chart indicates a *trend*. Thus, if the Mt. Evans Dialysis Facility had been using a line chart, they would have realized that an unacceptable trend was occuring when they charted the July results on machine #2. July was the third consecutive month with a significant increase in colony count. Since no changes had been made in disinfection protocols, or any other policies or procedures that would affect bacterial growth, they could have anticipated that the month-to-month increase in colony count would continue.

In the end, the problem was determined to be a buildup of biofilm in the inlet water line of the machine. This part of the system was not subject to the routine disinfection performed at the Mt. Evans facility.

Thorough disinfection and cleaning, through the water distribution loop eliminated the problem. No permanent patient injury occurred.

The purpose of the anecdote is to illustrate the usefulness of trend analysis in anticipating problems, and in solving them before serious consequences do occur. Tools and methods such as those described in this appendix section should be used in any of the areas discussed in this manual where trend analysis is recommended.

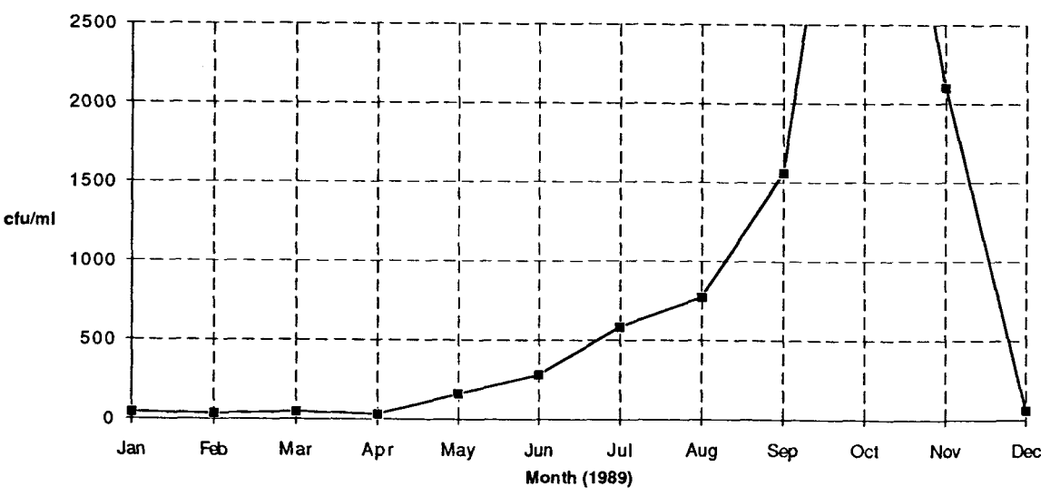
Figure 1

Delivery System Dialysate Culture Results

MACHINE #	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	22	18	44	25	67	35	26	31	NG	NG	12	52
2	45	33	48	30	160	280	580	770	1560	30000	2100	60
3	45	NG	33	22	NG	13	44	25	67	15	NG	20
4	79	18	33	48	30	67	15	NG	20	55	36	80
5	56	NG	61	33	56	22	80	70	NG	25	20	33
6	85	22	NG	67	15	25	20	33	NG	30	89	22

Figure 2

Machine #2 Dialysate Culture Results



Appendix C

Glossary of Terms

Automated hemodialyzer reprocessing system: A device that automatically rinses the dialyzer of residual blood and blood products, performs some manner of "cleaning" process, tests the dialyzer for leaks and performance parameters, and fills the dialyzer with an appropriate concentration of a germicide.

Blending valve: A device, generally at the beginning of the "pre-treatment," that mixes warm and cold water to achieve an optimum temperature for operation of the reverse osmosis membranes.

Carbon filter (or granular activated carbon filter): A cylindrical tank containing an activated carbon filter medium with a central drainage core. This type of filter is used primarily to remove chlorine and chloramine, as well as some organics.

Central dialysate delivery system: A system that utilizes a single "central" dialysate proportioner which prepares dialysate for a number of bedside consoles or bedside stations.

Clearance: Describes the performance of the dialyzer for solute removal; the amount of blood completely cleared of a solute by the dialyzer per minute expressed in ml/min.

Concurrent monitoring: The process of observing or measuring something at the time it is occuring.

Deionizer (or deionization tank or DI): A tank of insoluble spheres or beads, called resin, which exchanges all types of cations and anions and replaces them with hydrogen and hydroxide ions which combine to form water. Deionizers may be categorized as "mixed bed", containing both cation and anion resin in a single vessel, or "dual bed", where each resin type is in a separate vessel.

Depth filter (or sand filter or multi-media filter or diatomaceous earth filter): A tank-type filter, usually including a backflushing system, which is used as a first stage treatment to remove suspended matter, colloidal material or silt from the water before introduction to other downstream water treatment components.

Dialysance: Describes dialyzer efficiency when solute concentration in the dialysate is not zero (such as recirculating dialysate delivery systems); the volume of blood cleared of that solute per minute if the dialysate concentration is zero.

Dialysate (or dialysis fluid): A non-sterile aqueous solution with an electrolyte composition near that of normal extra cellular fluid.

Dialysate concentrate: A preparation of salts which, when diluted with water, yields dialysate for use in dialysis. These concentrates are manufactured commercially in liquid or powder form.

Dialysis delivery system: A device that delivers dialysate to the hemodialyzer maintaining proper concentration, temperature, pressures, and flow in the dialysate circuit. The dialysis delivery system (delivery system) also monitors various functions related to the dialysate compartment and the blood compartment: dialysate pressure, ultrafiltration rate, blood leaks into the dialysate, changes in the pressure of the blood circuit, air or air foam in the blood.

Dialyzer: The device where the exchange between blood and the dialysis fluid takes place; a semi-permeable membrane separates two compartments, one in which flows the patient's blood, and the other the dialysis fluid, or dialysate.

Diffusion (or conductive transfer): The passive transport of solutes across a membrane in the absence of net solvent transfer.

Endotoxin: Bacterial lipopolysaccharide found in the bacterial cell wall. It is a pyrogenically active material

Fixed-ratio proportioning system: A delivery system in which cylinders of known volumes are used to proportion dialysate concentrate and treated water in exact amounts, and through a series of valves control the cyclic filling and emptying of each cylinder.

Important aspects of care: Those things that are performed or provided in a health care setting that are most important. These aspects tend to be high volume, high risk or problem prone.

Kinetic modeling: A means of quantifying and individualizing dialysis treatment and nutritional plan.

Langelier saturation index: A calculation of the propensity of a reverse osmosis membrane for scaling with calcium carbonate crystals performed by using total dissolved solids, total alkalinity, calcium concentration, pH, and temperature of the R.O. reject stream.

Limulus amoebocyte lysate assay: A laboratory test for pyrogenicity which employs a material derived from the blood of the horseshoe crab.

Mass solute transfer: The quantity of a solute transferred from the blood into the dialysis fluid (or vice-versa) across the semipermeable membrane of the dialyzer per unit of time.

Pyrogen: A fever-producing substance.

Pyrogen reaction: A patient reaction characterized by shaking chills and fever.

Quality assurance: A cyclical process by which problems and opportunities for improvement are identified and analyzed, solutions are developed and implemented, and reassessment occurs.

Quality control: The process by which a product's performance is measured.

Retrospective monitoring: The process of measuring something that has already occurred.

Reverse osmosis: A membrane separation process for removing solvent from a solution. In an RO system feed water is pressurized on one side of a semi-permeable membrane. The pressure is high enough to exceed the osmotic pressure and cause reverse osmotic flow of water.

Sediment filter: A cylindrical cartridge filter used to remove particulates.

Servo-controlled proportioning systems: A delivery system that uses a control sensor to monitor the conductivity of the dialysate and regulate the flow of the dialysate concentrate within the specific conductivity limits. Flow can be regulated using variable speed pumps, variable orifice values, or other mechanisms.

Servo-feedback ultrafiltration control system: A delivery system where dialysate inflow (Q_{Di}) and outflow (Q_{Do}) are measured constantly, using sensitive flow meters. By subtracting Q_{Di} from Q_{Do} the system measures ultrafiltration flow rate (Q_{UF}). Once that value is known, the microprocessor (in which a desired Q_{UF} has been programmed by the user) automatically adjusts the machine's TMP so that desired Q_{UF} equals measured Q_{UF}.

Sieving coefficient: A mathematical expression that describes the fraction of specific solute retained by a membrane during ultrafiltration (C_{UF}/C_{pw}).

Silt density index: A measurement of the membrane-fouling and filter-plugging characterisitics of tap water.

Single patient, single pass dialysate delivery systems: A system where dialysate is delivered to one patient at a time; also called "negative pressure systems."

Sorbent (or regenerative) dialysis system: A delivery system that involves the reprocessing of dialysate through a cartridge to remove uremic toxins from the spent dialysate, as well as adjusting electrolytes to the desired level.

Threshold for compliance: A percentage of compliance with the indicators that are expected to be found when monitoring the activities of the facility.

Toxic substance: Any chemical that is corrosive to living tissues; carcinogenic; toxic when administered orally, cutaneously, or through inhalation; irritant; sensitizer; toxic to target organs.

Ultrafilter: A membrane filter that will remove smaller particles (10,000 to 50,000 MW cutoff) than depth filters.

Ultrafiltration: The process by which plasma water is removed from the blood due to a pressure gradient between the blood and dialysate compartments; expressed in ml/min, ml/hr, or L/hr.

Ultraviolet radiation: A means of disinfecting hemodialysis water that utilizes radiant energy for the destruction of bacteria. UV light is produced by means of a low pressure mercury vapor lamp that emits the majority of its light at a bactericidal wave length. Water passing through an ultraviolet radiator typically flows over and around a quartz sleeve and does not contact the lamp itself.

Volumetric ultrafiltration control system: A delivery system that employs a fluid-filled, closed, non-compliant dialysate circuit from which a controlled and measured amount of fluid (dialysate) is removed, generally, via a volumetric pump, from a closed circuit.

Water softener: A tank of insoluble spheres or beads, called resin, which exchange cations in removing calcium and magnesium from incoming hard water.

Appendix D
List of Tables, Figures, and Forms

Chapter 7: Ancillary Devices and Equipment

Form 1	Conductivity Meter Calibration Check Log
Form 2	Patient Daily Dialysis Record
Form 3	Dialysis Systems Checklist
Form 4	Conductivity Meter Trend Analysis

Chapter 8: Anticoagulation

Form 1	Patient Daily Dialysis Record
Form 2	Automated Clotting Time Meter Calibration Log

Chapter 10: Hemodialyzer Reuse

Table 1	AAMI Recommended Practice: Reuse of Hemodialyzers (summary)
Form 1	Reuse Labeling and Recordkeeping Monitor (concurrent monitor)
Form 2	Reused Dialyzer Preparation for Use Monitor (concurrent monitor)
Form 3	Reuse Physical Plant and Environmental Safety Monitor (concurrent monitor)
Form 4	Dialyzer Reprocessing Log
Form 5	Patient Daily Dialysis Record
Form 6	Reuse Problems Trend Analysis

Chapter 11: Infection Control

Form 1	Universal Precautions Monitor (concurrent monitor)

Chapter 12: Handling of Toxic Chemicals

Form 1	Toxic Chemicals Handling Trend Analysis
Form 2	Toxic Chemicals Handling Monitor (concurrent monitor)

Chapter 13: Medical Device Reporting

Form 1	Problem Reporting Form
Form 2	Problem Reporting Program Summary

Appendix E

Annotated Bibliography

Contents

NOTE TO THE READER

In performing the research necessary to produce this document, *Quality Assurance Guidelines for Hemodialysis Devices*, an extensive literature search was performed. Although a few of the principle references for the material provided are included at the end of each of the individual chapters, significant additional citations were reviewed prior to writing the manual.

In order to allow the reader to further review the literature available between 1980 and 1989 on these topics, this section, Appendix E, contains an additional annotated bibliography related to the devices included in the above subject areas.

This appendix is also included to allow the reader to pursue additional study of these areas and to assist the facility as a training tool.

Chapter 2

The Basics of Quality Assurance

Technical requirements for rapid high-efficiency therapies. Keshaviah, P., Luehmann, D., Ilstrup, K. and Collins, A. *Artif Organs,* 10 (3), pp. 189-94 (Jun 1986). The key technical elements necessary for such implementation include high blood flow rates, higher efficiency dialyzers/diafilters, ultrafiltration control systems, and bicarbonate as the buffer source. In addition, hemodiafiltration requires schemes to ensure sterility and nonpyrogenicity of the infusion fluid and appropriate balancing of the rates of ultrafiltration and reinfusion.

A digital computer model for optimal programming of hemodialytic treatment. Lamberti, C., Sarti, E., Santoro, A., Spongano, M., Zucchelli, P. and Rossi, M. *Int J Artif Organs,* 11 (4), pp. 235-42 (Jul 1988). A mathematical model of hydroelectrolyte exchanges and arterial pressure regulation in the human body during dialysis has been set up. It is conceived as a tool for a new dialysis unit which will be able to "interpret" the signals supplied by suitable instruments connected to the patient and modify the machine set-points in real time in order to obtain clinical results defined by the physician.

An advanced, user-friendly microcomputer program for hemodialysis kinetics. Buur, T. *Adv Exp Med Biol,* 223, pp. 239-44 (1987).

Relative importance of membrane Limulus amebocyte lysate-reactive material and ethylene oxide in hypersensitivity reactions. Pearson, F.C. *Contrib Nephrol,* 59, pp. 134-44 (1987).

Evaluation report: dialysis and ancillary equipment. *J Med Eng Technol,* 10 (3), pp. 141-7 (May-Jun 1986). Report of the continuing programme of evaluation of medical equipment sponsored by the UK Health Departments, the evaluation of dialysis and ancillary equipment carried out within the University of Sheffield, under the direction of Professor M.M. Black. 'Health Equipment Information' Number 148, published in December 1985, carries full reports. Two-pool model analysis of data in hemodialysis by means of programmable pocket calculator TI 59.

Guthke, R., Gunther, K., Stein, G. and Knorre, W.A. *Comput Programs Biomed,* 19 (2-3), pp. 189-95 (1985). Four parameters of a two-pool model are evaluated by an iterative method using the explicit solutions of the linear differential equations.

Insufficient documentation of the hemodialysis prescription: delaying the definition of adequate dialysis. Lundin, A.P., Tarras, M. and Friedman, E.A. *Nephron,* 37 (3), pp. 200-2 (1984). The authors analyzed 953 articles published in three established nephrology journals to select those pertaining to treatment with hemodialysis. A total of 152 papers were selected on the criteria that the reported results might have been affected by variation in the dialysis prescription. Only a small proportion of the papers studied (11.8%) detailed the complete dialysis prescription including type of dialyzer, blood flow rate, and duration and frequency of dialysis. A surprising 29% of papers provided no details of the dialyzer employed. Other potentially important variables such as the type of blood tubing or method of water treatment used were rarely mentioned. Comparative studies of the course and outcome of hemodialysis regimens require specification of exactly how dialysis was performed. It is suggested that manuscripts provide this information as a condition of suitability for publication.

Quality of treatment issues in maintenance dialysis. Stewart, J.H. *Med J Aust,* 2 (9), pp. 430-3 (Oct 30 1982).

The dialysis nurse's role in an interdisciplinary program. Hopper, S.A. *J Am Assoc Nephrol Nurses Tech,* 6 (1), pp. 20-4 (1979).

Adjustment and quality of patient-nurse interaction among dialysis patients. Tucker, C.M., Mulkerne, D.J., Panides, W.C. and Ziller, R.C. *Nephrol Nurse,* 3 (2), pp. 26-32 (Jan-Feb 1981).

Implementation of ANA's quality assurance program for clients with end-stage renal disease. Bruce, G.L., Hinds, P., Hudak, J., Mucha, A., Taylor, M.C. and Thompson, C.R. *ANS,* 2 (2), pp. 79-95 (Jan 1980).

The change from functional to primary nursing. Dean, L.P. *Nurs Clin North Am,* 14 (2), pp. 357-64 (Jun 1979).

Nursing management of multiple dialysis units: roles and responsibilities. Morrissey, Z.M. *Nephrol Nurse,* 1 (1), pp. 43-5 (Jan-Feb 1979).

Satisfaction with health care of hemodialysis patients. Ferrans, C.E., Powers, M.J. and Kasch, C.R. Department of Medical-Surgical Nursing, College of Nursing, University of Illinois, Chicago 60680. *Res Nurs Health,* 10 (6), pp. 367-74 (Dec 1987). The purpose of this study was to assess the satisfaction with care of hemodialysis patients, and to explore the relationships between satisfaction with care, quality of life, and background variables. No generalizations can be made.

Minimum performance standards for double-lumen subclavian cannulas for hemodialysis. Bregman, H., Miller, K. and Berry, L. *ASAIO Trans,* 32 (1), pp. 500-2 (Jul-Sep 1986).

Technology assessment. How effective is medical care? Hazelton, A.E. *Clin Geriatr Med,* 2 (3), pp. 481-90 (Aug 1986). Technology assessment helps the physician by determining which technologies are most apt to benefit the patient, allowing the physician to recommend a prudent course of action. Technology assessment should encourage skepticism of new technology, causing the clinician to be more rigorous about accepting the latest invention. By shunning the useless technologies, physicians can prevent rationing of the useful techniques and avoid being caught in the ethical dilemma of doing what is best for the patient but is detrimental to society.

Quality hemodialysis: a "gold standard" treatment for survival. Lundin, A.P. *Kidney Int,* Suppl, 17, pp. S12-4 (Dec 1985).

Investigation of the Karnofsky Performance Status as a measure of quality of life. Grieco, A. and Long, C.J. *Health Psychol,* 3 (2), pp. 129-42 (1984). The Karnofsky Performance Status appears to be the most widely used scale for objective assessment of medical patients' quality of life. Evidence for its reliability and validity is reviewed and new data presented. Tests of inter-rater reliability, concurrent validity, and discriminant validity indicate that, with standardized observational procedures based on a mental status exam, the Karnofsky scale is acceptably reliable and valid as a global measure but it does not adequately capture the conceptual domain of quality of life.

Mortality, morbidity, and life satisfaction in the very old dialysis patient. Westlie, L., Umen, A., Nestrud, S. and Kjellstrand, C.M. *Trans Am Soc Artif Intern Organs,* 30, pp. 21-30 (1984). Discussion of mortality, morbidity and life satisfaction of 157 patients 70 years of age and above. The authors conclude that older patients are excellent dialysis candidates and it is wrong not to consider them for dialysis.

Assessing the quality of nursing care in a dialysis unit. Rajki, K.L., Feltman, B.A. and Smeltzer, C.H. *ANNA J,* 12 (1), pp. 11-5, 53 (Feb 1985).

A protest movement in a private clinic: an analysis of a patient strike. Waissman, R. *Soc Sci Med,* 20 (2), pp. 129-32 (1985). Behind this protest movement among chronic patients on dialysis was a dispute between the specialist who headed the service and the director of the clinic. This dispute eventually involved the patients, who felt that the quality of care was at stake. Their 'therapy strike', as exceptional as it is in the world of illness, brings to mind forms of action used by the consumer movement or by labour unions. The reasons that this small group of patients interrupted treatment are analysed in terms of their relations to medicine and their conceptions of illness.

Monthly home patient checklist: a dialysis assessment tool. Rhodes, V.S. *J Nephrol Nurs,* 2 (1), pp. 28-9 (Jan-Feb 1985).

The computer in medicine. Its application to medical practice, quality control, and cost containment. Pollak, V. *JAMA,* 253 (1), pp. 62-8 (Jan 4, 1985).

The liaison psychiatrist and the outpatient hemodialysis unit. Part I: Reliability and validity of staff assessments of patient compliance on a hemodialysis unit. Manley, M. *Clin Exp Dial Apheresis,* 7 (4), pp. 349-56 (1983). Staff ratings for global impressions of patient compliance are collected in an outpatient hemodialysis unit, inter-rater reliability is calculated, and the rating averages are correlated with three biological markers. A high degree of exact inter-rater agreement is found and correlation of ratings with inter-dialysis weight gain, mean BUN, and mean K are determined.

Reliability and validity of a quality assurance instrument for a renal dialysis unit. Molzahn-Yanitski, A.E. *Nephrol Nurse,* 5 (6), pp. 8-12 (Nov-Dec 1983).

A statistical review of variables predictive of adjustment in hemodialysis patients. Olsen, C.A. *Nephrol Nurse,* 5 (6), pp. 16-27 (Nov-Dec 1983). Document Type: Review (68 refs.).

Effect of an algorithm and patient information on serum phosphorus levels. Deimling, A., Denny, M., Harrison, M., Kerr, B., Mayfield, M., Pelle-Shearer, M., Seaby, N. and Townsend S. *AANNT J,* 11 (1), pp. 35-8, 50 (Feb 1984).

Assessment of rehabilitation outcomes among chronic dialysis patients. Kutner, N.G. and Cardenas, D.D. *Am J Nephrol,* 2 (3), pp. 128-32 (1982). The physical status of 137 chronic dialysis patients was assessed by both objective and subjective measures; education and employment statuses were also determined. Below normal grip strength characterized the majority of patients; slowed nerve conduction and subjective fatigue were also observed among a subset of patients. However, patients demonstrated good to normal muscle strength and relatively normal pinch strength, and activities of daily living presented no problems for the large majority of patients. Employment probability was directly related to educational status. Despite dialysis requirements and other employment disincentives, 42% of non-diabetic men aged 21-59 were employed.

Monitoring standards instead of problems. Hexum, J.M. *J Nurs Qual Assur,*1 (3), pp. 8-13 (May 1987).

The computer in quality control of hemodialysis patient care. Pollak, V.E., Peterson, D.W. and Flynn J. *QRB,* 12 (6), pp. 202-10 (Jun 1986). Describes a computerized, custom-designed medical information system (MIS) that has been used for more than eight years in the care of patients with chronic renal failure treated by hemodialysis in a medical center. Application of the MIS in the day-to-day management of patients in one limited-care dialysis clinic is detailed, with particular attention to its capacity to contribute to the quality of care of the individual patient.

Morbidity and mortality of long-term haemodialysis: a review. Gabriel, R. *J R Soc Med,* 77 (7), pp. 595-601 (Jul 1984). Document Type: Review (90 refs.).

Selected health care maintenance policies in chronic dialysis centers. Dillingham, M.A. and Anderson, R.J. *Am J Kidney Dis,* 6 (4), pp. 237-40 (Oct 1985). After a survey approach, the authors postulate that prospective studies to determine optimal methods of health care maintenance in the chronic dialysis center are indicated.

Risks and hazards associated with dialyzers and dialysate delivery systems. Keshaviah, P.R. and Luehmann, D.A. *Crit Rev Biomed Eng,* 9 (3), pp. 201-44 (1983). Document Type: Review (83 refs.).

Factors influencing survival of patients on chronic hemodialysis: implications for nursing. Rogers, K., Tzamaloukas, A.H. and Avasthi, P.S. *J Nephrol Nurse,* 3 (3), pp. 101-4 (May-Jun 1986).

Sudden death in hemodialysis patients. Cohle, S.D. and Graham, M.A. *J Forensic Sci,* 30 (1), pp.158-66 (Jan 1985). Hemodialysis patients may die suddenly and unexpectedly from a number of causes. These deaths may be divided into those due directly to and occurring during hemodialysis, those occurring while the patient is not undergoing dialysis, and those that may occur at any time. The first group includes brain herniation, air embolism, acute hemorrhage as a result of machine malfunction or fistula rupture, electrocution, cardiac arrhythmia caused by hypokalemia, complications of subclavian intra-venous catheter insertion, third-degree heart block as a result of triglyceride emulsion, and disseminated intravascular coagulation (DIC) or hyperkalemia caused by overheated dialysate. The second group includes deaths due to pericardial tamponade because of effusion and suicidal causes of death (exsanguination, electrolyte imbalance as a result of excessive intake of salt, fluid, or potassium) as well as more conventional methods of suicide. The last category includes people dying of arterio-sclerotic cardiovascular disease, hypertensive cardiovascular disease, and internal hemorrhage. Investigation of these deaths, including pertinent historical, laboratory, and autopsy data and investigation of dialysis equipment is discussed.

An unsuspected cause of acute hemolysis during hemodialysis. Francos, G.C., Burke, J.F. Jr, Besarab, A., Martinez, J., Kirkwood, R.G. and Hummel, L.A. *Trans Am Soc Artif Intern Organs,* 29, pp. 140-5 (1983).

Computer modelling of haemodialysis/ultrafiltration explaining the pathogenesis of the disequilibrium syndrome. Dawids, S.G. and Caspersen, A.H. *Proc Eur Dial Transplant Assoc,* 19, pp. 360-5 (1983). Based on the hypothesis that rapid corrections of pH, Na+ and osmolality give rise to disequilibrium (DES) during efficient haemodialysis (HD), a 14 compartment model has been designed for dynamic analysis of the induced fluid shifts and the resulting haemodynamic reactions. The model reactions correlated remarkably with clinical findings and indicate how far a patient's haemodynamic compensation can prevent circulatory collapse and hypovolaemia, mainly through lowering the mean pressure in a major portion of the capillaries. Steady weight dialysis causes reduction of blood volume up to 65 percent before circulatory collapse occurs.

Mortality risk factors in patients treated by chronic hemodialysis. Report of the Diaphane collaborative study. Degoulet, P., Legrain, M., Reach, I., Aime, F., Devries, C., Rojas, P. and Jacobs, C. *Nephron,* 31 (2), pp. 103-10 (198). A survival analysis was applied to 1,453 patients treated between 1972 and 1978 in 33 French dialysis centers and prospectively followed up in the computerized Diaphane Dialysis Registry; 198 deaths (overall mortality (OM) were registered, of which 87 (43%) were secondary to cardiovascular complications (cardiovascular mortality=CVM)). Risk factors for OM and CVM (p values less than 0.05) were age, male sex, nephroangiosclerosis or diabetic nephropathy as the primary renal disease, elevated systolic and diastolic blood pressure and two weekly dialysis rather then three. In contrast with the results observed for the general population, a high body mass index and elevated cholesterol, triglycerides and uric acid were not found to be associated with significantly increased CVM or OM. On the contrary, low body mass index (less than 20 kg/m2), low cholesterol (less than 4.5 mmol/l) and low mean predialysis blood urea (less than 4.6 mmol/l) were associated with increased OM and CVM, and more especially with high stroke mortality. Results for urea but not for cholesterol remain significant after adjustment for age, sex, weekly dialysis schedule and body mass index. They suggest that, in addition to elevated blood pressure, a poor nutritional state and/or low protein intake may be important factors for explaining the high cardiovascular mortality, particularly for strokes, observed in dialyzed patients.

The Joint Commission Guide to Quality Assurance. *JCAHO,* Chicago, IL (1988). An in-depth presentation of the "10-Step Monitoring and Evaluation process" providing explanations of each step and examples on how to accomplish each phase.

Standards of Clinical Practice for Nephrology Nursing. American Nephrology Nurses Association: Pitman, NJ, (130 pp.) (1988). A complete set of structure, process, and outcome standards for clinical nephrology nursing practice.

Quality Assurance for Nephrology Nursing. American Nephrology Nurses Association; Pitman, NJ (1989). A guide for the application of the quality assurance process in nephrology nursing. Follows the JCAHO 10-Step process and presents clinical/practical examples for all areas of nephrology nursing.

Core Curriculum for Nephrology Nursing. L. Lancaster [ed.]. American Nephrology Nurses Association; Pitman, NJ (1990). Designed to provide a foundation from which the professional nurse can apply the nursing process to the care of renal patients, prepare for certification, and continue the study of nephrology nursing practice.

Evolution of a Quality Assurance Program. Seaby N. *Nephrology News & Issues,* 2 (8), p. 34 (1988). A brief step-by-step description on how to put together a QA program for a dialysis facility.

Quality Assurance: You Can Do It Too! Seaby, N., Bower, M. and Burrows-Hudson, S. *ANNA Journal,* 14(1), pp. 15-21 (1987).

Quality Assurance for Dialysis. Burrows-Hudson, S. ESRD Network #3: Sausalito, CA (89 pp.) (1984).

Quality assurance vs. cost containment: "damned if you do, damned if you don't." Schron, S.R. *AANNT J,* 9 (2), pp. 13-23 (Apr 1982).

Control and prevention of infection on hemodialysis units. Clarke, B.H. *Nurs Clin North Am,* 15 (4), pp. 883-90 (Dec 1980). An approach is presented which illustrates that effective control and prevention measures evolve from an organized method of identifying the pertinent data, defining the problems, creating workable and reasonable control measures, implementing the measures, and then evaluating their effectiveness. Since infection control and prevention measures affect them directly, nurses must assume a predominant role in the development, application, and evaluation of these measures.

Home monitoring of diabetes: a comparison of four field methods for analysing glucose levels. Baumgart, R., Cregan, D., France, M.W. and Drury, M.I. *Ir Med J,* 74 (11), pp. 319-20 (Nov 1981).

Tracking Problems. Stoten, S. *ANNA J,* 14, 5, p. 328 (Oct 1987). A problem-tracking model was developed to identify and resolve problems that existed in a dialysis facility and serve as a communications link among unit coordinators, physicians, and staff. The article presents a tool for recording topic, date, suspected problem, investigation results, cause, action needed, and date resolved.

Chapter 3

Water Treatment

Effect of water deionisers on 'fracturing osteodystrophy' and dialysis encephalopathy in Plymouth. Leather, H.M., Lewin, I.G., Calder, E., Braybrooke, J. and Cox, R.R. *Nephron,* 29 (1-2), pp. 80-4 (1981). When water deionisers were not used routinely, a bone disease with multiple fractures, 'fracturing osteodystrophy,' and dialysis encephalopathy occurred in a significant number of patients. When water deionisers were used commonly, fracturing osteodystrophy and dialysis encephalopathy occurred extremely infrequently. Duration of dialysis without a water deioniser appeared to be the most important factor in the development of these two conditions. The use of water deionisers usually led to healing of fractures in patients with fracturing osteodystrophy and also led to improvement in 4 of the 11 patients with dialysis encephalopathy. Neither condition has occurred in any patient using a water deioniser from the first dialysis. Water deionisers, therefore, appeared to be effective in both the treatment and prevention of fracturing osteodystrophy and dialysis encephalopathy.

Surgeon General's advisory on treatment of water for use in dialysis. *FDA Drug Bull,* 11 (1), p. 3 (Mar 1981).

FDA safety alert: sodium azide contamination of hemodialysis water supplies. *ANNA J,* 16 (4), p. 273 (Jun 1989).

Bacterial contamination of dialysate in dialysis-associated endotoxaemia. Watzke, H., Mayer, G., Schwarz, H.P., Stanek, G., Rotter, M., Hirschl, A.M. and Gra, H. *J Hosp Infect,* 13 (2), pp. 109-15 (Feb 1989). Bacteriological investigations and endotoxin (ET) determinations were performed during a routine haemodialysis session for six patients. Inspection of the dialyzer machines revealed that air-traps and heater-unit for the incoming (untreated) tap water before mixing with the dialysate concentrate were the only sites where high bacterial release was feasible, as this part of the machine escaped disinfection due to the construction of these devices. Regular disinfection of all parts of a dialyzer machine is recommended, including heating units, air traps and valves.

Serum nickel concentrations in hemodialysis patients with environmental exposure. Hopfer, S.M., Fay, W.P. and Sunderman, F.W. Jr. *Ann Clin Lab Sci,* 19 (3), pp. 161-7 (May-Jun 1989). Nickel was analyzed by electrothermal atomic absorption spectrophotometry in serum specimens from 22 healthy hospital workers and 30 patients with end-stage renal disease treated by extracorporeal hemodialysis, who resided in Sudbury, Ontario, Canada, a city with extensive nickel mines and smelters. This study confirms the presence of hypernickelemia in hemodialysis patients, but does not suggest that hemodialysis patients have significantly increased risk of nickel toxicity in Sudbury, compared to Hartford, despite the high nickel concentrations in Sudbury tap water. The outcome is attributed to the efficient deionization of water used to prepare hemodialysis solutions in Sudbury.

Correction of microcytosis following elimination of an occult source of aluminum contamination of dialysate. Abreo, K., Brown, S.T., Sella, M. *Am J Kidney Dis,* 13 (6), pp. 465-8 (Jun 1989). A higher prevalence of aluminum-associated microcytic anemia was noted in hemodialysis unit A (n=67) compared to unit B (n=39). This finding could not be explained by differences in the aluminum content of reverse osmosis (RO) water or intake of antacids containing aluminum by patients in the two units. Because contamination was missed in spite of water testing at the RO site, these findings underscore the importance of measuring water aluminum and TDS content at the dialysis stations. Frequent water testing at dialysis stations, familiarity with the design of water treatment facilities, and recognition of aluminum overload can lead to early detection and correction if similar types of aluminum contamination should occur.

Uptake of trihalomethanes by patients during hemodialysis. Cailleux, A., Subra, J.F., Riberi, P. and Allain P. *Clin Chim Acta,* 181 (1), pp. 75-80 (Apr 28

1989). Trihalomethanes (THM) present in tap water were also found in dialysis fluid because they were not eliminated by water treatment. THM, absorbed through the dialyser membranes, increased considerably in blood and in expired air of patients on hemodialysis during the dialysis sessions. The uptake of THM during each dialysis session was about 1 mg.

Aluminium and fluoride in the water supply and their removal for haemodialysis. Cameron, A.P., Drury, P.J., Harston, G.A., Ineson, P.R. *Sci Total Environ*, 76 (1), pp. 19-28 (Sep 15, 1988). Aluminium and fluoride in the water supply and their removal for haemodialysis were investigated in the Trent Region, U.K., and wide variations noted. A comparison of new and older water treatment systems showed that there is a deterioration in performance with use. However, some cases poor removal may be due to the installation of unsuitable equipment or, more probably, due to a change in the waters used to supply the different homes. Thus, adequate maintenance of equipment and frequent sampling of both untreated and treated waters are required in order to maintain the provision of waters suitable for the preparation of dialysate.

Aluminum and chronic renal failure: sources, absorption, transport, and toxicity. Wills, M.R. and Savory, J. *CRC Crit Rev Clin Lab Sci*, 27 (1), pp. 59-107 (1989). Document Type: Review. An increased brain content of aluminum appears to be the major etiological factor in the development of a neurological syndrome called either "dialysis encephalopathy" or "dialysis dementia," an increased bone content, causing a specific form of osteomalacia. An excessof aluminum also appears to be an etiological factor in a microcytic, hypochromic anemia that occurs in some patients with chronic renal failure on long-term treatment with hemodialysis.

Prevalence of non-tuberculous mycobacteria in water supplies of hemodialysis centers. Carson, L.A., Bland, L.A., Cusick, L.B., Favero, M.S., Bolan, G.A., Reingold, A.L. and Good, C. *Appl Environ Microbiol*, 54 (12), pp. 3122-5 (Dec 1988). This study was conducted to determine the prevalence of NTM and other bacteria in water samples collected over a 13-week period from 115 randomly selected dialysis centers in the United States. The results of this study support recommendations to use 4% HCHO or a chemical germicidal equivalent for disinfecting dialyzers that are to be reused.

FDA safety alert: chloramine contamination of hemodialysis water supplies [letter]. *Am J Kidney Dis*, 11 (5), p. 447 (May 1988).

Ethylene glycol intoxication due to contamination of water systems. *MMWR*, 36 (36), pp. 611-4 (Sep 18, 1987).

Aluminium-related osteomalacia: response to reverse osmosis water treatment. Smith, G.D., Winney, R.J., McLean, A. and Robson, J.S. *Kidney Int*, 32 (1), pp. 96-101 (Jul 1987). Those patients in whom bone mineralization status improved developed hyperparathyroidism after reverse osmosis water-treatment, whereas the static patients remained euparathyroid. The results suggest that resolution of aluminium related osteomalacia may occur with reduction in dialysis fluid aluminium, and that parathyroid hormone plays a role in the healing of aluminium related osteomalacia. The therapeutic implications are twofold: attempts to remove all traces of hyperparathyroidism may be detrimental to the bone mineralization status; and stimulation of the parathyroid glands by means of a mild reduction in dialysis fluid calcium may be of value in the management of those cases with persistent osteomalacia and low bone turnover.

Bacterial colonization and endotoxin content of a new renal dialysis water system composed of acrylonitrile butadiene styrene. du Moulin, G.C., Coleman, E.C. Jr. and Hedley-Whyte, J. *Appl Environ Microbiol*, 53 (6), pp. 1322-6 (Jun 1987). The authors measured endotoxin and bacterial levels in tap water, in water purified by reverse osmosis, and in dialysate samples over a 4-month period in a new 10-bed renal dialysis unit. Even after disinfection of the system, there was no significant decrease in culturable bacteria from the water even though endotoxin levels were lower. Species isolated from the renal dialysis system were predominately pseudomonads, whereas species isolated from the tap water were Bacillus and Flavobacterium species.

Water quality—a neglected problem in hemodialysis. Bommer, J. and Ritz, E. *Nephron*, 46 (1), pp. 1-6 (1987). Document Type: Review (25 refs.).

Aluminum in the dialysis fluid. Rahman, H., Channon, S.M., Parkinson, I.S., Skillen, A.W., Ward, M.K. and Kerr, D.N. *Clin Nephrol*, 24 Suppl 1, pp. S78-83 (1985). Document Type: Review (44 Refs.) The major source of aluminum in patients with chronic renal

failure treated by hemodialysis is the hemodialysis fluid. The aluminum is derived from both the water and the chemical concentrate used in the preparation of the hemodialysis fluid. Due to the complex physico-chemistry of aluminum in water and dialysis fluid, both the total aluminum concentration and the proportion of aluminum species able to cross the hemodialysis membrane may vary from water supply to water supply and from day to day within a supply.

Hemodialyzer reuse: practices in the United States and implication for infection control. Bland, L., Alter, M., Favero, M., Carson, L. and Cusick, L. Nontuberculous mycobacteria were isolated from the water in 83% of 115 hemodialysis centers surveyed across the United States and could constitute a potential infection risk because of the organisms' greater germicide resistance than most other naturally occurring water bacteria. Two percent formaldehyde is not an effective germicide for high level disinfection of hemodialyzers. Reprocessed hemodialyzers should be disinfected with 4% formaldehyde or an equivalent disinfectant.

Nitrate induced anaemia in home dialysis patients. Salvadori, M., Martinelli, F., Comparini, L., Bandini, S. and Sodi A. *Proc Eur Dial Transplant Assoc Eur Ren Assoc,* 21, pp. 321-5 (1985). Many home dialysis patients in Florence and the surrounding area suddenly showed an unusual anaemia. All used a softener for water treatment. They demonstrated methaemoglobinaemia, Heinz bodies and reduction in plasma haptoglobin, indicating Hb oxidation. Tap water analysis showed excessive nitrates. The substitution of the softeners with deionisers solved this important and unusual clinical problem.

Aluminium-induced anaemia in haemodialysis patients. McGonigle, R.J. and Parsons, V. *Nephron,* 39 (1), pp. 1-9 (1985). Evidence has accumulated that aluminium is the most likely ion responsible for anemia, but other ions, trace metals in excess or deficiency, and potentially toxic substances cannot be excluded yet.

The use of ion exchange to remove aluminum from water used in hemodialysis. Petrie, J.J., Fleming, R., McKinnon, P., Winney, R.J. and Cowie, J. *Am J Kidney Dis,* 4 (1), pp. 69-74 (Jul 1984). A discussion of a modified ion exchange resin for the removal of aluminum.

Water purification and the incidence of fractures in patients receiving home haemodialysis supervised by a single centre: evidence for "safe" upper limit of aluminium in water. Platts, M.M., Owen, G. and Smith, S. *Br Med J* [Clin Res], 288 (6422), pp. 969-72 (Mar 31, 1984). The authors discuss the fact that when aluminium was removed from water by deionisation the incidence of fractures diminished during the next year and no patient developed dialysis encephalopathy. Their findings show that 1.0 mumol/L is a safe maximum concentration of aluminium in water for use in home haemodialysis.

Granular activated carbon usage in chloramine removal from dialysis water. Meyer, M.A. and Klein, E. *Artif Organs,* 7 (4), pp. 484-7 (Nov 1983). This is a report on the bench-scale testing of five kinds of GAC from three manufacturers. The experimental results were used to estimate the capacity of a 9" diameter, 45" tall column of the best carbon. These scale-up estimations indicate that this sorbent may safely last through 156 5-h.

Heparin inactivation, acidosis and copper poisoning due to presumed acid contamination of water in a hemodialysis unit. Eastwood, J.B., Phillips, M.E., Minty, P., Gower, P.E. and Curtis, J.R. *Clin Nephrol,* 20 (4), pp. 197-201 (Oct 1983). An accident in a hemodialysis unit involving 13 patients is reported. Circumstantial evidence suggests that acid contamination of the water supply to the unit resulted in inactivation of heparin with widespread extracorporeal clotting and secondary copper intoxication which proved fatal in one patient. Serum copper concentrations were raised in 6 of the11 patients and whole blood copper concentrations were raised in four patients. Results of serum ceruloplasmin, whole blood lead and zinc analyses are reported, together with tissue analyses for copper in the fatal case. The majority of the patients showed evidence of a metabolic acidosis.

Generation of dimethylnitrosamine in water purification systems. Detection in human blood samples during hemodialysis. Simenhoff, M.L., Dunn, S.R., Fiddler, W., Pensabene, J.W. and Smiley, J. *JAMA,* 250 (15), pp. 2020-4 (Oct 21, 1983). Dimethylnitrosamine (DMNA), a carcinogen, was detected at levels up to 32 micrograms/L in dialysate from 5 of 16 dialysis units surveyed. Blood drawn from patients at one of these units in which DMNA was raised in the dialysate showed a significant increase in the amount of DMNA in the patient's blood when predialysis levels were compared with 15-minute intradialysis levels. The presence of a mixed-bed deionizer without an antecedent carbon filter appeared to be necessary for DMNA production.

Heinz-body haemolysis in haemodialysed patients caused by chloramines in Sydney tap water. Caterson, R.J., Savdie, E., Raik, E., Coutts, D. and Mahony, J.F. *Med J Aust,* 2 (8), pp. 367-8 (Oct 16 1982). In August 1981, there was an outbreak of Heinz-body-positive haemolytic anaemia among patients who were undergoing dialysis in Sydney Hospital. This appeared to be due to excessive chloramines in, and inadequate carbon filtration of, the water used for haemodialysis. After improvement of the carbon filtration system, there were no further cases of anaemia.

Water supply aluminium concentration, dialysis dementia, and effect of reverse-osmosis water treatment. Davison, A.M., Walker, G.S., Oli, H. and Lewins, A.M. *Lancet,* 2 (8302), pp. 785-7 (Oct 9, 1982). Dialysis dementia appeared in 18 of 258 patients treated by haemodialysis. All cases developed in patients treated by home dialysis (150) and none in patients treated exclusively by hospital dialysis (108). Analyses of the domestic water supply for each month on dialysis showed that dementia occurred only in those whose water supply had a high aluminium concentration (greater than 80 micrograms/L). Reverse osmosis treatment satisfactorily removes aluminium and many other substances from water. Its application had a beneficial effect on 7 of 9 patients previously exposed to dialysate prepared from water with a high aluminium content and prevented the appearance of dementia in 24 patients whose water was so treated from the start of haemodialysis.

Ionic and nonionic fluoride in plasma (or serum). Singer, L. and Ophaug, R. *Crit Rev Clin Lab Sci,* 18 (2), pp. 111-40 (1982). Document Type: Review (113 refs.).

Bone aluminum deposition in maintenance dialysis patients treated with aluminium-free dialysate: role of aluminium hydroxide consumption. Heaf, J.G., Podenphant, J., Andersen, J.R. *Nephron,* 42 (3), pp. 210-6 (1986). It is concluded that bone aluminium deposition occurs despite the use of aluminium-free dialysate and is associated with total and present aluminium hydroxide consumption; heavy aluminium deposition is associated with severe and symptomatic osteomalacia, but can also be observed in the presence of predominant hyperparathyroidism.

Side effects in bicarbonate dialysis due to low dialysate pH. Wagner, L., Schindler, B., Marhoffer, W., vanEyl, O., Strauch, M. *Proc Eur Dial Transplant Assoc,* 19, pp. 346-50 (1983). In six commercially available bicarbonate-containing dialysates, pH and pCO2 were determined. Side effects resulted from low pH and high pCO2. Use of two of the six dialysates was associated with fatigue, muscle cramps and somnolence.

Bone disease in patients on maintenance haemodialysis using softened or deionized water. Hudson, G.A., Milne, F.J., Oliver, N.J., Reis, P., Murray, J. and Meyers, A.M. *S Afr Med J,* 56 (11), pp. 439-43 (Sep 8, 1979). The results showed that symptomatic osteomalacia/osteopenia occurs more frequently in the units using softened water, which has a higher aluminium content, than in the deionized water unit. The patients dialysed on softened water also have significantly higher serum calcium and phosphorus levels. It is suggested that in Johannesburg, water softening alone is inadequate, and that the high aluminium levels in our water may be responsible for accelerated osteomalacia/osteopenia.

Acute nickel intoxication by dialysis. Webster, J.D., Parker, T.F., Alfrey, A.C., Smythe, W.R., Kubo, H., Neal, G. and Hull, A.R. *Ann Intern Med,* 92 (5), pp. 631-3 (May 1980). Nickel intoxication was observed in a group of dialyzed patients when leaching of nickel-plated stainless steel water heater tank contaminated the dialysate. Symptoms occurred during and after dialysis at plasma nickel concentrations of approximately 3 mg/L. Symptoms included nausea, vomiting, weakness, headache, and palpitation. Remission of symptoms occurred spontaneously, generally 3 to 13 hours after cessation of dialysis. The evidence indicated that the nickel became bound in the plasma after crossing the membrane, resulting in a higher concentration in the plasma than in the dialysate and preventing its removal by dialysis.

Dialysis dementia: the role of dialysate pH in altering the dialyzability of aluminum. Gacek, E.M., Babb, A.L., Uvelli, D.A., Fry, D.L. and Scribner, B.H. *Trans Am Soc Artif Intern Organs,* 25, pp. 409-15 (1979).

Bacterial colonization and endotoxin content of a new renal dialysis water system composed of acrylonitrile butadiene styrene. duMoulin, G.C., Coleman, E.C. Jr. and Hedley-Whyte J. *Appl Environ Microbiol,* 53 (6), pp. 1322-6 (Jun 1987). The authors measured endotoxin and bacterial levels in tap water, in water purified by reverse osmosis, and in dialysate samples over a 4-month period in a new 10-bed renal dialysis unit. Even after disinfection of the system, there was no significant decrease in culturable bacteria from the water even though endotoxin levels were lower.

Chapter 4

Dialysis Delivery System

Shear-induced formation of aggregates during hemodialysis. Leonard, E.F., Van Vooren, C., Hauglustaine, D. and Haumont, S. *Contrib Nephrol,* 36, pp. 34-45 (1983).

The current status and future of the artificial kidney. Funck-Brentano, J.L. *Artif Organs,* 9 (2), pp. 119-26 (May 1985). Document Type: Review (32 refs.) Discussion of the technology, use and determination of adequacy and related cost.

Comparative analysis of two volumetrical ultrafiltration monitors for hemodialysis. Berden, J.H., Wokke, J.M. and Koene RA. *Int J Artif Organs,* 9 (3), pp.163-6 (May 1986). Controlled ultrafiltration (UF) during hemodialysis may prevent dialysis associated hypotension. A prerequisite for controlled ultrafiltration is an accurate measurement of ultrafiltration. Volumetric measurement is the best currently available method for this purpose. In this study the authors compared in a clinical setting two volumetric ultrafiltration monitors. Volumetric monitoring of UF is accurate and reliable, but its accuracy is dependent on the type of dialyzer used.

Technical aspects of high-flux hemodiafiltration for adequate short (under 2 hours) treatment. Miller, J.H., von Albertini, B., Gardner, P.W. and Shinaberger, J.H. *Trans Am Soc Artif Intern Organs,* 30, pp. 377-81 (1984). The efficiency of hemodialysis can be more than doubled by using much higher than normal blood and dialysate flows, employing dialyzers with greater surface area and permeability, bicarbonate dialysate, and an apparatus capable of rigid volumetric control of the dialysate. Coupled with the better treatment tolerance described elsewhere in this volume, this self-contained and automated technique, providing high diffusive and convective transfer, permits drastic reductions in treatment time over conventional dialysis: to under 6 hrs/wk in this study.

Long-term hemodialysis at reduced dialysate flow rates. Kirchner, K.A., White, A.R., Kiley, J.E. and Bower, J.D. *Am J Nephrol,* 4 (1), pp. 7-12 (1984). Twenty stable hemodialysis patients were maintained on a dialysate flow rate of 300 ml/min (QD 300) to determine the safety of prolonged reductions in dialysate flow rate. Authors conclude that QD 300 does not impair dialysis efficiency for most small molecules and saves $1.38 per patient per dialysis.

Mechanical Aspects of Dialysis Including Dialysate Delivery Systems and Water for Dialysate. Easterling, R. in *Clinical Dialysis.* A.R. Nissenson, R.N. Fine and D.E. Gentile [eds]. Appleton-Century-Crofts, Norwalk, CT; pp. 53-96 (1984). Excellent in-depth overview of water treatment basics and components operation as well as on operation of dialysis delivery systems.

Staying Tuned into the High-Tech World Part Two: Dialysis Delivery Systems. Vlchek, D. *Dial &Transplant,* p. 453 (Aug 1989). A review of ultrafiltration control principles, risks and hazards associated with dialysate, variable sodium, and other considerations necessary for today's advanced dialytic techniques.

Inadequacy of Heat Alone for Dialysis Machine Disinfection. Francos, G.C., Murphy, S.A., Jungkind, D.L. and Bondi, J.M. *Dialy & Transplant,* p. 438 (Aug 1987). Heavy bacterial overgrowth is described of each dialysis machine in a facility that chemically disinfected monthly and heat disinfected daily. Weekly chemical disinfection and daily heat deinfection was finally the protocol that was able to maintain acceptable bacterial levels.

Hemolysis and consumption coagulopathy due to overheated dialysate. Tielemans, C.L., Herbaut, C.R., Geurts, J.O. and Dratwa, M. *Nephron,* 30 (2), pp. 190-1 (1982).

Overview of renal assist systems. Smith, J.W. *Ann Biomed Eng,* 8 (4-6), pp. 473-86 (1980).

Volumetic microcomputer-based ultrafiltration monitor for hemodialysis. Wokke, J.M.P., Berden, J.H.M., Slegere, J.F.G. and Koene, R.A.P. *Int J Art Org,* 8, 1, pp. 33-6 (1985). This article describes the UFM (ultrafiltration monitor) which uses two micro-oval flowmeters that measure the flow rate of the diaysate entering and leaving the dialyzer. It showed an

accuracy of 90% using a conventional cuprophan membrane dialyzer.

On the Origin and Control of Rust-Colored Precipitates in Bicarbonate Dialysate Lines. Stephens, D. *Dial & Transplant*, 15, 5, pp. 250-4 (May 1986). Due to the particular chemistry of the solution involved, bicarbonate dialysates are particularly prone to precipitation of iron in the delivery system. These precipitates are not only unsightly, but can result in machine malfunction if allowed to accumulate. The article discusses methods of avoiding and eliminating such an accumulation.

Disinfection of Hemodialysis Machines. Townsend, T.R., Wee, S.B. and Bartlett J. *Dial & Transplant*, 14, 5 (May 1985). The article notes that none of three disinfectants tested (3.7% formaldehyde, 1:34 dilution Cidex HD, or 1:34 dilution of Sporicidin) was effective in disinfecting a Psuedomonas aeruginosa contaminated dialysis machine when contact time was 5, 10, or 15 minutes. However, after 24 or 72 hours, the formaldehyde and the Cidex were effective.

Chapter 5

Dialysate and Dialysate Concentrate

Bacterial contamination of dialysate in dialysis-associated endotoxaemia. Watzke, H., Mayer, G., Schwarz, H.P., Stanek, G., Rotter, M., Hirschl, A.M. and Gra, H. *J Hosp Infect,* 13 (2), pp. 109-15 (Feb 1989). Bacteriological investigations and endotoxin (ET) determinations were performed during a routine haemodialysis session for six patients. Inspection of the dialyzer machines revealed that air-traps and heater-unit for the incoming (untreated) tap water before mixing with the dialysate concentrate were the only sites where high bacterial release was feasible, as this part of the machine escaped disinfection due to the construction of these devices. Regular disinfection is recommended of all parts of a dialyzer machine, including heating units, air traps and valves.

Correction of microcytosis following elimination of an occult source of aluminum contamination of dialysate. Abreo, K., Brown, S.T. and Sella M. *Am J Kidney Dis,* 13 (6), pp. 465-8 (Jun 1989). A higher prevalence of aluminum-associated microcytic anemia was noted in hemodialysis unit A (n=67) compared to unit B (n=39). This finding could not be explained by differences in the aluminum content of reverse osmosis (RO) water or intake of antacids containing aluminum by patients in the two units. Because contamination was missed in spite of water testing at the RO site, these findings underscore the importance of measuring water aluminum and TDS content at the dialysis stations. Frequent water testing at dialysis stations, familiarity with the design of water treatment facilities, and recognition of aluminum overload can lead to early detection and correction if similar types of aluminum contamination should occur.

Easy production of sterile, pyrogen-free dialysate. Erley, C.M., vonHerrath, D., Hartenstein-Koch, K., Kutschera, D., Amir-Moazami, B. and Schaefer, K. *ASAIO Trans,* 34 (3), pp. 205-7 (Jul-Sep 1988). Hemodialysis (HD) hypotension is frequently encountered during conventional acetate HD. The data obtained in this study show that the filtered dialysate was always pyrogen-free when tested with a limulus-amebocyte-lysate assay. In addition, in 80% of cases no bacteria were detected after the sterilizing filter. Almost no febrile episodes were observed when sterile dialysate was used.

The role of dialysate in the stimulation of interleukin-1 production during clinical hemodialysis. Port, F.K., VanDeKerkhove, K.M., Kunkel, S.L. and Kluger, M.J. *Am J Kidney Dis,* 10 (2), pp. 118-22 (Aug 1987). Authors conclude that IL-1 is produced during clinical HD and that endotoxin or its fragments play a role in the stimulation of IL-1 production, probably through monocytes adhering to the dialysis membrane. In addition to this dialysate factor, IL-1 production appears also to be stimulated by a blood-membrane interaction.

Aluminum in the dialysis fluid. Rahman, H., Channon, S.M., Parkinson, I.S., Skillen, A.W., Ward, M.K. and Kerr, D.N. *Clin Nephrol,* 24 Suppl 1, pp. S78-83 (1985). Document Type: Review (44 refs.) The major source of aluminum in patients with chronic renal failure treated by hemodialysis is the hemodialysis fluid. The aluminum is derived from both the water and the chemical concentrate used in the preparation of the hemodialysis fluid. Due to the complex physico-chemistry of aluminum in water and dialysis fluid, both the total aluminum concentration and the proportion of aluminum species able to cross the hemodialysis membrane may vary from water supply to water supply and from day to day within a supply. A "safe" level of aluminum in dialysis fluid, which will prevent aluminum transfer from dialysis fluid to blood, and promotes aluminum removal from blood, has yet to be determined.

Effect of an optimum dialysis fluid calcium concentration on calcium mass transfer during maintenance hemodialysis. Carney, S.L. and Gillies, A.H. *Clin Nephrol,* 24 (1), pp. 28-30 (Jul 1985). The effect of an optimum dialysis fluid calcium concentration (1.625mmol/l) on calcium mass transfer from dialysis fluid to patient was assessed in patients on routine hemodialysis. A significant correlation was noted between the mass transfer of calcium and the dialysis fluid calcium concentration (r=0.834, p less than 0.01) which was found to vary by at least 5%. This

variation was due to a manufacturing variation and not due to inaccurate dilution of the dialysis fluid concentrate. These data suggests that such a manufacturing variation may expose maintenance hemodialysis patients to periods of excessive calcium loss or gain and thereby favor renal osteodystrophy or soft tissue calcification.

Sodium modeling during hemodialysis: a new approach. Petitclerc, T., Man, N.K. and Funck-Brentano, J.L. *Artif Organs*, 8 (4), pp. 418-22 (Nov 1984). Sodium volume modeling during hemodialysis encounters several difficulties. First, the actual sodium distribution volume is the extracellular water, whereas the ultrafiltration flow reflects the variation of total body water. Thus, a two-pool model must be considered. This will complicate the model by increasing the number of parameters and boundary conditions. An alternative is to consider the total body water as the apparent distribution volume of loaded or removed sodium, which leads to a single-pool model. Second, convective sodium transfer induced by ultrafiltration is not negligible compared with diffusive sodium transfer. Therefore, sodium transfer modeling must simultaneously take into account the diffusive and the convective part, with the coupling part related to both processes. Third, the Donnan effect, due to nondiffusible anionic plasma proteins, modifies the sodium transfer through the membrane.

Pseudomonas stutzeri bacteremia associated with hemodialysis. Goetz, A., Yu, V.L., Hanchett, J.E. and Rihs, J.D. *Arch Intern Med*, 143 (10), pp. 1909-12 (Oct 1983). Pseudomonas stutzeri bacteremia developed in six patients undergoing hemodialysis. Fever, shaking chills, nausea, and vomiting were observed. All patients recovered, although only two received specific antibiotic therapy. The infections occurred sporadically over a period of nine months. Pseudomonas stutzeri was subsequently isolated from the dialysate. The ultimate source was the deionized water. The emphasis on handwashing, strict compliance with disinfection procedures, and elimination of prolonged sitting times for the filled machine after disinfection resulted in no further cases of P stutzeri infection.

The untoward effects of the anions of dialysis fluids. Veech, R.L. *Kidney Int*, 34 (5), pp. 587-97 (Nov 1988). A review containing 124 references. Dialysis fluids in current use contain unphysiological amounts of the anions, acetate and D-lactate, both of which may induce specific toxic syndromes. Use of bicarbonate in place of acetate may: improve control of cellular energy status, improve ion and water distribution across plasma a mitochondrial membranes, and decrease most of the untoward reations now associated with dialysis, while at the same time improving the sense of well being in patients.

Potential bacteriologic and endotoxin hazards associated with liquid bicarbonate concentrate. Bland, L.A., Ridgeway, M.R., Aguero, S.M., Carson, L.A. and Favero, M.S. *ASAIO Trans*, 33 (3), pp. 542-5 (Jul-Sep 1987). Using liquid bicarbonate concentrate from two commercial sources and one facility source, bacterial contamination and excessive endotoxin levels were found in all cases. This contamination was amplified in dialysis fluid to levels well in excess of AAMI's Recommended dialysate standard.

Microbiologic contamination of liquid bicarbonate concentrate for hemodialysis. Ebben, J.P., Hirsch, D.N., Luehmann, D.A., Collins, A.J. and Keshaviah, P.R. *ASAIO Trans*, 33 (3), pp. 269-73 (Jul-Sep 1987). With the growing use of bicarbonate dialysate, caution must be paid to microbiology of dialysate. The following precautions are suggested: (1) avoid prolonged storage of liquid bicarbonate concentrate (LBC), (2) perform UV sterilization of RO water and LBC, (3) thoroughly clean storage and mixing containers, (4) disinfect dialysis machines at least twice weekly, and (5) when performing bacterial cultures, use standard plating techniques with a medium supplemented with NaCl (e.g., commercially available trypic soy agar).

Pressure controlled single needle hemodialysis using high flux dialysers and volume regulated ultrafiltration: the problem of dialysate back flow. Zbinden, M. and Binswanger, U. *Life Support Syst*, (England) 3, Suppl 1 (1985).

Dialysate concentrate: a potential source for lethal complications. Brueggemeyer, C.D. and Ramirez, G. *Nephron*, 46 (4), pp. 397-8 (1987). Report of two incidents where patients were dialyzed with acid concentrate on an acetate machine. Recommends that placement of dialysate concentrate be regarded as an important medical task with concomitant care and liablility for the responsible individuals that set up the machines. Any additional available safeguards should be used.

Rapid high-efficiency bicarbonate hemodialysis. Keshaviah, P. and Collins, A. *ASAIO Trans*, 32 (1), pp. 17-23 (Jul-Sep 1986). A dialysis time of approximately 2.5 hours was achieved by using blood flow rates of approx 400 ml/min and large surface area dialyzers in order to achieve BUN clearances of

approx 280 ml/min. Rapid bicarbonate hemodialysis was associated with lower incidence of hypotension, nausea, and vomiting than rapid acetate or standard acetate therapies.

Stable liquid bicarbonate hemodialysate (LBD). Nissenson, A.R., Ackerman, R.A., Meyers, S.A. and Birdsall, S.K. *Trans Am Soc Artif Intern Organs,* 30, pp. 630-4 (1984). Normally bicarbonate concentrate must be prepared shortly before dialysis to prevent destabilization before or during dialysis and also requires a dual pump proportioning system. This paper describes a trial of a liquid bicarbonate concentrate that is stable over a 2.5 year period, and has been shown to be safe and easy to use.

Hypoxemia during hemodialysis: effect of different membranes and dialysate compositions. DeBacker, W.A., Verpooten, G.A., Borgonjon, D.J., VanWaeleghem, J.P., Vermeire, P.A. and DeBroe, M.E. *Contrib Nephrol,* 37 pp. 134-41 (1984). Comparing AN69 membrane, cuprophan membrane, acetate dialysate, and bicarbonate dialysate, it is found that the degree of dialysis-related hypoxemia increases in severity as follows: combination of AN69 and bicarbonate shows little hypoxemia; AN69 and acetate, as well as cuprophan and bicarbonate, show intermediate results; and acetate and cuprophan the most significant drop. Indications are that there are two components to the dialysis hypoxemia: a membrane-related component, and a dialysate buffer component.

Side effects in bicarbonate dialysis due to low dialysate pH. Wagner, L., Schindler, B., Marhoffer, W., vanEyl, O. and Strauch, M. *Proc Eur Dial Transplant Assoc,* 19, pp. 346-50 (1983). In six commercially available bicarbonate containing dialysates pH and pCO_2 were determined. Side effects resulted from low pH and high pCO_2. Use of two of the six dialysates was associated with fatigue, muscle cramps and somnolence. The importance of bicarbonate dialysate with a higher pH (7.48) and low pCO_2 (< 60 mmHg) in alleviating patient symptomology is confirmed.

Pancreatic affection after acute hypotonic hemodialysis. Paus, P.N., Larsen, E.W., Sodal, G. and Erichsen, A. *Acta Med Scand,* 212 (1-2), pp. 83-4 (1982). Four male outpatients, all on stable long-term hemodialysis, were by accident simultaneously exposed to hypotonic dialysate. Three of them developed increased serum amylase values and one died from the consequences of a fulminant pancreatitis, which had been verified by laparatomy.

Hemolysis and consumption coagulopathy due to overheated dialysate. Tielemans, C.L., Herbaut, C.R., Geurts, J.O. and Dratwa, M. *Nephron,* 30 (2), pp. 190-1 (1982). A patient on chronic hemodialysis was accidentally accidentally exposed to overheated dialysate (52°C) for 100 minutes due to the audible and visual alarms not being activated due to human error (the system contained a freely adjustable alarm range of 0° to 60° C which had not been set to the proper range of 35- 2 °C) and a malfunctioning of the heater. This resulted in acute hemolysis and consumption coagulapathy.

Reversal of aluminum-induced hemodialysis anemia by a low-aluminum dialysate. O'Hare, J.A. and Murnaghan, D.J. *N Engl J Med,* 306 (11), pp. 654-6 (Mar 18, 1982).

Acetate vs. bicarbonate dialysis. Lesch. E/M. *Nephrol Nurse,* 2 (5), pp. 14-7 (Sep-Oct 1980). Life threatening hypokalemia during hemodialysis. Wiegand, C., Davin, T., Raij, L. and Kjellstrand, C. *Trans Am Soc Artif Intern Organs,* 1979, 25, pp. 416-8. The serum potassium concentration can be dependent on acid-base status of the patient's serum. Even with a dialysate concentration of potassium 42% higher than that of the serum, the authors report of decrease in serum potassium. If a patient is in metabolic acidosis, they recommend a dialysate potassium of 6.3 mEq/L.

Dialysis dementia: the role of dialysate pH in altering the dialyzability of aluminum. Gacek, E.M., Babb, A.L., Uvelli, D.A., Fry, D.L. and Scribner, B.H. *Trans Am Soc Artif Intern Organs,* 25, pp. 409-15 (1979). The pH can alter dialyzability of aluminum. If the pH is between 6.5 and 7.6 there is negligible dialyzability; if lower or higher, the clearance is significant.

Trace metal changes in dialysis fluid and blood of patients on hemodialysis. Salvadeo, A., Minoia, C., Segagni, S. and Villa, G. *Int J Artif Organs,* 2 (1), pp. 17-21 (Jan 1979). Discussion of trace metals in dialysate which can dialyze across the membrane and result in harmful effects or harmful accumulation in the patient.

Haemolytic anaemia caused by overheated dialysate. Lynn, K.L., Boots, M.A., Mitchell, T.R. *Br Med J,* 1 (6159), pp. 306-7 (Feb 3, 1979). Home patient admitted with hemolysis several times. Finally, the patient noted that the blood lines were "hot" during dialysis. Upon investigation it was found that the dialysate temperature was 58°C due to a defective heater and defective temperature gauge.

The mechanisms of arterial hypoxemia during hemodialysis. Romaldini, H., Rodriguez-Roisin, R., Lopez, F.A., Ziegler, T.W., Bencowitz, H.Z. and Wagner, P.D. *Am Rev Respir Dis,* 129 (5) pp. 780-4 (May 1984). The findings suggest that the hypoxemia observed during hemodialysis is primarily due to a decrease in alveolar ventilation and respiratory quotient associated with removal of metabolic CO2 in the dialyzer. Secondary factors affecting arterial PO2 were the slight improvement in ventilation-perfusion relationships, tending to increase it, and the decrease in cardiac output tending to decrease it. There was no evidence for diffusion impairment because the measured VA/Q inequality accounted for the degree of hypoxemia.

Calcium carbonate precipitation in bicarbonate hemodialysis. Klein, E., Ward, R.A. and Harding, G.B. *Artif Organs,* 10 (3), pp. 248-50 (Jun 1986). Sparging of the bicarbonate-containing concentrate with carbon dioxide converts any carbonate to bicarbonate, thus avoiding the formation of precipitates on addition of calcium ions.

Dialysis-induced hypoxemia and hypotension are not causally related. Keshaviah, P., Carlson, L., Contantini, E. and Shapiro, F. *Trans Am Soc Artif Intern Organs,* 30, pp. 159-62 (1984).

Dialysis leukopenia, hypoxemia, and anaphylatoxin formation: effect of membrane, bath, and citrate anticoagulation. Wiegmann, T.B., MacDougall, M.L. and Diederich, D.A. *Am J Kidney Dis,* 11 (5) pp. 418-24 (May 1988). The findings indicate that leukopenia is directly and exclusively related to membrane composition while hypoxemia only relates in part to membrane effects.

Sodium fluxes during hemodialysis. Bosch, J., Ponti, R., Glabman, S. and Lauer, A. *Nephron,* 45 (2), pp. 86-92 (1987). Three sets of experiments were performed to determine the effect of the dialysate sodium concentration on the sodium balance of patients undergoing maintenance hemodialysis. First, we demonstrated that the pretreatment plasma sodium concentration was independent of the sodium concentration of the dialysate used. Second, the plasma sodium concentration available for diffusion during the treatment was calculated from the plasma sodium concentration and the plasma proteins. Third, the sodium fluxes using a hypernatremic or hyponatremic dialysate were calculated for 100 ml of plasma going through the dialyzer. At steady state, no significant differences in net sodium fluxes were demonstrated between hyper- and hyponatremic dialysis.

Acetate dialysate versus bicarbonate dialysate: a continuing controversy. Diamond, S.M. and Henrich, W.L. *Am J Kidney Dis,* 9 (1), pp. 3-11 (Jan 1987). Document Type: Review (91 refs.). The use of bicarbonate dialysate as the buffer during routine dialysis is growing. This discussion reviews several of the comparative trials in which bicarbonate and acetate buffers have been tested. Patients who seem most likely to benefit from bicarbonate dialysate include those with a reduced muscle mass in whom a high sodium dialysate has not prevented hypotension.

Benefits of bicarbonate dialysis. Mastrangelo, F., Rizzelli, S., Corliano, C., Montinaro, A.M., DeBlasi, V., Alfons, L., Aprile, M., Napoli, M. and Laforgia, R. *Kidney Int,* Suppl, 17, pp. S188-93 (Dec 1985).

A mechanism of hypoxemia during hemodialysis. Consumption of CO2 in metabolism of acetate. Oh, M.S., Uribarri, J., Del Monte, M.L., Heneghan, W.F., Kee, C.S., Friedman, E.A. and Carroll, H.J. *Am J Nephrol,* 5 (5), pp. 366-71 (1985). The present study is an investigation of the role of acetate metabolism in dialysis-induced hypoxemia and of the relative roles of acetate metabolism, bicarbonate loss, and CO2 gas (g) loss in causation of hypoxemia. The results indicate that acetate metabolism can lead to reduction in respiratory exchange ratio and hypoxemia and suggest that the same mechanism is responsible for hypoxemia during hemodialysis using acetate dialysate.

Effects of high sodium dialysate during maintenance hemodialysis. Cybulsky, A.V., Matni, A. and Hollomby, D.J. *Nephron,* 41 (1), pp. 57-61 (1985). The effects of high sodium 144 mmol/l (mEq/l) dialysate were studied in normotensive, hypertensive and anephric chronic hemodialysis patients. High sodium dialysate is beneficial for normotensive and anephric patients in reducing dialysis-induced hypotension and was not associated with any deleterious effects on long-term blood pressure control. In hypertensive patients, the benefit is less clear, and hypertension may increase.

Comparison of high and low sodium bicarbonate and acetate dialysis in stable chronic hemodialysis patients. Bijaphala, S., Bell, A.J., Bennett, C.A., Evans, S.M. and Dawborn, J.K. *Clin Nephrol,* 23 (4), pp. 179-83 (Apr 1985). Eight stable center dialysis patients completed four, 10-week study periods in which either acetate or bicarbonate dialysis was used, each with high or low sodium concentration. During high sodium dialysis, blood pressure was better controlled, weight loss more easily tolerated and dialysis was

most satisfactory from the patient's point of view with regard to dialysis-associated symptoms. Careful choice of dialysate sodium concentration appears to be important in lessening dialysis side-effects. Substitution of bicarbonate for acetate in chronic stable dialysis patients has comparatively little benefit and the choice can legitimately be made on the basis of cost and technical considerations.

Effect of variations in dialysate temperature on blood pressure during hemodialysis. Sherman, R.A., Faustino, E.F., Bernholc, A.S. and Eisinger, R.P. *Am J Kidney Dis,* 4 (1), pp. 66-8 (Jul 1984). The effect on BP of alteration in dialysate temperature was studied in 150 hemodialysis treatments in 17 patients using a randomized, double-blind protocol. Each patient was treated using dialysate at 35.6°C, 36.7°C, and 37.8°C. Dialysate cooler than that routinely employed has a beneficial effect while warmer dialysate has a detrimental one on intradialytic BP. The use of dialysate at least 1°C cooler than "isothermic" levels may be appropriate.

Cold as cardiovascular stabilizing factor in hemodialysis: hemodynamic evaluation. Coli, U., Landini, S., Lucatello, S., Fracasso, A., Morachiello, P., Righetto, F., Scanferla, F., Onesti, G. and Bazzato, G. *Trans Am Soc Artif Intern Organs,* 29, pp. 71-5 (1983). Vascular instability represents the most frequent intradialytic complication of uremic patients. Catecholamine impairment, changes in plasma sodium or osmolality and, more recently, temperature (T) of dialysate have been proposed to explain this phenomenon. Our hemodynamic study confirms the important role played by T on intradialytic vascular stability and may explain the better control observed during hemofiltration compared to standard W-HD.

Risks and hazards associated with dialyzers and dialysate delivery systems. Keshaviah, P.R. and Luehmann, D.A. *Crit Rev Biomed Eng,* 9 (3), pp. 201-44 (1983). Document Type: Review (83 refs.).

Increment in dialysate sodium with sodium chloride or bicarbonate addition. Raja, R.M., Fernandes, M., Kramer, M.S., Rosenbaum, J.L. and Barber, K. *Artif Organs,* 7 (2), pp. 154-8 (May 1983). Hemodialysis was performed in 12 patients for 2 weeks each utilizing acetate dialysate containing 134 mEq/L sodium and dialysate containing 143 mEq/L sodium, achieved by the addition of sodium chloride or sodium bicarbonate to the acetate dialysate. Intradialytic morbidity was lower, dialysis hypoxemia less marked, and predialysis blood pH higher with the bicarbonate than with the chloride-added dialysate.

Advantages of bicarbonate hemodialysis. Hampl, H., Klopp, H., Wolfgruber, M., Pustelnik, A., Schiller, R., Hanefeld, F. and Kessel, M. *Artif Organs,* 6 (4), pp. 410-6 (Nov 1982). During acetate dialysis the patients showed a frequent onset of sudden hypotension and arrhythmia with concomitant symptoms of the so-called disequilibrium syndrome, whereas these symptoms were nonexistent in the same patients during bicarbonate dialysis.

The role of acetate in the etiology of symptomatic hypotension. Keshaviah, P.R. *Artif Organs,* 6 (4), pp. 378-87 (Nov 1982). Studies comparing cardiovascular stability during acetate and bicarbonate dialysis indicate that bicarbonate dialysis is beneficial only when the fall in serum osmolality during dialysis is significant. If the fall in serum osmolality is blunted either with a high-sodium dialysate or mannitol infusions, there is little difference between acetate and bicarbonate. From a practical viewpoint, high-sodium dialysis is technically less complex and expensive than bicarbonate dialysis.

The untoward effects of the anions of dialysis fluids. Veech, R.L. *Kidney Int,* 34 (5), pp. 587-97 (Nov 1988). A review containing 124 references.

Hemodialysis with low-temperature dialysate: a long-term experience. Marcen, R., Quereda, C., Orofino, L., Lamas, S., Teruel, J.L., Matesanz, R. and Ortuno, J. *Nephron,* 49 (1), pp. 29-32 (1988). This study shows that dialysis at a lower dialysate temperature (35°C) as compared to the normal (37°C) offered a reduction of some intradialytic symptoms including symptomatic hypotension. Lower temperature also assisted in stabilization of predialysis systolic blood pressure (SBP) at a lower level and was associated with a higher ultrafiltration.

Hypoxemia during hemodialysis: a critical review of the facts. Cardoso, M., Vinay, P., Vinet, B., Leveillee, M., Prud'homme, M., Tejedor, A., Courteau, M., Gougoux, A., St-Louis, G., Lapierre, L; et al. *Am J Kidney Dis,* 11 (4), pp. 281-97 (Apr 1988). The literature describing the fall in PaO2 during dialysis is intensively and critically reviewed. This phenomenon is related to both the type of membrane used (cellulosic v noncellulosic membrane), and to the composition of the dialysate (acetate *vs.* bicarbonate), which results in hypoventilation and is the major cause of hypoxemia (92 refs.).

Potential bacteriologic and endotoxin hazards associated with liquid bicarbonate concentrate. Bland, L.A., Ridgeway, M.R., Aguero, S.M., Carson, L.A. and Favero, M.S. *ASAIO Trans,* 33 (3), pp. 542-5 (Jul-Sep 1987).

Microbiologic contamination of liquid bicarbonate concentrate for hemodialysis. Ebben, J.P., Hirsch, D.N., Luehmann, D.A., Collins, A.J. and Keshaviah, P.R. *ASAIO Trans,* 33 (3), pp. 269-73 (Jul-Sep 1987).

Hemodialysis associated hypotension and dialysate temperature. Quereda, C., Marcen, R., Lamas, S., Hernandez-Jodra, M., Orofino, L., Sabater J., Villafruela, J. and Ortuno, J. *Life Support Syst,* 3, Suppl 1, pp. 18-22 (1985). Incidence of intradialytic symptomatic hypotension was significantly reduced by lowering dialysate temperature from 37°C to 35°C. This improvement seems not to be mediated by temperature-induced changes in membrane biocompatibility, since leukocytes, platelets and complement activation were similar in both situations.

Dialysate concentrate: a potential source for lethal complications. Brueggemeyer, C.D. and Ramirez, G. *Nephron,* 46 (4), pp. 397-8 (1987).

Hypersensitivity reactions related to acetate dialyzate and cellulose acetate membrane. Caravaca, F., Pizarro, J.L., Arrobas, M., Cubero, J.J., Antona, J.M. and Sanchez, E. *Nephron,* 45 (2), pp. 158-9 (1987).

Rapid high-efficiency bicarbonate hemodialysis. Keshaviah, P. and Collins, A. *ASAIO Trans,* 32 (1), pp. 17-23 (Jul-Sep 1986).

The role of glucose in hemodialysis: the effects of glucose-free dialysate. Ramirez, G., Bercaw, B.L., Butcher, D.E., Mathis, H.L., Brueggemeyer, C. and Newton, J.L. *Am J Kidney Dis,* 7 (5), pp. 413-20 (May 1986). Glucose-free dialysate has been traditionally used in patients on chronic hemodialysis, reportedly without any side effects. Although hypoglycemia is not produced, several other metabolic changes must occur to maintain the euglycemic state. This study looks at patients on chronic hemodialysis using both a glucose-free bath and a glucose bath. Abnormal EEG changes were observed after dialysis without glucose that were not present or were minimal with a glucose bath.

Bone aluminum deposition in maintenance dialysis patients treated with aluminium-free dialysate: role of aluminium hydroxide consumption. Heaf, J.G., Podenphant, J., Andersen, J.R. *Nephron,* 42 (3), pp. 210-6 (1986). It is concluded that bone aluminium deposition occurs despite the use of aluminium-free dialysate and is associated with total and present aluminium hydroxide consumption; heavy aluminium deposition is associated with severe and symptomatic osteomalacia, but can also be observed in the presence of predominant hyperparathyroidism.

Influence of blood temperature on vascular stability during hemodialysis and isolated ultrafiltration. Maggiore, Q., Pizzarelli, F., Zoccali, C., Sisca, S. and Nicolo, F. *Int J Artif Organs,* 8 (4), pp. 175-8 (Jul 1985). It is concluded that the temperature changes in blood flowing through the extracorporeal circuit largely account for the differing vascular stability between isolated UF and simultaneous ultrafiltration-hemodialysis.

Amelioration of hemodialysis-associated hypotension by the use of cool dialysate. Sherman, R.A., Rubin, M.P., Cody, R.P. and Eisinger, R.P. *Am J Kidney Dis,* 5 (2), pp. 124-7 (Feb 1985). Cool dialysate reduced the frequency of symptomatic hypotension. In addition, the rate of fall of mean BP during treatment was substantially slowed with the reduction in dialysate temperature. Cool dialysate (34.4°C) substantially ameliorates hemodialysis-associated hypotension.

Carbon dioxide removal in acetate hemodialysis: effects on acid base balance. Bosch, J.P., Glabman, S., Moutoussis, G., Belledonne, M., vonAlbertini, B. and Kahn, T. *Kidney Int,* 25 (5), pp. 830-7 (May 1984). Studies were performed in patients on maintenance acetate hemodialysis to assess the quantity and processes involved in the removal of carbon dioxide (CO2) during the treatment. The data presented suggest that multiple factors related to the removal of CO2 during acetate dialysis may be responsible in part for the low plasma bicarbonate observed in patients on chronic maintenance hemodialysis.

A report of data acquired under varying conditions and a review of the literature. Sherlock, J., Ledwith, J. and Letteri, J. *Am J Nephrol,* 4 (3), pp. 158-68 (1984). The major reason for hypoxemia during acetate dialysis is a decrease in alveolar oxygen tension due to changes in metabolism and a decrease in pulmonary CO2 excretion when CO2 is lost from the dialyzer. The increasing pH may contribute to the metabolic change during acetate dialysis and the hypoventilation during bicarbonate dialysis. There is little evidence to support an effect of pulmonary capillary obstruction or changes in oxy-hemoglobin association on the decrease in arterial oxygen tension observed.

Long-term hemodialysis at reduced dialysate flow rates. Kirchner, K.A., White, A.R., Kiley, J.E. and Bower, J.D. *Am J Nephrol,* 4 (1), pp. 7-12 (1984). Twenty stable hemodialysis patients were maintained on a dialysate flow rate of 300 ml/min (QD 300) to determine the safety of prolonged reductions in dialysate flow rate. Authors conclude that QD 300 does not impair dialysis efficiency for most small molecules and saves $1.38 per patient per dialysis.

Bacterial contamination of the blood compartment originating from the dialysate in haemodialysers. Kolmos, H.J. *J Hosp Infect,* 5 (1), pp. 70-5 (Mar 1984). Microorganisms originating from the dialysate compartment invaded the blood compartment of 'Rhodial RP6' 2.5 percent of the time. Analysis of the data suggested that the probable access of bacteria to the blood compartment was by way of minor defects in the dialysis membrane. The patients experienced no obvious symptoms or signs of sepsis which could be ascribed to the presence of microorganisms in the blood compartment.

A difference in complement and neutrophil activation. Ivanovich, P., Chenoweth, D.E., Schmidt, R., Klinkmann, H., Boxer, L.A., Jacob, H.S. and Hammerschmidt, D.E. *Contrib Nephrol,* 37 pp. 78-82 (1984).

Side effects in bicarbonate dialysis due to low dialysate pH. Wagner, L., Schindler, B., Marhoffer, W., vanEyl, O. and Strauch, M. *Proc Eur Dial Transplant Assoc,* 19, pp. 346-50 (1983). In six commercially available bicarbonate containing dialysates pH and pCO2 were determined. Side effects resulted from low pH and high pCO2. Use of two of the six dialysates was associated with fatigue, muscle cramps and somnolence.

Contrasting alterations in pulmonary gas exchange during acetate and bicarbonate hemodialysis. Eiser, A.R., Jayamanne, D., Kokseng, C., Che, H., Slifkin, R.F. and Neff, M.S. *Am J Nephrol,* 2 (3), pp. 123-7 (1982). Our studies revealed that oxygen consumption increased significantly during acetate dialysis, while it decreased slightly during bicarbonate dialysis. Since CO2 production decreased with both baths, the respiratory exchange ratio decreased during acetate dialysis but did not change during bicarbonate dialysis. We conclude that hypoxemia during dialysis relates to decreases in minute ventilation and that a greater decrease during acetate dialysis is a consequence of enhanced oxygen consumption and its effect on respiratory exhange ratio. Bicarbonate dialysis does not increase oxygen consumption.

Electroencephalogram investigations of the disequilibrium syndrome during bicarbonate and acetate dialysis. Hampl, H., Klopp, H.W., Michels, N., Mahiout, A., Schilling, H., Wolfgruber, M., Schiller, R., Hanefeld, F. and Kessel, M. *Proc Eur Dial Transplant Assoc,* 19, pp. 351-9 (1983). Continuous long-time electroencephalographic (EEG) monitoring was performed during acetate and bicarbonate dialysis. Persisting normal basic activity of the EEG without neurological symptoms was found only during the course of bicarbonate dialysis. The decrease in PaCO2 and the deterioration in EEG activity in the patients during acetate dialysis was concomitant with severe neurological alterations, e.g., the typical symptoms of so-called 'disequilibrium' causing a cessation of dialysis in three patients.

Danger of haemodialysis using acetate dialysate in combination with a large surface area dialyser. Viljoen, M. and Gold, C.H. *S Afr Med J,* 56 (5), pp. 170-2 (Aug 4, 1979). Large surface area, high mass transfer dialysers have recently come into widespread use, and it has been shown that they promote the loss of large amounts of bicarbonate when acetate is used in the dialysate. In the chronic dialysis patient in a steady state, these effects may be inconsequential but, in an acutely ill patient, the combination of a dialysate containing acetate and a high-efficiency dialyser may be extremely hazardous. A return to the use of bicarbonate as the source of base would avoid such hazards and would promote the more physiological correction of the metabolic acidosis of renal failure.

Acute nickel intoxication by dialysis. Webster, J.D., Parker, T.F., Alfrey, A.C., Smythe, W.R., Kubo, H., Neal, G. and Hull, A.R *Ann Intern Med,* 92 (5), pp. 631-3 (May 1980). Nickel intoxication was observed in a group of dialyzed patients when leaching of nickel-plated stainless steel water heater tank contaminated the dialysate. Symptoms occurred during and after dialysis at plasma nickel concentrations of approximately 3 mg/L. Symptoms included nausea, vomiting, weakness, headache, and palpitation. Remission of symptoms occurred spontaneously, generally 3 to 13 hours after cessation of dialysis. The evidence indicated that the nickel became bound in the plasma after crossing the membrane, resulting in a higher concentration in the plasma than in the dialysate and preventing its removal by dialysis.

Life threatening hypokalemia during hemodialysis. Wiegand, C., Davin, T., Raij, L. and Kjellstrand, C. *Trans Am Soc Artif Intern Organs,* 25, pp. 416-8 (1979).

Trace metal changes in dialysis fluid and blood of patients on hemodialysis. Salvadeo, A., Minoia, C., Segagni, S. and Villa, G. *Int J Artif Organs,* Jan 1979, 2 (1), pp. 17-21.

A Clinical Test of a New Device for On-line Preparation of Dialysis Fluid from Bicarbonate Powder: The Gambro BiCart. Delin, K., Attman, P.O., Dahlberg, M. and Aurell, M. *Dial & Transplant,* p. 468 (Sep 1988).

Issues in Dialysis: Reuse, Dialysate Toxicity, Short Dialysis. Vlchek, D. *Dialy & Transplant,* p.127 (March 1988). A review of an ASN conference on the three title topics. The benefits and limits of each of these highly topical factors in dialysis are discussed.

A double-blind controlled trial of acetate versus bicarbonate dialysate. Uldall, P.R., Kennedy, I., Craske, H., Porrett, E., Aid, J., Woods, F. and Levine D. *Proc Clin Dial Transplant Forum,* 10, pp. 220-3 (1980). A significantly lower incidence of dialysis-related symptoms has been shown during dialysis with bicarbonate rather than the previously used acetate. The level of well-being in the intervals between dialysis was not appreciably affected by the dialysis mode. It is suggested that bicarbonate dialysis should be made available to all patients receiving regular hemodialysis for end-stage renal failure provided that this can be done reliably and safely.

Hemolysis and consumption coagulopathy due to overheated dialysate. Tielemans, C.L., Herbaut, C.R., Geurts, J.O. and Dratwa, M. *Nephron,* 30 (2), pp. 190-1 (1982).

Acute haemolysis due to concentrated dialysis fluid. Mulligan, I., Parfrey, P., Phillips, M.E., Brown, E.A. and Curtis, J.R. *Br Med J* [Clin Res], 284 (6323), pp. 1151-2 (Apr 17, 1982). Fatal acute haemolysis occurred in a 65-year-old man undergoing regular home haemodialysis for terminal renal failure. Circumstantial evidence indicating that the haemolysis resulted from exposure to concentrated dialysis solution was supported by in-vitro studies. Frank haemolysis in blood samples occurred at a dilution of greater than or equal to 1/2 of dialysis fluid. Osmotic fragility tests of surviving red blood cells showed 47% haemolysis at a dilution of 1/2 and greater than 90% haemolysis at a dilution of 1/1. Urgent design modifications to the proportioning machine are being undertaken to prevent such an accident recurring.

Dialysate aluminium concentration and renal bone disease. Walker, G.S., Aaron, J.E., Peacock, M., Robinson, P.J. and Davison, A.M. *Kidney Int,* 21 (2), pp. 411-5 (Feb 1982). Bone fractures were significantly more common in patients exposed to high dialysate aluminium concentrations. The histologic indices of osteomalacia were significantly related to the prevailing dialysate aluminium concentration, in such a way that higher aluminium levels were associated with more osteomalacia. These findings suggest that aluminium is a toxic agent associated with a mineralizing defect in the bone of renal failure patients.

"Physiological" and "pharmacological" dialysate sodium concentrations. Bocatelli, F., Pedrini, L., Ponti, R., Costanzo, R., DiFilippo, S., Marai, P., Pozzi, C. and Bonacina, G.P. *Int J Artif Organs,* 5 (1), pp. 17-24 (Jan 1982). Using "physiological" and "pharmacologically high" sodium dialysate, the removal of water and sodium by convection improves the cardiovascular stability and the patient's well-being, without bringing about the feared long-term cardiovascular side effects, if an appropriate dry body weight is achieved, because of better correction of the cellular overhydration.

Severe hypokalemia induced by hemodialysis. Wiegand, C.F., Davin, T.D., Raij, L. and Kjellstrand, C.M. *Arch Intern Med,* 141 (2), pp. 167-70 (Feb 1981). During dialysis, it is assumed that the serum electrolyte levels asymptotically approach the concentration in the dialysate. In five patients, we observed an average 20% fall in serum potassium level, although the dialysate contained 42% more potassium than the predialysis serum. The cause of the hypokalemia was a rapid shift of potassium from the extracellular to the intracellular space secondary to correction of acidosis. All patients entered dialysis with a history suggesting prolonged potassium loss, marked acidosis, and moderate hypokalemia; thus, the dialysate potassium concentration should be higher than normal, and frequent determinations of the serum potassium level should be performed. Therapy resulting in rapid correction of acidosis in uremic patients undergoing hemodialysis may cause large transcompartmental shifts of potassium. Potassium transfer across the dialysis membrane may be inadequate to compensate for such shifts, and life-threatening hypokalemia may occur.

A Short Study on the Sodium Controller. Murray, M.K. *J. Nephrol Nursing,* pp. 106-8 (Sept/Oct, 1984). The device is safe and effective and provides the following benefits: fewer medications required to control hyovolemic hyotension, incidence of complica-

tions reduced with higher sodium dialysate, no appreciable different of blood pressure or weight gain on higher sodium, and weight losses increased with fewer attendant complications.

Sodium Balance. Fleming, S. *Dial & Transplant,* pp. 55-65 (Jan 1988). The article discusses the cation, sodium, as the principal osmotic component of the extracellular fluid. It gives an overview of the inappropriate fluid movement between the intraocclular compartment and the extracellular compartment that can cause blood pressure changes, hydrational imbalances, edema, and other pathologic conditions.

Measurement of the effective dialyzer Na diffusion gradient in vitro and in-vivo. Gotch, F.A., Evans, M.C. and Keen, M. *Trans Am Soc Artif Intern Organs,* 31, pp. 354-8 (1985).

Haemodialysis-induced respiratory changes. Fawcett, S., Hoenich, N.A., Laker, M.F., Schorr, W. Jr., Ward, M.K. and Kerr, D.N. *Nephrol Dial Transplant,* 2 (3), pp. 161-8 (1987). Amelioration of hypoxaemia may be achieved by the use of bicarbonate, but its cause is multifactorial, with contributions from hypoventilation secondary to dialyser CO2 losses and pulmonary dysfunction due to leucostasis. These observations suggest that the treatment of patients who have compromised cardiovascular function is most optimal with the use of biocompatible membranes which induce minimal leucopenia, used in conjunction with dialysate that utilises bicarbonate as the base replacement.

Chapter 6

Hemodialyzers

A study on limulus amebocyte lysate (LAL) reactive material derived from dialyzers. Yoshioka, T., Ikegami, K., Ikemura, K., Shiono, S., Uenishi, M., Sugimoto, H. and Sugimoto, T. *Jpn J Surg,* 19 (1), pp. 38-41 (Jan 1989). The amebocytes of horseshoe crab (Limulus) hemolymph contain a coagulation system highly sensitive to bacterial endotoxins. Limulus amebocyte lysate (LAL) reactive material derived from cuproammonium membranes, however is not an endotoxin and acts as a pathway in the coagulation cascade found in Limulus amebocyte lysate. This study confirmed these facts by using the coagulation system of Limulus without factor G, which is a substrate of the alternative pathway.

Beta 2-microglobulin kinetics in maintenance hemodialysis: a comparison of conventional and high-flux dialyzers and the effects of dialyzer reuse. DiRaimondo, C.R., Pollak and V.E. Division of Nephrology, University of Cincinnati Medical Center and Dialysis Clinics, Inc. *Am J Kidney Dis,* 13 (5), pp. 390-5 (May 1989). To define the kinetics of beta 2M during hemodialysis and the effects of dialyzer reprocessing, serum beta 2M, plasma C3a, and neutrophil counts were measured immediately predialysis; 15, 90, and 180 minutes after beginning dialysis; and 15 minutes postdialysis in ten chronic hemodialysis patients. Complement activation and neutropenia during dialysis were significantly more marked with cuprammonium, but were not affected by reprocessing of either dialyzer. In-vitro adsorption of 124I-beta 2M to polysulfone fibers was greater than to cuprammonium; adsorption was not influenced by dialyzer reprocessing.

Interleukin-1—its multiple biological effects and its association with hemodialysis. Dinarello, C.A. *Blood Purif,* 6 (3), pp. 164-72 (1988). Document Type: Review (29 refs.). The conclusion was made that pyrogens, solutes, complement components and the physical nature of the dialysis membrane itself contribute to monocyte activation and cytokine release.

Detection of endotoxin-like interleukin-1-inducing activity during in-vitro dialysis. Lonnemann, G., Bingel, M., Floege, J., Koch, K.M., Shaldon, S. and Dinarello, C.A. *Kidney Int,* 33 (1), pp. 29-35 (Jan 1988). In order to study the integrity of dialysis membranes to pyrogens, the dialysate side of a closed loop hemodialysis (HD) circuit was challenged with E. coli microfiltrate containing 500 ng/ml endotoxin. These studies demonstrate that: (a) in the presence of plasma, IL-1-inducing factors pass into the blood compartment of a dialysis system challenged with bacterial pyrogen; and (b) MNC production of IL-1 is enhanced in the presence of plasma.

Foreign particles contaminating hemodialyzers and methods of removing them by rinsing. Inagaki, H., Hamazaki, T., Kuroda, H. and Yano, S. *Nephron,* 1987, 46 (4), pp. 343-6. Foreign particles contaminating hemodialyzers constitute a risk of microembolism and allergic reactions in hemodialysis patients. Authors investigated the size distribution of particles, and the effects of striking headers of dialyzers and flow rates of rinsing saline on the elimination of foreign particles from dialyzers. To rinse dialyzers effectively, at least 1,000 ml of saline are necessary, and striking the headers of dialyzers throughout the rinsing procedure is important.

The possible role of Limulus-amebocyte-lysate-reactive material in hemodialysis. First-use syndrome. Pearson, F.C. *Blood Purif,* 5 (2-3), pp. 115-22 (1987). In this chapter, current knowledge about LAL-RM is presented and integrated with the major mechanisms generally recognized to induce hypersensitivity-type reactions. These mechanisms include: classical induction of allergy by IgE and classical complement activation by IgG and IgM.

Ultrafiltration to reject human interleukin-1-inducing substances derived from bacterial cultures. Dinarello, C.A., Lonnemann, G., Maxwell, R. and Shaldon, S. J *Clin Microbiol,* 25 (7), pp. 1233-8 (Jul 1987). The results indicate that: the IL-1-inducing material(s) present in bacterial cultures of gram-negative organisms is rejected by a factor of 100 to 100,000 by molecular size exclusion and by absorption; rejection is sustained for at least 32 liters of fluid; the rejection of Limulus-reactive material by the ultrafilter is greater for purified endotoxin than for native endotoxins de-

rived from live bacterial cultures; and nonendotoxin IL-1-inducing toxins (molecular weight, 24,000) from Staphylococcus aureus are not rejected or absorbed.

No evidence for endotoxin transfer across high flux polysulfone membranes. Bommer, J., Becker, K.P., Urbaschek, R., Ritz, E., and Urbaschek B. *Clin Nephrol,* 27 (6), pp. 278-82 (Jun 198). To evaluate the safety of high-flux polysulfone dialyzers, an in-vitro recirculation system was examined. It was concluded that LPS and lipid A do not pass from either side through the filter system used when saline was recirculated for more than 10 h on both sides of the membrane.

Acute anaphylactoid reactions during hemodialysis in France. Foret, M., Kuentz, F., Meftahi, H., Milongo, R, Hachache, T., Elsener, M., Dechelette, E and Cordonnier, D. *Artif Organs,* 11 (2), pp. 168-72 (Apr 1987). A retrospective survey of anaphylactoid reactions during dialysis in France was conducted. The presence of cellulose-derived particles in the rinsing fluid of such dialyzers and the possible increased incidence of reactions after the long (weekend) interdialytic interval suggest that allergy to cellulose-derived particles eluted from cellulosic dialyzers may contribute to dialyzer hypersensitivity reactions.

Effect of dialyzer reprocessing methods on complement activation and hemodialyzer-related symptoms. Dumler, F., Zasuwa, G. and Levin, N.W. *Artif Organs,* 11 (2), pp. 128-31 (Apr 1987). The effects of different dialyzer processing methods and of reuse on complement activation and dialyzer-related symptoms were studied in 96 maintenance hemodialysis patients. The percentage of patients without symptoms during dialysis was significantly greater with reused dialyzers than with new dialyzers. The severity of total symptoms correlated significantly (p=0.0004) with complement activation. The results suggest that total symptoms during dialysis are correlated with the degree of complement activation. However, trends in the data pertaining to chest pain suggest that factors other than complement activation may be important in the pathogenesis of some dialyzer-related symptoms.

Technical requirements for rapid high-efficiency therapies. Keshaviah, P., Luehmann, D., Ilstrup, K. and Collins, A. *Artif Organs,* 10 (3), pp. 189-94 (Jun 1986). The key technical elements necessary for such implementation include high blood flow rates, higher efficiency dialyzers/diafilters, ultrafiltration control systems, and bicarbonate as the buffer source. In addition, hemodiafiltration requires schemes to ensure sterility and nonpyrogenicity of the infusion fluid and appropriate balancing of the rates of ultrafiltration and reinfusion.

The current status and future of the artificial kidney. Funck-Brentano, J.L. *Artif Organs,* 9 (2), pp. 119-26 (May 1985). Document Type: Review (32 refs.). Discussion of the technology, use and determination of adequacy and related cost.

Role of dialyzer contaminants in the allergic epiphenomena of hemodialysis. Ward, R.A., Feldhoff, P.W. and Klein E. *Artif Organs,* 8 (3), pp. 338-49 (Aug 1984). Cuprophan hollow-fiber dialyzers contain contaminants including 1,2,3-propanetriol, carbohydrates, Limulus amebocyte lysate-reactive material, and particulates. In a clinical study, the role of these substances in the allergic-type response seen in some hemodialysis patients was examined. Dialyzer preparation had no effect on predialysis eosinophil counts or IgE levels. All patients demonstrated transient leukopenia and complement activation during dialysis, the magnitudes of which were unaffected by the type of dialyzer preparation. At the levels found in the dialyzers studied, it was questioned whether water-soluble extractables or particulates play any role in the allergic epiphenomena of hemodialysis.

Anaphylactoid reactions due to haemodialysis, haemofiltration, or membrane plasma separation. Nicholls, A.J. and Platts, M.M. *Br Med J* [Clin Res], 285 (6355), pp. 1607-9 (Dec 4, 1982). A previously undescribed anaphylactoid reaction to haemodialysis, haemofiltration, or membrane plasma separation occurred in 15 patients receiving regular dialysis. The illness varied in severity from urticaria, sneezing, and watering of the eyes to severe bronchospasm and cardiovascular collapse, and began within a minute of blood being returned from the dialyser or filtration device to the patient. Reactions developed only when a dialyser sterilised with ethylene oxide was used for the first time and never after sterilisation with formalin. Several patients had more than one reaction while three had a reaction each time a new dialyser was used. Incorrect priming of the dialysers may be a partial explanation of these attacks, but the exact reason for their occurrence is unknown.

Beta 2-microglobulin kinetics in maintenance hemodialysis: a comparison of conventional and high-flux dialyzers and the effects of dialyzer reuse. DiRaimondo, C.R. and Pollak, V.E. Division of Nephrology, University of Cincinnati Medical Center and Dialysis Clinics, Inc. *Am J Kidney Dis,* 13 (5), pp. 390-5

(May 1989). To define the kinetics of beta 2M during hemodialysis and the effects of dialyzer reprocessing, serum beta 2M, plasma C3a, and neutrophil counts were measured immediately predialysis, 15, 90, and 180 minutes after beginning dialysis, and 15 minutes postdialysis in ten chronic hemodialysis patients. Complement activation and neutropenia during dialysis were significantly more marked with cuprammonium, but were not affected by reprocessing of either dialyzer. In-vitro adsorption of 124I-beta 2M to polysulfone fibers was greater than to cuprammonium; adsorption was not influenced by dialyzer reprocessing.

Biocompatibility of artificial organs: an overview. Henderson, L.W. and Chenoweth, D. *Blood Purif,* 5 (2-3), pp. 100-11 (1987). Review (41 refs.).

Cellulose acetate hemodialysis membranes are better tolerated than Cuprophan. A difference in complement and neutrophil activation. Ivanovich, P., Chenoweth, D.E., Schmidt, R., Klinkmann, H., Boxer, L.A., Jacob, H.S. and Hammerschmidt, D.E. Contrib *Nephrol*, 37, pp. 78-82 (1984). The newer cellulose acetate membranes show lower degree of complement activation and a smaller drop in neutrophil count during the first 30 minutes of dialysis than do the cuprophan dialyzers. It is suggested that patients with intradialytic symptoms related to membrane biocompatibility will tolerate the procedure better on these newer membranes.

Hypoxemia during hemodialysis: effects of different membranes and dialysate compositions. DeBacker, W.A., Verpooten, G.A., Borgonjon, D.J., Vermeire, P.A., Lins, R.R. and DeBroe, M.E. *Kidney Int,* (5), pp. 738-43 (May 23, 1983). Comparing AN69 membrane, cuprophan membrane, acetate dialysate, and bicarbonate dialysate, it is found that the degree of dialysis-related hypoxemia increases in severity as follows: combination of AN69 and bicarbonate shows little hypoxemia; AN69 and acetate as well as cuprophan and bicarbonate showing intermediate results; and acetate and cuprophan the most significant drop. Indications are that there are two components to the dialysis hypoxemia: a membrane-related component, and a dialysate buffer component.

Bacterial endotoxin in new and reused hemodialyzers: a potential cause of endotoxemia. Petersen, N.J., Carson, L.A. and Favero, M.S. *Trans Am Soc Artif Intern Organs,* 27, pp. 155-60 (1981). New dialyzers may contain an LAL-reactive material, but it is not pyrogenic. However, if reuse dialyzers are reprocessed and stored with a disinfectant that contains endotoxin, that pyrogenic material may stay in the membrane even after rinseout of the disinfectant. Methods for avoiding introduction of this endotoxin to the patient include discarding the recirculating solution to waste. Water used for dilution of germicide should be endotoxin-free.

Neutrophil behavior during hemodialysis. Role of membrane contact. Neveceral, P., Markert, M. and Wauters, J.P. *ASAIO Trans,* 34 (3), pp. 564-7 (Jul-Sep 1988). The in-vivo effect of membrane contact on oxygen radical production and chemotaxis of dialyzed neutrophils isolated simultaneously from the arterial and venous sites during dialysis with cuprophane, polycarbonate, polysulfone, and polyacrilonitrile membranes was studied. Cells remaining in circulation after 15 minutes of dialysis showed defective responses only when collected at the venous site of the cuprophane dialyzer, in spite of a similar leukopenia at the venous and arterial sites. With the other membranes tested, no defects in neutrophil functions were evidenced. These results suggest that down-regulation occurs within the dialyzer and that, besides complement activation, the membrane plays an additional role.

First-use syndrome in patients treated with hollow-fiber dialyzers. Villarroel, F. *Blood Purif,* 5 (2-3), pp. 112-4 (1987). A two-year survey on first-use syndrome (FUS) in hemodialysis showed that there were an average of 181 FUS reactions per year. Nearly 39% of the patients who experienced a FUS reaction had experienced previous FUS reactions. A strong correlation was found with respect to the age and race of the patients. The fact that a patient recently started dialysis treatment or has been treated with dialysis for some time appears to have no bearing in the risk of experiencing a FUS reaction.

Hypersensitivity to hemodialysis: the United Kingdom experience. Nicholls, A.J. *Artif Organs,* 11 (2), pp. 87-9 (Apr 1987). A survey of all U.K. hemodialysis centers was conducted to investigate the prevalence of hypersensitivity in the first use of disposable dialyzers. A total of 117 patients with 243 separate reactions were identified, suggesting that 1 in 20 to 1 in 50 patients may be susceptible to an anaphylactoid reaction to a new hemodialyzer at some time, while the risk of reaction occurring with any single hemodialysis is approximately 1 in 1,000 to 1 in 5,000. No particular brand or type of hemodialyzer nor any identifiable technique of priming procedure was associated with reactions, but in those few patients who suffered repeated reactions, further problems were avoided by increasing the volume of saline in the

initial rinse of the hemodialyzer or by changing to another brand of hemodialyzer.

Effect of first and subsequent use of hemodialyzers on patient well-being: the rise and fall of a syndrome associated with new dialyzer use. Charoenpanich, R., Pollak, V.E., Kant, K.S., Robson, M.D. and Cathey, M. *Artif Organs,* 11 (2), pp. 123-7 (Apr 1987). In a single large dialysis unit in which dialyzers are routinely subjected to multiple use, the incidence rates of intradialytic symptoms during first use and reuse were compared. The results of this investigation suggest that subjecting dialyzers to an automated reuse processing system before first use can markedly diminish the incidence of first-use syndrome.

Effect of first and subsequent use of hemodialyzers on patient well-being. Analysis of the incidence of symptoms and events and description of a syndrome associated with new dialyzer use. Robson, M.D., Charoenpanich, R., Kant, K.S., Peterson, D.W., Flynn, J., Cathey, M. and Pollak, V.E. *Am J Nephrol,* 6 (2), pp. 101-6 (1986). To determine the effect of multiple dialyzer use on intradialytic symptoms, data from 26,592 successive dialyses on 147 patients were analyzed. Over the 26-month period of study 4,933 new dialyzers were used. All symptoms, considered together, occurred 1.3 times more frequently during the initial than during the subsequent use of the dialyzer. No symptom occurred more frequently in the second or subsequent use of the dialyzer. Concurrent chest and back pain were 41 times more frequent when the dialyzer was used for the first time. A syndrome associated with the first use of the dialyzer is described.

A survey on hypersensitivity reactions in hemodialysis. Villarroel, F., Ciarkowski, A.A. *Artif Organs,* 9 (3), pp. 231-8 (Aug 1985). This survey was conducted from 1982 through 1984 by a cooperative effort among the Health Industries Manufacturers Association, seven dialyzer manufacturers, and the Food and Drug Administration. This article presents an analysis of the 1982-83 survey data and a summary of the 1984 data.

Anaphylatoxin formation during hemodialysis: effects of different dialyzer membranes. Chenoweth, D.E., Cheung, A.K. and Henderson, L.W. *Kidney Int,* 24 (6), pp. 764-9 (Dec 1983). Measurable complement activation resulting in the formation of both C3a and C5a anaphylatoxins was observed in 12 patients undergoing maintenance dialysis treatment with cuprophan hollow fiber dialyzers. The authors surmise that their observations provide direct evidence that anaphylatoxin formation during hemodialysis is a transient phenomenon and indicate that the biocompatibility of dialysis membranes, as reflected by their complement activating potential, may be significantly different.

Nursing management of the new dialyzer syndrome. Butsick, E.A., Clyde, C.A., Hudson, P.C., Manion, B.A. and Smith, L.J. *AANNT J,* 10 (7), pp. 35-9 (Dec 1983).

Long-term results of dialysis therapy with a highly permeable membrane. Chanard, J., Brunois, J.P., Melin, J.P., Lavaud, S. and Toupance, O. *Artif Organs,* 6 (3), pp. 261-6 (Aug 1982). A five-year study of short-term dialysis using highly permeable polyacrylonitrile membrane AN 69 was started in March 1973 to compare the effects of AN 69 and Cuprophan membrane (CM). The dialysis sessions were significantly better tolerated with AN 69 than with CM, however, the main advantage of using AN 69 is the shortening of dialysis time. The duration of dialysis was 9.5±0.2 hours per week with AN 69 and 16.4±0.2 hours per week with CM. Shortening of dialysis time permits better social rehabilitation of the patients. The shorter dialysis was not associated with any recognizable side effects that could be demonstrated by routine clinical and biological analysis.

Hemodialysis-associated complications due to sterilizing agents ethylene oxide and formaldehyde. Kessler, M., Cao-Huu, T., Mariot, A. and Chanliau J. *Contrib Nephrol,* 62, pp. 13-23 (1988). Document Type: Review (57 refs.).

Allergy in long-term hemodialysis II: Allergic and atopic patterns of a population of patients undergoing long-term hemodialysis. Bousquet, J., Maurice, F., Rivory, J.P., Skassa-Brociek, W., Florence, P., Chouzenoux, R., Mion, C. and Michel, F.B. *J Allergy Clin Immunol,* 81 (3), pp. 605-10 (Mar 1988). Patients did not have serum-specific IgE against the released chemicals. Five of 17 patients who had a pruritus during dialysis had either positive RAST to released chemicals or skin tests to the effluent. Five of 8 patients who suffered from anaphylaxis had positive RAST to released chemicals, but only those who had a positive RAST presented a severe reaction.

Ethylene oxide in dialyzer rinsing fluid: effect of rinsing technique, dialyzer storage time, and potting compound. Ansorge, W., Pelger, M., Dietrich, W. and Baurmeister, U. *Artif Organs,* 11 (2), pp. 118-22 (Apr 1987). Ethylene oxide (ETO) is recognized as one of

the main causes of dialyzer-associated hypersensitivity reactions. The authors results suggest that the dose of ETO administered to the patient at the outset of dialysis can be minimized by rinsing the dialyzer with 2 L of fluid at 37°C and by avoiding administration of rinsing fluid that has been allowed to remain in contact with the dialyzer for more than several minutes. Use of a long storage interval and use of dialyzers containing reduced amounts of potting material will also reduce the ETO load.

Mediation of hypersensitivity reactions during hemodialysis by IgE antibodies against ethylene oxide. Lemke, H.D. *Artif Organs,* 11 (2), pp. 104-10 (Apr 1987). We conclude that ETO causes most severe hypersensitivity reactions by an IgE-mediated mechanism. On the other hand, the pathogenesis of mild (type I) reactions is less clearly associated with ETO allergy. The results also suggest that other potentially allergenic substances in dialyzers (e.g., IPM, 2-chloroethanol) rarely induce specific IgE antibodies in dialysis patients.

Extractable ethylene oxide from cuprammonium cellulose plate dialyzers: importance of potting compound. Ing, T.S. and Daugirdas, J.T. *ASAIO Trans,* 32 (1), pp. 108-10 (Jul-Sep 1986). The results suggest that ethylene oxide retention after sterilization is increased in cuprammonium cellulose plate dialyzers containing potting compound. In contrast, cuprammonium cellulose plate dialyzers without potting compound were characterized by a rapid disappearance of retained ethylene oxide after sterilization. Whether these findings explain the low incidence of SARD with cuprammonium cellulose plate dialyzers that do not contain potting material is a matter for continued study and experimentation.

Association of ethylene-oxide-induced IgE antibodies with symptoms in dialysis patients. Rumpf, K.W., Seubert, S., Seubert, A., Lowitz, H.D., Valentin, R., Rippe, H., Ippen, H. and Scheler, F. *Lancet,* 2 (8469-70), pp. 1385-7 (Dec 21-28 1985). High RAST values were commonly associated with anaphylactoid reactions during dialysis and with chronic asthma. Ethylene oxide antibodies should be sought routinely in patients presenting with these symptoms and the necessity of ethylene oxide sterilisation of disposable dialysis equipment should be re-evaluated.

Dialyzer hypersensitivity syndrome: possible role of allergy to ethylene oxide. Report of four cases and review of the literature. Caruana, R.J., Hamilton, R.W. and Pearson, F.C. *Am J Nephrol,* 5 (4), pp. 271-4 (1985). Document Type: Review (12 refs.). Dialyzer hypersensitivity syndrome presents as an acute anaphylactoid reaction, the symptoms of which may range from mild to life-threatening in severity. The cause of this syndrome is unknown, but affected patients appear to have a high incidence of positive radioallergosorbent tests to a conjugate of human serum albumin and ethylene oxide, suggesting that ethylene oxide, a substance used to dry sterilize artificial kidneys, may be an offending allergen.

Severe reactions during hemodialysis. Rault, R. and Silver, M.R. *Am J Kidney Dis,* 5 (2), pp. 128-31 (Feb 1985). Severe reactions during dialysis occurred in 1.7% of hemodialysis patients. Respiratory distress, agitation, pruritus, and alterations in BP were the dominant clinical findings, and one patient suffered a respiratory arrest. Current evidence implicates the dialyzer as the most likely culprit, and experience suggests that none of the commonly used dialysis membranes are truly biocompatible.

Anaphylatoxin formation during hemodialysis: comparison of new and re-used dialyzers. Chenoweth, D.E., Cheung, A.K., Ward, D.M. and Henderson, L.W. *Kidney Int,* 24 (6), pp. 770-4 (Dec 1983). Hemodialysis of 11 endstage renal failure patients with new cuprophan hollow fiber dialyzers produced significant leukopenia as well as increased plasma levels of both C3a and C5a antigens during the initial phases of the procedure. These observations suggest that C3b deposition on the cellulosic membrane surface during first use markedly diminishes the complement-activating potential of cuprophan dialyzers when they are subsequently reused.

Risks and hazards associated with dialyzers and dialysate delivery systems. Keshaviah, P.R. and Luehmann, D.A. *Crit Rev Biomed Eng,* 9 (3), pp. 201-44 (1983). Document Type: Review (83 refs.).

Hypersensitivity reaction on first-time exposure to cuprophan hollow fiber dialyzer. Key, J., Nahmias, M. and Acchiardo, S. *Am J Kidney Dis,* 2 (6), pp. 664-6 (May 1983). The cause of the hypersensitivity reaction is unknown. It could be due to substances used in the sterilization procedure, to the membrane itself, or to substances that leach out of the potting compound or membrane. Hypersensitivity reaction during hemodialysis has been reported to be very severe or even fatal. Personnel delivering direct patient care should be aware of the symptoms and react quickly with proper treatment. Patients suspected to have this reaction should be changed to a dialyzer without a cuprophan membrane.

Severe reactions to Cuprophan capillary dialyzers. Popli, S., Ing, T.S., Daugirdas, J.T., Kheirbek, A.O., Viol, G.W., Vilbar, R.M. and Gandhi, V.C. *Artif Organs,* 6 (3), pp. 312-5 (Aug 1982). Five severe reactions occurred in four maintenance hemodialysis patients 1 to 5 minutes after initiating dialysis with Cuprophan capillary dialyzers. All reactions were life-threatening and one resulted in death. Inadequate rinsing of the dialyzers was probably the cause of the reactions. The severe reactions were managed by immediate discontinuation of dialysis and the institution of supportive treatment. Antianaphylactic measures were also attempted, but their therapeutic effectiveness remains to be determined.

Hemodialysis-associated neutropenia and hypoxemia: the effect of dialyzer membrane materials. Hakim, R.M. and Lowrie, E.G. *Nephron,* 32 (1), pp. 32-9 (1982). The fall in white blood cells (WBC) and arterial oxygen pressure that occurs during hemodialysis was investigated as a function of different dialysis membranes and different sterilization methods. No significant differences were seen in pH, PCO2 or bicarbonate. The results indicate differences in biocompatibility between different membranes. Clinical implications are discussed.

Bacterial contamination of the blood compartment originating from the dialysate in haemodialysers. Kolmos, H.J. *J Hosp Infect*, 5 (1), pp. 70-5 (Mar 1984). Microorganisms originating from the dialysate compartment invaded the blood compartment of 'Rhodial RP6' 2.5 percent of the time. Analysis of the data suggested that the probable access of bacteria to the blood compartment was by way of minor defects in the dialysis membrane. The patients experienced no obvious symptoms or signs of sepsis which could be ascribed to the presence of microorganisms in the blood compartment.

Hypoxemia during hemodialysis: effect of different membranes and dialysate compositions. DeBacker, W.A., Verpooten, G.A., Borgonjon, D.J., VanWaeleghem, J.P., Vermeire, P.A. and DeBroe, M.E. *Contrib Nephrol,* 37, pp. 134-41 (1984).

Dynamic behavior of plasma phosphate in chronic dialysis patients. Sugisaki, H., Onohara, M. and Kunitomo, T. *Trans Am Soc Artif Intern Organs,* 28, pp. 302-7 (1982). (1) Change in the plasma P concentration during intra- and interdialytic phases is notably different from that for BUN, CR and UA. Reduction rate for P depends on its pretreatment concentration. Plasma P is apt to level off or rebound even during a treatment and quickly returns to the pretreatment level after it is terminated. (2) In short-term evaluations, occurrence of P rebound during a treatment does not correlate with factors such as meal, Al gel, dialyzer type, dialyzer membrane and therapeutic mode, but with the pretreatment P concentration. Once it reaches a threshold level inherent to each patient, plasma P seems to rebound. (3) Pretreatment P concentration in each patient seemed to be controlled in a relatively narrow range. (4) While apparent generation rates (G) estimated with a single compartmental kinetic model are stable during intra- and interdialytic phases as to BUN, CR and UA, G for P seems to be significantly enhanced, especially during the latter period of the treatment and immediately after the termination of the treatment.

A clinical study on different cellulosic dialysis membranes. Falkenhagen, D., Bosch, T., Brown, G.S., Schmidt, B., Holtz, M., Baurmeister, U., Gurland, H. and Klinkmann, H. *Nephrol Dial Transplant,* 2 (6), pp. 537-45 (1987). A comparison of dialysis membranes made of modified cellulose (Hemophan) with classical regenerated cellulose (Cuprophan). The efficacy of the modified cellulosic membrane with respect to urea and creatinine clearance was shown to be comparable to that of regenerated cellulose and cellulose acetate. However, modified cellulose showed an increased clearance for inorganic phosphate, significantly different from that demonstrated by both regenerated cellulose and cellulose acetate. Demonstrated that in comparison to regenerated cellulose, modified cellulose resulted in significantly less complement activation and WBC reduction, and appears to be due to the substitution of hydroxyl groups of regenerated cellulose.

Compartmental distribution of complement activation products in artificial kidneys. Cheung, A.K., Chenoweth, D.E., Otsuka, D. and Henderson, L.W. *Kidney Int,* 30 (1), pp. 74-80 (Jul 1986). Hemodialysis membranes may differ with regard to their complement-activating potential as well as their ability to remove circulating anaphyla-toxins from the blood path. Clinical measurements of anaphylatoxin production during hemodialysis reflect these dynamic events.

Direct calculation of KT/V. A simplified approach to monitoring of hemodialysis. Barth, RH. *Nephron,* 50 (3), pp. 191-5 (1988). A simple formula for calculation of KT/V from pre-, post- and mid-dialysis blood urea nitrogen is presented. An evaluation by measurement of total dialysate urea revealed that urea ki-

netic modeling consistently overestimated V and K, and that KT/V derived from the simple formula more precisely estimated true KT/V.

A study on hemodialysis leukopenia using various dialyzers. Shin, J., Matsuo, M., Shinko, S., Fujita, Y., Inoue, S., Sakai, R. and Nishioka, M. *J Dial,* 4 (1), pp. 51-62 (1980). Hemodialysis leukopenia was studied using various dialyzers and membranes. The authors found that dialyzers with cellulosic membranes caused marked leukopenia, but in recently developed non-cellulosic membranes, its occurrence was significantly less. Additionally, the results showed a newly developed cellulose acetate membrane to correlate well with the non-cellulose membranes regarding leukopenia, in spite of it being a derivative of cellulose.

Absence of bacteremia and endotoxemia despite contaminated dialyzate. Bernick, J.J. and Port, F.K. *Clin Nephrol,* 14 (1), pp. 13-7 (Jul 1980). Fevers associated with hemodialysis have been attributed to the transfer of relatively large endotoxin molecules and/or bacteria from contaminated dialyzate across the dialyzing membrane. In this study, due to a malfunction, dialysis fluids contained bacteria and endotoxin at levels previously reported to be associated with pyrogenic reactions. Neither endotoxin nor bacteria was detected; venous and arterial blood specimens were collected at the termination of hemodialysis. Temperature elevations did not occur. In an extended study, 20 dialyzers were collected after single patient use and the dialyzate compartment was filled with highly contaminated dialyzate, while the blood compartment was filled with sterile pyrogen-free saline. Following 5 to 7 days incubation, bacteria were present in the blood compartments of 4 of 20 dialyzers, probably due to contamination during dialyzer handling. However, the much smaller endotoxin molecule could not be detected in the absence of bacterial contamination. These results indicate that the intact cellophane membrane is an effective barrier to endotoxin and bacteria under clinical conditions.

Comparison of solute permeability and rejection characteristics of normal and flux cellulose haemodialysis membranes. Klein, E., Holland, F.F. and Eberle, K. *Proc Eur Dial Transplant Assoc,* 16, pp. 198-204 (1979). Permeability and rejection properties of new, high flux cellulose membranes and fibres have been compared with Cuprophan. The greater solute and water flux is explained in terms of larger "pores," which permit greater transport of large molecules.

Bacterial and endotoxin permeability of hemodialysis membranes. Bernick, J.J., Port, F.K., Favero, M.S. and Brown, D.G. *Kidney Int,* 16 (4), pp. 491-6 (Oct 1979). Dialysis fluids containing at least 10(7) bacteria per milliliter and as much as 12,500 ng of endotoxin equivalents per milliliter were dialyzed and ultrafiltered with three types of disposable hemodialyzers. Neither bacteria nor endotoxin, as measured by the Limulus lysate assay, was detected in the sterile compartment despite ultrafiltration. Under these favorable conditions for endotoxin transfer, the maximum transfer rate was calculated to be less than 3.5 ng of endotoxin equivalents per hour. At this rate, it is unlikely that pyrexia during hemodialysis is due to the transfer of endotoxin across an intact dialyzing membrane. Provided that the integrity of the dialyzing membrane is maintained, this investigation indicates that the risk of endotoxemia or bacteremia associated with the use of contaminated dialysis fluids is negligible.

Chapter six: clinical evaluation. Evaluation of hemodialyzers and dialysis membranes. Report of a study group for the Artificial Kidney-Chronic Uremia Program NIAMMDD-1977. Klein, E., Autian, J., Bower, J.D., Buffaloe, G., Centella, L.J., Colton, C.K., Darby, T.D., Farrell, P.C., Holland, F.F., Kennedy, R.S., Lipps, B. Jr, Mason, R., Nolph, K.D., Villarroel, F. and Wathen, R.L. *Artif Organs,* 3 (1), pp. 47-61 (Feb 1979).

Mannitol and maintenance hemodialysis. Swamy, A.P. and Cestero, R.V. *Artif Organs,* 3 (2), pp. 116-9 (May 1979). The extensive use of mannitol during maintenance hemodialysis prompted a study of mannitol kinetics. Despite an apparently adequate clearance rate, mannitol administered during dialysis is incompletely removed. Repeated use of mannitol during dialysis leads to mannitol accumulation. Clinical significance of the residual mannitol levels needs further evaluation.

Characteristics of Available Dialyzers. Shinaberger, J.H., Miller, J.H. and Gardner, P.W. in *Clinical Dialysis.* A.R. Nissenson, R.N. Fine, and D.E. Gentile, [eds]. Appleton-Century-Crofts, Nowalk CT, pp. 53-98 (1984). Methods for characterization of dialyzers and performance characteristics of many dialyzers used.

Issues in Dialysis: Reuse, Dialysate Toxicity, Short Dialysis. Vlchek, D. *Dial & Transplant,* p. 127 (March 1988). A review of an ASN conference on the three title topics. The benefits and limits of each of these highly topical factors in dialysis are discussed.

Staying Tuned into the High-Tech World (Part One). Vlchek, D. *Dialy & Transplant,* p. 305 (Jun 1989). A review of treatment modalities used in the late 1980's with descriptions of each, dialyzers and dialysis membranes, including functional characteristics.

Volumetrically controlled ultrafiltration. Current experiences and future prospects. Roy, T., Ahrenholz, P., Falkenhagen, D. and Klinkmann, H. *Int J Artif Organs,* 5 (3), pp. 131-5 (May 1982). Exact control of ultrafiltration (UF) is a prerequisite for high flux dialysis and hemodiafiltration. Volumetric dialysate balancing is the best current method for the use of dialyzers with high water permeabilities. The precision of UF control by volumetric dialysate balancing is in agreement with all medical requirements. A positive influence of volumetric UF control on patients undergoing chronic hemodialysis can be shown by the frequencies of dialysis side effects. Volumetric UF control is only a first step towards an intelligent UF module to correlate water removal, solute removal and sodium balance.

Dialyzer ultrafiltration coefficients: comparison between in-vitro and in-vivo values. Keshaviah, P.R., Constantini, E.G., Luehmann, D.A., Shapiro, F.L. *Artif Organs,* 6 (1), pp. 23-6 (Feb 1982). This study describes a simple, convenient method for the in-vivo measurement of the ultrafiltration coefficient of hemodialyzers. The method is based on a scheme of isolated ultrafiltration, i.e., ultrafiltration without dialysate flow through the dialyzer. Results with this method indicate that it is more accurate than the conventional bed scale technique. Measurements on three different dialyzers demonstrate that the in-vivo ultrafiltration coefficient is only between 1% and 10% lower than the corresponding in-vitro value. This is in contrast to the rule of thumb used by some manufacturers that in-vivo coefficients are 30% lower than in-vitro values. The deviation of the in-vivo value from the in-vitro one seems to be higher with higher dialyzer ultrafiltration coefficients. Based on these results it is recommended that to estimate ultrafiltration rates in the clinical setting, the in-vitro ultrafiltration coefficient be used, transmembrane pressures being corrected for the colloid osmotic pressure of plasma proteins.

Toxicity of middle molecules: clinical evaluation using a selective filtration artificial kidney. Jorstad, S., Smeby, L.C. and Wideroe, T.E. *Artif Organs,* 4, Suppl, pp. 98-103 (1981). Patients were treated with a dialyzer able to remove molecules between 10,000-40,000 daltons. Returning substances with mol wt 200-10,000 back to the patients was compared with the effect of conventional hemodialysis. The patients treated with this system obtained a more stable hemoglobin concentration without blood transfusions. They also increased mean nerve conduction velocity and their plasma increased in quality as culture medium on human mononuclear phagocytes grown in-vitro.

Hemodialysis hypoxemia: evaluation of mechanisms utilizing sequential ultrafiltration-dialysis. Brautbar, N., Shinaberger, J.H., Miller, J.H. and Nachman, M. *Nephron,* 26 (2), pp. 96-9 (1980). The authors studied the role of blood-dialyzer-membrane interactions in hemodialysis-induced hypoxemia by measuring PaO2 and white blood cell counts during isolated ultrafiltration (UF) compared to hemodialysis (HD, utilizing the same dialyzer and membrane). Patients in the UF period displayed no hypoxemia and rather a slight increase in PaO2; on contrast, these patients displayed significant hypoxemia when HD was imposed. The authors suggest that the hypoxemia characteristic of HD initiation is not solely dependent on blood-dialyzer-membrane interactions, but also requires blood-dialysate interactions.

Evaluation of dialysis adequacy. Gotch, F.A. *Contrib Nephrol,* 69, pp. 101-8; discussion 162-7 (1989). Review (20 refs.).

Preliminary clinical results with sodium-volume modeling of hemodialysis therapy. Gotch, F.A., Lam, M.A., Prowitt, M. and Keen, M. *Proc Clin Dial Transplant Forum,* 10, pp. 12-7 (1980).

Mathematic modeling of dialysis therapy. Sargent, J.A. and Gotch, F.A. *Kidney Int,* Suppl, Suppl 10, pp. S2-10 (Sep 1980).

American National Standard: First Use Hemodialyzers. (ANSI/AAMI RD16—1984). Association for Advancement of Medical Instrumentation; Arlington, VA (1984). This standard is intended to provide minimum requirements to ensure safe and effective performance of hemodialyzer devices that are manufactured ready-to-use.

Is a Clean Dialyzer a Good Dialyzer? A Hypersensitivity Data Collection Proposal. Chenoweth, D.E. and Henderson, L.W. *Contemp Dial* (Mar 1984). Discussion of possible causes of First Use Syndrome, or dialyzer hypersensitivity reactions. Includes a proposal for further study of the phenomenon.

Recommendations to Dialysis Facilities Regarding Dialyzer Hypersensitivity Reactions (letter). Haffner, M.E. Food and Drug Administration (Nov 1983). Recommendations made: strictly follow manufacturer's rinsing procedures; all staff should be informed of those rinsing procedures; any reaction be fully and promptly reported.

Dialysis of the future. Gotch, F.A. *Kidney Int,* Suppl, 24, pp. S100-4 (Mar 1988). The following predictions, scientifically based, are made for dialysis of the 1990's: (1) treatment time will approach two hours; (2) a Kt/V U=1.0 must be provided in two hours; (3) this will require a dialyzer KoA U 750-1250, QB 200-500, and QD 500-750 for individual patients; (4) bicarbonate dialysate will be required; (5) delivery systems with precise UF control will be required; (6) sodium, urea, and possiblly potassium modeling will probably required; (7) high hydraulic permeability membranes and high biocompatibility membranes and pyrogen free dialysate may be required. The article includes background on all of these issues.

A mechanistic analysis of the National Cooperative Dialysis Study (NCDS). Gotch, F.A. and Sargent, J.A. *Kidney Int,* 28 (3), pp. 526-34 (Sep 1985). The purpose of the NCDS was to determine the probability of clinical failure (PF) as a function of the level of dialysis and protein catabolic rate (pcr, g/kg/day). The level of dialysis prescribed in the NCDS was mechanistically defined as Kt/V (product of dialyzer urea clearance and treatment time divided by body urea volume), which exponentially determines decrease in BUN during dialysis and is also a mathematical analogue of pcr, BUN.

Calculation of combined diffusive and convective mass transfer. Sigdell, J.E. *Int J Artif Organs,* 5 (6), pp. 361-72 (Nov 1982). In this study, the permeabilities of the boundary layers on both sides are treated as included in the (equivalent) membrane. In an appendix, the stacking of membranes is studied, giving a general law for the calculation of overall permeabilities of a stack of individual membranes, regarded as one (equivalent) membrane (such as a physical membrane with two boundary layers). Permeability data for boundary layers are quoted from earlier works. In other appendices, the variation of the local ultrafiltration along the dialysis path is studied, as well as its effect on the effective permeability of the membrane.

Clinical Estimates of Treatment Adequacy. Teschan, P.E. *Artif Organs,* 10 (3), pp. 201-4 (1986).

Principles and biophysics of Dialysis. Sargent, J. and Gotch, F. *Replacement of Renal Function by Dialysis,* [ed. Drukker], Marinus Nijhoff, pp. 53-93 (1983).

National Cooperative Dialysis Study. Lowrie, E.G. and Laird, N.M. [eds.]. *Kidney Int,* S-13 (1983).

Effect of the Hemodialysis Prescription on Patient Morbidity (Report from the National Cooperative Dialysis Study). Lowrie, E.F., Laird, N.M., Parker, T.F. and Sargent, J.A. *NEJM,* 305: 20, pp. 1176-81 (1981).

Release of pyrogens during clinical hemodialysis. Weingast, J.A., VanDeKerkhove, K.M., Eiger, S.M., Kluger, M.J. and Port, F.K. *Trans Am Soc Artif Intern Organs,* 31, pp. 359-62 (1985).

Chapter 8
Anticoagulation

Outbreak of pyrogenic reactions at a dialysis center. Association with infusion of heparinized saline solution. Kantor, R.J., Carson, L.A., Graham, D.R., Petersen, N.J. and Favero, M.S. *Am J Med,* 74 (3), pp. 449-56 (Mar 1983). An epidemiologic and laboratory investigation documented that reactions occurred only in patients who had anticoagulation with a dilute solution of heparin. Analyses of heparinized saline solution used during the outbreak revealed a bacterial count of 7.4 X 10(5)/ml and a bacterial endotoxin level of 1,300 ng/ml. Acinetobacter calcoaceticus var. Iwoffi was isolated from the solution. Diluted heparin solution was prepared at the dialysis center by adding commercially supplied sodium heparin to 0.9 percent sodium chloride infusion fluid. Bacteria and endotoxin were not detected in vials of stock heparin and bags of unopened 0.9 percent sodium chloride infusion fluid. The authors conclude that contamination of the solution occurred at the dialysis center. After changes in the preparation and use of heparin were instituted on December 4, 1978, no pyrogenic reactions occurred in more than 400 subsequent dialyses.

Regional citrate anticoagulation: a report of 10 months experience. Boyd, L.M., Felton, S.E., Highfill, B.K. and Underhill, V.L. *J Nephrol Nurs,* 2 (4) pp. 162-4 (Jul-Aug 1985).

Coagulation problems in artificial organs. Flamenbaum, W. *ASAIO Trans* (United States), 32 (2), pp. 656-61 (Oct-Dec 1986).

Comparative clinical trial of regional anticoagulation for hemodialysis. Akizawa, T., Kitaoka, T., Sato, M., Koshikawa, S., Hirasawa, Y., Kazama, M., Mimura, N. and Ota, K. *ASAIO Trans* (United States), 34 (3), pp. 176-8 (Jul-Sep 1988). The regional anticoagulating effects of FUT-175 (protease inhibitor), and regional or low dose heparinization (RH or LH) were examined comparatively by randomized controlled protocol on 157 hemodialysis (HD) patients with hemorrhagic complications. Increases in bleeding because of HD were milder in FUT as compared with RH and LH, and the bleeding time after needle removal was significantly shorter in FUT than that in heparin. During HD, the prolongation of celite-activated coagulation time (CCT) of the intracorporeal blood was significantly milder in FUT in heparin than that of blood passing through the dialyzer, increased in FUT compared with LH. FUT showed no prolongation of CCT after HD.

Hemodialysis without anticoagulation. One-year prospective trial in hospitalized patients at risk for bleeding. Schwab, S.J., Onorato, J.J., Sharar, L.R. and Dennis, P.A. *Am J Med,* 83 (3), pp. 405-10 (Sep 1987). This prospective study evaluated a protocol for hemodialysis without anticoagulation in a diverse group of hospitalized patients in unstable condition with relative contraindications to anticoagulation. Of 262 attempts at hemodialysis without anticoagulation in 49 patients, 239 hemodialysis treatments (91 percent) were successfully completed. This study concludes that hemodialysis without anticoagulation can be reliable and effective in closely monitored situations.

Heparin free dialysis: comparative data and results in high risk patients. Caruana, R.J., Raja, R.M., Bush, J.V., Kramer, M.S. and Goldstein, S.J. *Kidney Int,* 31 (6), pp. 1351-5 (Jun 1987). Heparin-free hemodialysis was compared to systemic heparinization, intermittent saline flushes and constant saline infusions in eight, stable chronic patients dialyzing on hollow-fiber artificial kidneys (HFAK) at blood flows of 250 to 300 ml/min. Since the data showed that heparin-free hemodialysis without supplemental saline was feasible in this patient group of stable, chronic patients, 29 judged to be at increased risk of hemorrhage from heparinization were then prospectively studied. Although higher hematocrit values were associated with greater degrees of dialyser clotting, stepwise discriminatory analysis employing blood flow, blood pressure, hematocrit and transfusion administration could not develop an accurate predictor or combination of predictors of clotting. No patient experienced de novo or increased bleeding and problems with inadequate dialysis were not observed.

Pharmacokinetic monitoring of heparin therapy for regular hemodialysis. Khazine, F. and Simons, O. *Artif Organs*, 9 (1) pp. 59-61 (Feb 1985). The paper describes the use of a pharmacokinetic model for heparin prescription during hemodialysis leads to a precise monitoring of the coagulation time (CT) with 25% less heparin required. Two different populations were distinguished: the first group maintained stable sensitivity and elimination constant, permitting stable prescription and giving stable CT values for up to 2 years. The other group exhibited wide variations of these parameters, necessitating daily dose monitoring.

The effect of in-vitro use of heparin in blood transfusions during dialysis on dialyzer clotting. Lowrey, S.J., Femea, P.L. *AANNT J*, 11 (2) pp. 26-9 (Apr 1984).

Dialysis membranes and coagulation system. Notohamiprodjo, M., Andrassy, K., Bommer, J. and Ritz, E. *Blood Purif*, 4 (1-3), pp. 130-41 (1986). Artificial membranes used for hemodialysis differ from endogenous membranes, i.e. endothelial cells, by their variable thrombogenicity. The key step in activation of the coagulation system by dialysis membranes is thrombocyte activation which is preceded by formation of a protein layer of critical thickness. Crucial questions concerning the quality of this protein membrane as a determinant of thrombocyte activation are not well understood.

Heparin and its biocompatibility. Stiekema, J.C. *Clin Nephrol*, 26, Suppl 1, pp. S3-8 (1986). Recently heparin fractions and a heparinoid of low molecular weight (LMW) have been developed because of their potential to diminish the hazard of hemorrhage while retaining their antithrombotic properties. Preliminary reports from pilot studies have confirmed the increased efficacy in preventing deep vein thrombosis (DVT) of some of the new LMW heparin(oid)s; however, improved safety with regard to bleeding still needs to be shown. The use of LMW heparins and of a new LMW heparinoid in acute and chronic hemodialysis has also been shown to be effective.

Prostacyclin and heparin during haemodialysis: comparative effects. Camici, M. and Evangelisti, L. *Life Support Syst*, 4 (3), pp. 205-9 (Jul-Sep 1986). Haemodialysis neutropenia was improved by prostacyclin. The membrane sieving coefficient factor and ultrafiltration volume were not improved by prostacyclin alone (dialysis II). Prostacyclin, together with heparin (dialysis III), showed, 60 minutes after the start, an unchanged sieving coefficient factor compared with that of heparin alone, while the ultrafiltration volume significantly (P less than 0.001) improved. The results of this study confirm those of earlier studies and suggest that prostaglandin I2 together with low-dose heparin improve the biocompatibility and efficiency of dialysis treatment.

Regional anticoagulation: hemodialysis with hypertonic trisodium citrate. vonBrecht, J.H., Flanigan, M.J., Freeman, R.M. and Lim, V.S. *Am J Kidney Dis*, 8 (3), pp. 196-201 (Sep 1986). Describes a simplified method for performing regional citrate anticoagulation during hemodialysis. This method of citrate dialysis is safe and effective during continuous blood flow (double-needle) hemodialysis, and is no more difficult to perform than conventional heparin dialysis. Single-needle (reciprocating blood flow) hemodialysis was successfully performed by the additional use of a calcium-free dialysate and separate calcium chloride infusion (10% calcium chloride), but risks the production of unexpected hypercalcemia.

Heparin-free hemodialysis with Cuprophan hollow fiber dialyzers by a frequent saline flush, high blood flow technique. Agresti, J., Conroy, J.D., Olshan, A., Conroy, J.F., Schwartz, A., Brodsky, I., Krevolin, L. and Chinitz, J. *Trans Am Soc Artif Intern Organs*, 1985, 31 pp. 590-4.

Clinical use of heparin fractions, fragments, and heparinoids. Messmore, H.L. Jr. *Semin Thromb Hemost*, 11 (2), pp. 208-12 (Apr 1985). Document Type: Review (37 refs.).

Hemodialysis without anticoagulation. Sanders, P.W., Taylor, H. and Curtis, J.J. *Am J Kidney Dis*, 5 (1), pp. 32-5 (Jan 1985). In patients at high risk of bleeding, however, use of heparin significantly increases their morbidity and, presumably, mortality. Over one year, the authors performed 156 hemodialysis procedures successfully without heparin in the transplant dialysis unit. No dialysis procedure produced or aggravated bleeding. Conversely, a coagulopathy was not induced or worsened by dialysis without heparin. A significant complication, defined as complete clotting of the artificial kidney with or without clotting in the lines occurred in eight dialyses (5.13% of the total) and resulted in an average blood loss of 150 ml. Partial clotting of the dialyzer did not interrupt the procedure and occurred nine times (5.8% of the total). These results compare favorably with previously documented complications from low-dose and regional heparin.

Hemodialysis without anticoagulants: efficiency and hemostatic aspects. Casati, S., Moia, M., Graziani, G., Cantaluppi, A., Citterio, A., Mannucci, P.M., and Ponticelli, *C. Clin Nephrol*, 21 (2), pp. 102-5 (Feb 1984). In 29 patients with high risk of bleeding, 111 hemodialyses have been performed without heparin (WHD) or other anticoagulants. The same patients were switched to low dose heparin dialysis (LDHD) as soon as the bleeding risk had ceased. The dialyzer had to be changed in 11 and the drip chamber in 20 WHDs because of partial clotting. This phenomenon did not occur during LDHD.

Regional citrate anticoagulation in chronic hemodialysis patients. Seaton, R.D., Duncan, K.A., Pinnick, R.V., Diederich, D.A. and Wiegmann, T.B. *Trans Am Soc Artif Intern Organs*, 29, pp. 414-8 (1983). The pronounced leukopenia caused by cuprophane dialyzer membranes was significantly blunted by citrate regional anticoagulation. Cellulose acetate produced less leukopenia than the cuprophane, regardless of anticoagulant. The pO2 response to the initiation of hemodialysis was not affected by dialyzer membrane or anticoagulant choice. The authors conclude that citrate anticoagulation reduces dialyzer-induced leukopenia. Citrate anticoagulation does not, however, change the hypoxemia present with acetate dialysis. The dissociation of leukopenia and hypoxemia with citrate anticoagulation suggests that pulmonary sequestration is not a major cause of hypoxemia during hemodialysis.

Heparin binding and release properties of DEAE cellulose membranes. Schmitt, E., Holtz, M., Klinkmann, H., Esther, G. and Courtney, J.M. *Biomaterials*, 4 (4), pp. 309-13 (Oct 1983). Heparin release was studied by contacting heparinized membranes with saline, glycine buffer, phosphate buffer and plasma. Incubation with plasma brought about the release of 50% of the attached heparin. Crosslinking of the heparinized membrane with glutaraldehyde reduced the heparin release by one half. The release reaction is more critical in the case of increased heparin uptake and a more efficient immobilization of heparin appears necessary.

Regional citrate anticoagulation for hemodialysis in the patient at high risk for bleeding. Pinnick, R.V., Wiegmann, T.B. and Diederich, D.A. *N Engl J Med*, 308 (5), pp. 258-61 (Feb 3, 1983).

Effect of heparin on platelet count and platelet aggregation. Shojania, A.M. and Turnbull, G. *Am J Hematol*, 26 (3), pp. 255-62 (Nov 1987). The authors speculate that the majority of subjects exposed to heparin develop an antibody or a proaggregator that can aggregate or agglutinate platelets in the presence of heparin and cause destruction of platelets, but only in a small percentage of subjects receiving heparin is this reaction severe enough to cause thrombocytopenia.

Citrate regional anticoagulation in haemodialysis. Hocken, A.G. and Hurst, P.L. *Nephron*, 46 (1), pp. 7-10 (1987). Using synchronous pre- and post-dialyser blood samples, measurement of the whole blood clotting times demonstrated the restriction of anticoagulation to the extracorporeal circulation. It is concluded that citrate anticoagulation is safe, acceptable and simple for use in haemodialysis for patients at risk from systemic anticoagulation.

Long-term comparisons of citrate and heparin as anticoagulants for hemodialysis. Wiegmann, T.B., MacDougall, M.L. and Diederich, D.A. *Am J Kidney Dis*, 9 (5), pp. 430-5 (May 1987). Citrate was compared to heparin as an anticoagulant during chronic hemodialysis. Use of citrate as the sole anticoagulant for periods of two months was easily accomplished, free of complications, and resulted in comparable clearance of solutes. Major laboratory parameters were similar with both anticoagulants.

Severe metabolic alkalosis complicating regional citrate hemodialysis. Kelleher, S.P. and Schulman, G. *Am J Kidney Dis*, 9 (3), pp. 235-6 (Mar 1987). Regional citrate hemodialysis has been effectively used as an alternative to heparin anticoagulation during dialysis of patients at increased risk for bleeding. This paper reports the occurrence of severe metabolic alkalosis in two patients requiring high infusion rates of citrate during hemodialysis while being mechanically ventilated. Careful monitoring of acid-base status is mandatory in this setting, and reduction of citrate dose may be advisable.

Reducing the hemorrhagic complications of hemodialysis: a controlled comparison of low-dose heparin and citrate anticoagulation. Flanigan, M.J., VonBrecht, J., Freeman, R.M. and Lim, V.S. *Am J Kidney Dis*, 9 (2), pp. 147-53 (Feb 1987). Dialysis-associated bleeding was more frequent following low-dose controlled heparin anticoagulation than during hypertonic citrate therapy. Dialysis effectiveness measured by postdialysis chemistries and weight loss was equivalent in the two groups.

Regional citrate anticoagulation: a report of 10 month's experience. Boyd, L.M., Felton, S.E., Highfill, B.K. and Underhill, V.L. *J Nephrol Nurs*, 2 (4), pp. 162-4 (Jul-Aug 1985).

Studies of coagulation and platelet functions in heparin-free hemodialysis. Ivanovich, P., Xu, C.G., Kwaan, H.C.. and Hathiwala, S. *Nephron*, 33 (2), pp. 116-20 (1983). Using a cellulose acetate dialyzer, both hemodialyzer and blood tubing were periodically flushed with physiologic saline, but no heparin was used. No significant clotting of the hemodialyzers was encountered in uneventful dialyses. These findings support clinical experience that this anticoagulation-free method can be used safely and effectively to dialyze patients at risk for bleeding.

Preventing hemorrhage in high-risk hemodialysis: regional versus low-dose heparin. Swartz, R.D. and Port, F.K. *Kidney Int*, 16 (4), pp. 513-8 (Oct 1979). Hemodialysis in patients with increased risk for hemorrhage can be accomplished with either a regional or a low total dose of heparin. The incidence of hemorrhage correlated with the estimated degree of bleeding risk both at expected and at occult bleeding sites, and was the same or higher with regional heparin in all categories. Hemorrhage was not correlated with preexisting coagulation abnormalities, concurrent anticoagulant drugs, level of azotemia, or ability to successfully limit systemic heparinization during dialysis. The incidence of partial clotting of the dialyzer was 3% to 5% with both heparin protocols. The authors conclude that regional heparinization has no clinical or practical advantage over low-total-dose heparin in preventing bleeding associated with hemodialysis.

Low-dose heparin in routine hemodialysis monitored by activated partial thromboplastin time. Shapiro, W.B., Faubert, P.F., Porush, J.G. and Chou, S.Y. *Artif Organs*, 3 (1), pp. 73-7 (Feb 1979). Use of the activated partial thromboplastin time (APTT), as measured by (Coag-A-Mate) semi-automatic unit, in lowering the dosage of heparin in stable chronic hemodialysis patients was analyzed. APTT, as measured by the Coag-A-Mate unit, provides a simple means of lowering heparin requirements in routine dialysis patients.

The effects of three different heparin regimes on heparin concentrations in plasma and fibrin formation in dialyzers. Gunnarsson, B., Asaba, H., Dawidson, S., Wilhelmsson, S. and Bergstrom, J. *Clin Nephrol*, 15 (3), pp. 135-42 (Mar 1981). Anticoagulation effects were studied during a 4-hour hemodialysis in six patients using 3 different heparin regimens: (1) intravenous loading dose only; (2) priming of the dialyzer and continuous infusion of heparin for two hours; and (3) intravenous loading dose and continuous infusion of heparin based on anticoagulation kinetics. The anticoagulation kinetic regimen offered no advantage over the single loading dose regimen with regard to the formation and deposition of fibrin in the dialyzers.

Measurement of fibrinopeptide A in the evaluation of heparin activity and fibrin formation during hemodialysis. Wilhelmsson, S., Asaba, H., Gunnarsson, B., Kudryk, B., Robinson, D. and Bergstrom, J. *Clin Nephrol*, 15 (5), pp. 252-8 (May 1981). In order to monitor heparin activity during hemodialysis, they evaluated three commonly used methods: whole blood activated coagulation time (WBACT), whole blood thrombin time (WBTT), and heparin concentration in plasma, determined with a chromogenic substrate. They three different heparin regimens: a single intravenous loading dose only, priming of the dialyzer with heparin followed by a heparin infusion and a pharmaco-kinetic model. Good correlations were found between WBACT, WBTT and heparin concentration. Heparin activity during a dialysis may be monitored with any of these three methods with equal reliability. However, from a practical point of view, WBACT appears most attractive because of its simplicity. FPA generation, frequency of visible clots in the dialyzer and hemorrhagic manifestations were essentially the same for each of the heparin dose regimens. The simple administration of a single loading dose was as safe as the more complicated infusion technique.

Hemodialysis using prostacyclin instead of heparin as the sole antithrombotic agent. Zusman, R.M., Rubin, R.H., Cato, A.E., Cocchetto, D.M., Crow, J.W. and Tolkoff-Rubin, N. *N Engl J Med*, 304 (16), pp. 934-9 (Apr 16, 1981). Anticoagulation during hemodialysis is necessary to prevent clotting of the blood on contact with the dialysis membrane. Heparin is the usual anticoagulant used, but systemic anticoagulation may persist for hours, and hemorrhage is common. The authors successfully used an infusion of prostacyclin, which has an in-vitro half-life of three to five minutes, as the sole anticoagulant on long-term hemodialysis. Prostacyclin caused no clinically important changes in the intrinsic clotting system, and there were no hemorrhages or clotting of the coil. The authors conclude that prostacyclin can safely replace heparin as the sole antithrombotic agent during hemodialysis and may be more advantageous if anticoagulation is contraindicated.

Regional Citrate Anticoagulation: A Viable Alternative? Boyd, L.M. and Felton, S.E. *ANNA J,* 13, 5, p. 267 (Oct 1986). Regional citrate anticoagulation is a positive alternative to conventional methods of anticoagulation during hemodialysis. For the patient at moderate to high risk of bleeding, as well as those patients with active bleeding at the time of dialysis, regional citrate anticoagulation can be a safe, effective approach, when performed properly. One of the major disadvantages, excessive cost, can be reduced to an acceptable level.

Chapter 9

Vascular Access Devices

Cannulation of arteriovenous fistulae. Stansfield, G. *Nurs Times*, 83 (4), pp. 38-9 (Jan 28-Feb 3 1987). Discussion of gaining and maintaining access to the A-V fistula for hemodialysis in order to obain maximum effects while creating the minimum of trauma to the fistula. The paper notes that there is a lack of research on this subject, but that there is strong evidence that good needling technique contributes to fitula survival. Evidence suggests that constant site insersion in an antegrade direction should be the method of choice. Needles and tubing sets should be chosen carefully (side holes are important, and internal diameter and length are important in minimizing pressure drop).

The fluid mechanics of hemodialysis catheters. Mahurkar, S.D. *Trans Am Soc Artif Intern Organs*, 31, pp. 124-30 (1985). Use of two individual catheters is the most efficient, but two procedures are required for treatment. Comparing Co-axial dual lumen catheters to two semi-circular dual lumen catheters, the latter is preferable due to ease of insertion, better efficiency, less trauma, and fewer complications.

Renal nursing. Vascular access techniques. Mackenzie, S. *Nurs Mirror*, 160 (15), pp. 27-9 (Apr 10, 1985). This article reviews the nursing techniques involved with subclavian catheters, femoral catheters, and the Scribner shunt. Requirements for care and complications of each are listed. Excellent tables listing the above in this article.

Evaluation tool for hemodialysis arterial-venous fistula needle. Parker, J. *Nephrol Nurse*, 5 (3), p. 9 (May-Jun 1983). This is a one-page format for evaluation of A-V fistula needles. It gives some reliable and consistent guidelines for evaluation of the needle most appropriate for the patient's needs.

Hemodialysis access site morbidity. Aman, L.C., Levin, N.W. and Smith, D.W. *Proc Clin Dial Transplant Forum*, 10, pp. 277-84 (1980).

Developing a teaching unit on vascular access of a hemodialysis client. Sell, D., Greenspan, B. and Hess, M. *AANNT J*, 9 (3), pp. 10-25, 66 (Jun 1982).

Renal replacement therapy. 2—1. Access for haemodialysis. Pavitt, L. *Nurs Times*, 78 (18), pp. 749-52 (May 5-11, 1982). Very basic article on different varieties of vascular access devices and long-term management of them. Short discussion on complications. Includes shunts, A-V fistula, subclavian.

Non-invasive blood flow measurement in expanded polytetrafluoroethylene grafts for hemodialysis access. Rittgers, S.E., Garcia-Valdez, C., McCormick, J.T. and Posner, M.P. *J Vasc Surg*, 3 (4), pp. 635-42 (Apr 1986). Volume flow rates were measured in 31 expanded polytetrafluoroethylene grafts (6 mm) of 26 patients undergoing hemodialysis. Flow was calculated from the known access graft diameter and by measurement of the mean Doppler shift frequency waveform. The study demonstrated a safe, repeatable noninvasive measure of access graft hemodynamics, which may be useful as a functional monitor and a warning of impending failure.

Dialysis performance of single lumen subclavian hemodialysis: a comparative study with single lumen fistula hemodialysis. Vanholder, R., Hoenich, N. and Ringoir, S. *Artif Organs*, 6 (4), pp. 429-32 (Nov 1982). Study of hemodialysis performance and recirculation ratios of subclavian catheter hemodialysis is reported. Data are compared to the results obtained when a conventional intrafistular single-lumen hemodialysis needle is used under similar conditions. However, the differences were not significant, and overall extraction ratios, calculated for the entire dialysis period with both access methods in 43 patients, were identical. Recirculation averaged 12.5% for the fistular approach and 20% for the subclavian approach. It is concluded that, as a whole, dialysis performance is somewhat lower with the subclavian vascular access method.

Percutaneous subclavian vein catheterization for hemodialysis: a report of 57 insertions. Al-Mohaya, S., Sadat-Ali, M., Al-Muhanna, F. and Ibrahim-Saeed, A. *Angiology*, 40 (6), pp. 569-73 (Jun 1989). The authors report an analysis of 57 subclavian vein catheterizations for hemodialysis. A total of 51

patients (34 men, 17 women) kept the Cobe single- and double-lumen catheters for 1,726 days. Their experience indicates that percutaneous subclavian vein catheterization is safe and provides quick access for hemodialysis with no morbidity and mortality if done correctly, patiently, and meticulously. The authors believe that this should be the first choice in patients with reversible renal failure and in patients with chronic renal failure, who are usually elderly and medically compromised, until a permanent vascular access is ready for use.

Clinical experience of arteriovenous fistulae for dialysis during an eighteen year period. Sisto, T. and Riekkinen, H. *Ann Chir Gynaecol*, 77 (3), pp. 108-10 (1988). 382 Brescia-Cimino type arteriovenous fistulae were created for chronic haemodialysis. Success rate at the first attempt was 73.6% of 281 cases. The most common method of anastomosis was end to side vein to artery type. Thrombosis was the most frequent complication, other miscellaneous complications were less common.

Complications from permanent hemodialysis vascular access. Zibari, G.B., Rohr, M.S., Landreneau, M.D., Bridges, R.M., DeVault, G.A., Petty, F.H., Costley, K.J., Brown, S.T. and McDonald, J.C. *Surgery*, 104 (4), pp. 681-6 (Oct 1988). Use of PTFE to construct permanent hemodialysis vascular access has a significantly higher incidence of thrombosis, infection, pseudoaneurysm formation, and limb loss (p less than 0.01 for all complications) and a significantly lower mean length of patency (p less than 0.0001) when compared with autogenous fistulas. Age, sex, hypertension, diabetes mellitus, and the use of perioperative antibiotics were not found to be related significantly to access complications.

An evaluation of expanded polytetrafluoroethylene (PTFE) loop grafts in the thigh as vascular access for haemodialysis in patients with access problems. Slater, N.D. and Raftery, A.T. *Ann R Coll Surg Engl*, 70 (4), pp. 243-5 (Jul 1988). A total of 21 patients with vascular access problems received 22 PTFE loop grafts in the thigh as vascular access for haemodialysis. Eighteen of 22 grafts supported haemodialysis during the patient's lifetime. Actuarial patient survival was 50% at two years with a cumulative graft patency in the survivors of 80.5%.

Complications related to subclavian catheters for hemodialysis. Report and review. Vanherweghem, J.L., Cabolet, P., Dhaene, M., Goldman, M., Stolear, J.C., Sabot, J.P., Waterlot, Y. and Marchal, M. *Am J Nephrol*, 6 (5), pp. 339-45 (1986). Personal experience with subclavian vein cannulations for hemodialysis are given, and the pertinent literature on the subject is reviewed. Taking into account all the complications discussed, recommendations are made for the use of subclavian dialysis catheters.

Subclavian vein thrombosis: a frequent complication of subclavian vein cannulation for hemodialysis. Vanherweghem, J.L., Yassine, T., Goldman, M., Vandenbosch, G., Delcour, C., Struyven, J. and Kinnaert, P. *Clin Nephrol*, 26 (5), pp. 235-8 (Nov 1986). Subclavian vein cannulation was suggested as a temporary vascular access for hemodialysis since one of its advantages was considered to be no damage to blood vessels. As they observed six patients with symptomatic subclavian vein thrombosis among 148 patients having received subclavian vein cannulation for hemodialysis, they systematically performed subclavian venogram in 42 asymptomatic patients selected on the basis of a history of previous subclavian vein cannulation. The authors conclude that the subclavian vein cannulation leads to significant damages of the vessels, excluding a whole arm, for future vascular access in some patients.

High incidence of subclavian dialysis catheter-related bacteremias. Pezzarossi, H.E., Ponce deLeon, S., Calva, J.J., Lazo, de la Vega, S.A. and Ruiz-Palacios, G.M. *Infect Control*, 7 (12), pp. 596-9 (Dec 1986). This retrospective cohort study reviews the incidence of bacteremia in 48 patients undergoing hemodialysis using subclavian vein dialysis catheters (SDC) as temporary vascular access. They found that the use of resterilized catheters was not a risk factor. Specific guidelines for SDC insertion and care were established and followed, after which the infection frequency was reduced to 7.5% (1 episode per 45.5 patient-weeks of catheter use) in this high-risk population.

Graft infection and bacteremia with a tolerant L-form of Streptococcus sanguis in a patient receiving hemodialysis. Chmel H. *J Clin Microbiol*, 24 (2), pp. 294-5 (Aug 1986). Report of a case of a tolerant L-form Streptococcus sanguis infection involving an artificial vascular access site. The organism was isolated from a pet dog of the patient. The organism was also felt to be tolerant to penicillin. The patient was successfully treated by removal of the artificial graft and intravenous erythromycin therapy. Microorganisms acquired from nonhuman sources are potential pathogens in the immunocompromised patient.

Internal jugular vein cannulation using 2 silastic catheters. A new, simple and safe long-term vascular access for extracorporeal treatment. Canaud, B., Beraud, J.J., Joyeux, H. and Mion C. *Nephron*, 43 (2), pp. 133-8 (1986). Subclavian vein cannulation, although a major progress in temporary vascular access, was associated with a significant morbidity and mortality. For the last two years, the authors developed a new approach consisting in internal jugular vein cannulation (IJVC) with two silicone rubber catheters with a long-term proved biocompatibility.

Infections associated with subclavian dialysis catheters: the key role of nurse training. Vanherweghem, J.L., Dhaene, M., Goldman, M., Stolear, J.C., Sabot, J.P., Waterlot, Y., Serruys, E. and Thayse, C. *Nephron*, 42 (2), pp. 116-9 (1986). The incidence was greater in hospitalized patients (15 bacteremias during 1,948 catheter days) than in ambulatory patients (2 bacteremias during 850 catheters-days) as well as during a period corresponding to a greater number of untrained nurses enrolled in the dialysis team. During this period, 6 sepsies occurred in 19 catheters (other periods: 7 sepsies/116 catheters, p less than 0.01). Six of 28 nurses had less than three months of professional experience (other periods: 1 of 25, p less than 0.01). These data underline the key role of nurse training in the prevention of catheter-related infections.

Staphylococcus aureus bacteremia in patients on chronic hemodialysis. Quarles, L.D., Rutsky, E.A and Rostand, S.G. *Am J Kidney Dis*, 6 (6), pp. 412-9 (Dec 1985). Staphylococcus aureus bacteremia occurred 96 times in 58 of 671 patients on chronic hemodialysis during a nine-year period. The authors suggest that chronic hemodialysis patients with S aureus bacteremia have a relatively low mortality and a low risk of infective endocarditis. Antibiotic treatment should be given for at least 28 days in order to minimize the risk of relapse.

Vascular access for hemodialysis. Patency rates and results of revision. Palder, S.B., Kirkman, R.L., Whittemore, A.D., Hakim, R.M., Lazarus, J.M. and Tilney, N.L. *Ann Surg*, 202 (2), pp. 235-9 (Aug 1985). Failures of Cimino fistulae usually occurred early in the postoperative period, secondary to attempts to use inadequate veins. Thrombosis caused the majority of PTFE graft failures and was generally the result of venous stenosis. Correction of such venous stenosis is mandatory to restore graft patency and can result in prolonged graft survival.

Incidence of subclavian dialysis catheter-related infections. Kozeny, G.A., Venezio, F.R., Bansal, V.K., Vertuno, L.L. and Hano, J.E. *Arch Intern Med*, 144 (9), pp. 1787-9 (Sep 1984). Report of more than 1,300 dialyses in 74 patients who have had subclavian dialysis catheters (SDCs) in place for a total of 3,065 days. Sixty-one of these patients (82%) have had their SDCs in place for 7 to 21 days, including 37 (50%) for longer than 21 days.

Complications of subclavian catheter hemodialysis: a 5-year prospective study in 257 consecutive patients. Vanholder, R., Lameire, N., Verbanck, J., vanRattinghe, R., Kunnen, M. and Ringoir, S. *Int J Artif Organs*, 5 (5), pp. 297-303 (Sep 1982). The complications related to the use of subclavian catheters for hemodialysis were prospectively studied in 257 consecutive acute and chronic renal failure patients. Using 394 catheters, 3006 single needle dialyses were performed. Most hazardous complications were sepsis (9), malposition (6), hemothorax (3), bleeding (2), vena cava thrombosis (2), and pneumothorax (2).

Single-needle venous dialysis: a comparison of three systems. Weinstein, A.M., Frederick, P.M. and Sullivan, J.F. *Uremia Invest 85*, 8 (2), pp. 69-77 (1984). A comparison of a pressure/time, a time/time device, and a pressure/pressure device. Recirculation was highest with the pressure/time system, but was easily compensated for with higher blood flow of that system. Clearances actually measured were in good agreement with those predicted from theoretical considerations of recirculation and blood flow in a countercurrent dialysis system.

High-flux hemodiafiltration: under six hours/week treatment. vonAlbertini, B., Miller, J.H., Gardner, P.W. and Shinaberger, J.H. *Trans Am Soc Artif Intern Organs* 1984, 30 pp. 227-31. Better utilization of existing high blood flow in mature vascular accesses with the described new technique of simultaneous high diffusion and convection results in a marked increase of treatment efficiency. Coupled with the better tolerance to high solute and weight removal rates, this approach permits drastic reduction of treatment time over conventional hemodialysis without sacrificing treatment adequacy.

Blood recirculation during hemodialysis with a coaxial counterflow single-needle blood access catheter. Ogden, D.A. and Cohen, I.M. *Trans Am Soc Artif Intern Organs*, 25, pp. 325-7 (1979). (1) The average

and the range of blood recirculation during hemodialysis employing a coaxial counterflow single needle blood access catheter are markedly reduced compared to those observed in the same patients using a standard "Y" type needle and external flow direction control device. (2) In a large group of patients, the average measured recirculation of blood of .8% at a blood flow rate of 200 ml/min is sufficiently small as to have little or no effect on the efficiency of dialysis. (3) Recirculation increases with increasing extracorporeal blood flow rate but remains sufficiently low to not significantly affect increased dialysis efficiency obtained at higher blood flow rates. (4) The coaxial counterflow single needle catheter permits single fistula puncture, eliminates the need for a flow direction control device, and is associated with negligible blood recirculation.

In-vivo measurement of blood recirculation during "Y" type single needle dialysis. Ogden, D.A. *J Dial*, 3 (2-3), pp. 265-76 (1979). A method has been described and validated for obtaining a sample of blood, without separate venapuncture, which has the same urea and creatinine composition as systemic venous blood during hemodialysis. Using this technique, recirculation in-vivo during "Y" type single needle dialysis, measured in 20 bovine fistulas, ranged from 6.9% to 56.5% and averaged 19.4%. These results suggest that fistula puncture methods and devices that eliminate recirculation in the ex-vivo blood circuit should be used to maximize dialysis efficiency.

Topical thrombin and control of bleeding from the fistula puncture sites in dialyzed patients. Vaziri, N.D. *Nephron*, 24 (5), pp. 254-6 (1979). The length of bleeding from the puncture sites of internal arteriovenous channels was markedly reduced with the use of topical thrombin in 12 patients treated with hemodialysis. This procedure can, therefore, save patient and staff time, minimize recurrent blood loss with each dialysis, and prolong the life of vascular access by diminishing the length of potentially hazardous compression needed for proper hemostasis.

A review of Hemodialysis Catheters and Access Devices. Hickman, R.O. and Watkin, S. *Dial & Transplant*, p. 481 (Sep 1987). A brief description of the access devices, other than the A-V fistula, often used in hemodialysis vascular access. Article includes a table that lists devices from 10 different manufacturers by product, catheter, material, size maximum flows, priming volume, and other information.

Successful use of double-lumen, silicone rubber catheters for permanent hemodialysis access. Shusterman, N.H., Kloss, K. and Mullen, J.L. *Kidney Int*, 35 (3), pp. 887-90 (Mar 1989), ISSN 0085-2538.

Topical anaesthesia for fistula cannulation in haemodialysis patients. Watson, A.R., Szymkiw, P. and Morgan, A.G. *Nephrol Dial Transplant*, 3 (6), pp. 800-2 (1988). A local anaesthetic cream (EMLA; Astra) gave more pain relief and improved the ease of venepuncture compared to lignocaine injections. Patients expressed a strong preference for the EMLA cream, which has advantages that outweigh the cost and convenience factors.

Subclavian stenosis: a major complication of subclavian dialysis catheters. Barrett, N., Spencer, S., McIvor, J. and Brown, E.A. *Nephrol Dial Transplant*, 3 (4), pp. 423-5 (1988). Subclavian catheterisation is frequently used for acute vascular access for haemodialysis and is thought to rarely result in long-term clinical problems. Venography in 36 cases, however, revealed subclavian stenosis in 18 (50%), of whom 5 developed clinical problems. The incidence of subclavian-vein stenosis was related to the duration of catheterisation (P less than 0.05). It may also be more common in black patients. Subclavian catheterisation is therefore not necessarily an ideal form of acute vascular access.

Recirculation: review, techniques for measurement, and ability to predict hemoaccess stenosis before and after angioplasty. Nardi, L. and Bosch, J. *Blood Purif*, 6 (2), pp. 85-9 (1988). The measurement of recirculation during two-needle hemodialysis provides valuable information about hemoaccess integrity and indicates potential problems with possible compromise of dialysis effectiveness (improper clearances). Recirculation greater than 10% is an indication for further study.

Morbidity and mortality of central venous catheter hemodialysis: a review of 10 years' experience. Vanholder, V., Hoenich, N. and Ringoir, S. *Nephron*, 47 (4), pp. 274-9 (1987). The morbidity and mortality of hemodialysis by internal central venous catheterization in the subclavian and internal jugular positions are reviewed. The most frequent complications were inadequate flow (7.6%), inadvertent withdrawal (5.6%), and bacteremia (5.1%). The overall complication rate was 27.2%. Kinking, bleeding, and bacteremia occurred more frequently in patients with chronic renal

failure, compared to patients with acute renal failure. Bacteremia occurred more frequently after prolonged periods of catheterization (greater than 10 days). The mortality of catheter dialysis could be estimated to be between 0 and 1.25/1,000 catheterizations.

Adequacy studies of fistula single-needle dialysis. Vanholder, R., Hoenich, N. and Ringoir, S. *Am J Kidney Dis*, 10 (6), pp. 417-26 (Dec 1987). It is concluded that urea kinetic data (KT/V averaged 0.98) and other parameters of dialysis adequacy indicate that the efficiency of the single-needle technique is at least as good as that obtained in the more currently used two-needle technique. Fistula survival was higher, and hospitalization rate and mortality not different from two-needle dialysis. Subsequently, the current reluctance towards single-needle dialysis as a routine procedure in chronic renal failure, appears to be unjustified.

Thrombotic complications of indwelling central catheters used for chronic hemodialysis. Caruana, R.J., Raja, R.M., Zeit, R.M., Goldstein, S.J. and Kramer, M.S. *Am J Kidney Dis*, 9 (6), pp. 497-501 (Jun 1987). A new double-lumen silicone-rubber dialysis catheter, designed to be placed surgically in central veins, is now available. A review of the literature suggests that pericatheter thrombus formation with or without occlusion of major veins has been a complication of chronic central venous catheterization with a variety of catheters, in both dialysis and nondialysis settings.

Complications related to subclavian catheters for hemodialysis. Report and review. Vanherweghem, J.L., Cabolet, P., Dhaene, M., Goldman, M., Stolear, J.C., Sabot, J.P., Waterlot, Y. and Marchal, M. *Am J Nephrol*, 6 (5), pp. 339-45 (1986). Complications include pneumothoraxes and hemothoraxes due to subclavian artery puncture; bacteremia related to subclavian catheter infections; clinical evidences of subclavian vein thrombosis; pericardial tamponade due to right atrium perforation; and mediastinal hematoma and right hemothorax due to superior vena cava perforation. Review of the literature indicates that pneumothoraxes and/orhemothoraxes occurred in 1.7% of the catheter insertions and that sepsis related to subclavian dialysis catheters occurred in 8.9% of the patients, as systematically investigated subclavian vein thrombosis involved at least 50% of the patients. Taking into account all these complications, recommendations are made for the use of subclavian dialysis catheters.

Cannulation of arteriovenous fistulae. Stansfield, G. *Nurs Times*, 83 (4), pp. 38-9 (Jan 28-Feb 3 1987).

When a vascular access site complicates care. Alt, D., Balduf, R. and Thompson, E. *RN*, 49 (10), pp. 36-9 (Oct 1986). High incidence of subclavian dialysis catheter-related bacteremias. Pezzarossi, H.E., Ponce de Leon, S., Calva, J.J., Lazo, de la Vega, S.A. and Ruiz-Palacios, G.M. *Infect Control* Dec 1986, 7 (12) pp. 596-9. This retrospective cohort study reviews the incidence of bacteremia in patients undergoing hemodialysis using subclavian vein dialysis catheters (SDC) as temporary vascular access. The presence of possible risk factors for SDC-related bacteremia, including duration of catheterization and number of hemodialysis procedures, were not statistically different when patients with and without bacteremia were compared, with the exception of a significantly lower incidence of bacteremia among those patients receiving antibiotic therapy at the time of catheter insertion. The use of resterilized catheters was not a risk factor. Specific guidelines for SDC insertion and care were established and followed, after which the infection frequency was significantly reduced.

Reassessment of fistula puncture site blood loss. Vaziri, N.D., Miyada, D.S., Saiki, J.K. and Robinson, MA. *J Dial*, 3 (4), pp. 361-6 (1979). Fistula puncture site blood loss during and after hemodialysis was measured in 12 patients with end-stage renal disease. The values obtained in this study are 5 to 10 folds less than those found in the original reports. Recent advances in dialytic technology are probably responsible for the observed improvement. The results also suggest that Cimino A-V fistulas are superior to the heterologous graft.

In flow time and recirculation in single-needle hemodialysis. Blumenthal, S.S., Ortiz, M.A., Kleinman, J.G. and Piering, W.F. *Am J Kidney Dis*, 8 (3), pp. 202-6 (Sep 1986). The recirculation of previously dialyzed blood in the lumen of the single-needle catheter reduces dialysis efficiency and is a drawback of single-needle dialysis. Maximizing the inflow volume is essential for minimizing recirculation in single-needle hemodialysis. Clinically insignificant recirculation ensues when inflow time is maintained between three to five seconds and time-time single-needle devices are used, even in patients dialyzed with single-lumen subclavian catheters.

A prospective study of the mechanisms of infection associated with hemodialysis catheters. Cheesbrough, J.S., Finch, R.G., Burden, R.P. *J Infect Dis*, 154 (4), pp. 579-89 (Oct 1986). Comparison of isolates with skin cultures from the insertion site suggested that the origin of the colonizing organisms was the skin (36% of total), intralumenal contamination (57%), or both routes (7%). Comparison of cultures taken during catheter insertion with those at removal rarely suggested that organisms introduced at insertion caused subsequent colonization. This study has demonstrated that infectious complications from using subclavian hemodialysis catheters exceed reported rates for all other modes of vascular access used for hemodialysis, as well as other indications for central venous catheterization.

Subclavian hemodialysis catheter infections. Dahlberg, P.J., Yutuc, W.R. and Newcomer, K.L. *Am J Kidney Dis*, 7 (5), pp. 421-7 (May 1986). Overall catheter colonization rate was 21.6% and catheter-associated bacteremia occurred in 9.4%. Catheters removed from febrile patients had much higher colonization (48.3%) and bacteremia (34.5%) rates. In a randomized study comparing infection rates in catheters tunneled subcutaneously or not tunneled, there was no significant difference in the incidence of infection. Catheters inserted over a guidewire to replace clotted or malfunctioning catheters were not associated with higher infection rates.

Prevention of thrombosis in arteriovenous fistulas. Uldall, R. *Blood Purif*, 3 (1-3), pp. 89-93 (1985). To prevent thrombosis in arteriovenous fistulas it is necessary to obtain the knowledgeable cooperation not only of the whole health care team, but also of the patient. The first step is preservation of forearm veins by avoiding unnecessary venipunctures in patients with chronic renal failure. Avoidance of premature fistula cannulation and correct needling techniques help to prevent vein wall damage. Alertness to the presence of high venous pressures on dialysis and observation of inefficient dialysis due to recirculation should lead to detection of narrowed segments which can be surgically corrected before thrombosis occurs.

Infections associated with subclavian dialysis catheters: the key role of nurse training. Vanherweghem, J.L., Dhaene, M., Goldman, M., Stolear, J.C., Sabot, J.P., Waterlot, Y., Serruys, E. and Thayse, C. *Nephron*, 42 (2), pp. 116-9 (1986). The incidence of sepsis was not significantly greater in diabetic patients, in patients with corticotherapy or in patients presenting an underlying systemic disease. On the contrary, the incidence was greater in hospitalized patients than in ambulatory patients as well as during a period corresponding to a greater number of untrained nurses enrolled in the dialysis team. These data underline the key role of nurse training in the prevention of catheter-related infections.

Complications of vascular access in a dialysis population. Porter, J.A., Sharp, W.V. and Walsh, E.J. *Curr Surg*, 42 (4), pp. 298-300 (Jul-Aug 1985).

High incidence of infectious complications with the Hemasite vascular access device. Barth, R.H., Schwartz, S. and Lynn, R.I. *Trans Am Soc Artif Intern Organs*, 30, pp. 450-7 (1984).

Renal nursing. Vascular access techniques. Mackenzie, S. *Nurs Mirror*, 160 (15), pp. 27-9 (Apr 10, 1985).

A morphological study of bacterial colonisation of intravenous cannulae. Cheesbrough, J.S., Elliott, T.S. and Finch, R.G. *J Med Microbiol*, 19 (2), pp. 149-57(Apr 1985). Microbiological findings indicated colonisation of the intravascular portion haemodialysis cannulae, largely with skin commensal organisms. Surface defects on the cannulae were shown to be associated with microbial colonisation which occurred either as isolated colonies or in association with a cellular fibrinous matrix. These observations are illustrated and discussed.

Fatal hemothorax caused by a subclavian hemodialysis catheter. Thoughts on prevention. Tapson, J.S., Uldall, P.R. *Arch Intern Med*, 144 (8), pp. 1685-7 (Aug 1984). A 19-year-old woman died when a subclavian catheter that had provided vascular access for plasmapheresis penetrated her right atrium, pericardium, and parietal pleural, causing a hemothorax. Precautions are recommended to minimize the risk of this complication in patients in whom subclavian catheters are used as a vascular access route for hemodialysis or plasmapheresis.

Avoiding deaths from subclavian cannulation for hemodialysis. Tapson, J.S. and Uldall, R. *Int J Artif Organs* Sep 1983, 6 (5) pp. 227-30.

Infections associated with subclavian Uldall catheters. Sherertz, R.J., Falk, R.J., Huffman, K.A, Thomann, C.A. and Mattern, WD. *Arch Intern Med*, 143 (1), pp. 52-6 (Jan 1983). The incidence of UC site infection and bacteremia based was higher than the incidence of infection reported with any other type of vascular access for hemodialysis.

Chapter 10

Hemodialyzer Reuse

Release of pyrogens during clinical hemodialysis. Weingast, J.A., VanDeKerkhove, K.M., Eiger, S.M., Kluger, M.J. and Port, F.K. *Trans Am Soc Artif Intern Organs*, 31, pp. 359-62 (1985).

Pathogenesis of fever during hemodialysis. Dinarello, C.A. *Contrib Nephrol*, 36, pp. 90-9 (1983).

Beta 2-microglobulin kinetics in maintenance hemodialysis: a comparison of conventional and high-flux dialyzers and the effects of dialyzer reuse. DiRaimondo, C.R. and Pollak, V.E. *Am J Kidney Dis*, 13 (5), pp. 390-5 (May 1989). To define the kinetics of beta 2M during hemodialysis and the effects of dialyzer reprocessing, serum beta 2M, plasma C3a, and neutrophil counts were measured immediately predialysis, 15, 90, and 180 minutes after beginning dialysis, and 15 minutes postdialysis in ten chronic hemodialysis patients. Complement activation and neutropenia during dialysis were significantly more marked with cuprammonium, but were not affected by reprocessing of either dialyzer. In-vitro adsorption of 124I-beta 2M to polysulfone fibers was greater than to cuprammonium; adsorption was not influenced by dialyzer reprocessing.

Prevalence of nontuberculous mycobacteria in water supplies of hemodialysis centers. Carson, L.A., Bland, L.A., Cusick, L.B., Favero, M.S., Bolan, G.A., Reingold, A.L. and Good, R.C. *Appl Environ Microbiol*, 54 (12), pp. 3122-5 (Dec 1988). This study was conducted to determine the prevalence of NTM and other bacteria in water samples collected over a 13-week period from 115 randomly selected dialysis centers in the United States. The results of this study support recommendations to use 4% HCHO or a chemical germicidal equivalent for disinfecting dialyzers that are to be reused.

Reuse of hemodialyzers. Results of nationwide surveillance for adverse effects. Alter, M.J., Favero, M.S., Miller, J.K., Coleman, P.J. and Bland, L.A. Hepatitis Branch, Centers for Disease Control, Atlanta, GA 30333. *JAMA*, 260 (14), pp. 2073-6 (Oct 14, 1988). In 1986, the Centers for Disease Control, in collaboration with the Health Care Financing Administration, surveyed 1350 chronic hemodialysis centers in the United States to ascertain practices associated with the reuse of disposable hemodialyzers and the frequency of pyrogenic reactions and septicemia among patients. Reusing hemodialyzers more than 20 times and, in some instances, also using manual reprocessing systems was significantly associated with clustering of pyrogenic reactions regardless of the type of germicide used. To detect membrane leaks developing after multiple reuses, air-pressure-leak tests should be performed on all reprocessed hemodialyzers.

Effects of disinfectants in renal dialysis patients. Klein, E. *Environ Health Perspect*, 69, pp. 45-7 (Nov 1986). Overview of the risks and hazards of a variety of disinfectants used in hemodialysis.

Effect of multiple use of dialyzers on intradialytic symptoms. Bok, D.V., Pascual, L., Herberger, C., Sawyer, R. and Levin, N.W. *Proc Clin Dial Transplant Forum*, 10, pp. 92-9 (1980). Patients were dialyzed on new and reused dialyzers via a double blind study. Incidents of many intradialytic symptoms including chest pain, back pain, and nausea and vomiting were significantly reduced with reused dialyzers as compared to new dialyzers.

Mass transport in reused dialyzers. Gotch, F.A. *Proc Clin Dial Transplant Forum*, 10, pp. 81-5 (1980).

Prevention of anti-N like antibodies development with nonformaldehyde reuse procedure. Man, N.K., Lebkiri, B., Polo, P., deSainte-Lorette, E., Lemaire, A. and Funck-Brentano, J.L. *Proc Clin Dial Transplant Forum*, 10, pp. 18-21 (1980).

Bacterial endotoxin in new and reused hemodialyzers: a potential cause of endotoxemia. Petersen, N.J., Carson, L.A. and Favero MS. *Trans Am Soc Artif Intern Organs*, 27, pp. 155-60 (1981). New dialyzers may contain an LAL-reactive material, but it is not pyrogenic. However, if reuse dialyzers are reprocessed and stored with a disinfectant that contains endotoxin, that pyrogenic material may stay in the membrane even after rinseout of the disinfectant.

Methods for avoiding introduction of this endotoxin to the patient includes discarding the recirculating solution to waste. Water used for dilution of germicide should be endotoxin-free.

Effect of first and subsequent use of hemodialyzers on patient well-being: the rise and fall of a syndrome associated with new dialyzer use. Charoenpanich, R., Pollak, V.E., Kant, K.S., Robson, M.D. and Cathey, M. *Artif Organs*, 11 (2), pp. 123-7 (Apr 1987). In a single large dialysis unit in which dialyzers are routinely subjected to multiple use, the incidence rates of intradialytic symptoms during first use and reuse were compared. The results of this investigation suggest that subjecting dialyzers to anautomated reuse processing system before first use can markedly diminish the incidence of first-use syndrome.

Repeated use of dialyzers is safe: long-term observations on morbidity and mortality in patients with end-stage renal disease. Pollak, V.E., Kant, K.S., Parnell, S.L. and Levin, N.W. *Nephron*, 42 (3), pp. 217-23 (1986). Through the examination of morbidity and mortality figures the authors suggest that there are no adverse long-term effects of multiple use of dialyzers.

National Kidney Foundation revised standards for reuse of hemodialyzers. *Am J Kidney Dis*, 3 (6), pp. 466-8 (May 1984). The National Kidney Foundation, Inc convened a group with expertise and experience in dialysis, including one or more physicians, nurses, consumers (patients), industry representatives, and microbiologists to formulate the described standards, which were subsequently approved by the Executive Committee of the National Kidney Foundation at its December 2, 1983 meeting.

Dialyzer reuse in a large dialysis program. Luehmann, D., Hirsch, D., Carlson, G., Constantini, E. and Keshaviah, P. *Trans Am Soc Artif Intern Organs*, 28, pp. 76-80 (1982).

Morbidity of nondiabetic home hemodialysis patients with and without dialyzer reuse. Siemsen, A.W., Wong, E.G., Sugihara, J.G. and Musgrave, J.E. *Trans Am Soc Artif Intern Organs*, 28, pp. 385-6 (1982).

Some aspects of residual formaldehyde testing when reusing haemodialysers. Woffindin, C. and Hoenich, N.A. *Int J Artif Organs*, 8 (6), pp. 313-8 (Nov 1985). To assess the adequacy of quantifying residual formaldehyde concentrations when reusing, four semi-quantitative methods of concentration estimation (Clinitest tablets, Schiff's reagent, Formalert Formotest) were compared. Two methods (Schiff's reagent and Clinitest) were inadequate in detecting low concentrations of formaldehyde and were associated with false positives from interference by chemicals contained in the dialysate. False positives were demonstrated with one (Formotest) while the other was capable of detecting formaldehyde concentrations as low as 4.5 mg/l. Recommended to select the most sensitive of these semi-quantitative techniques for routine use and to perform regular screening for anti-N antibodies and to periodically check formaldehyde levels by the use of the highly specific Hantzsch reaction.

Hemodialysis neutropenia and dialyzer reuse: role of the cleansing agent. Gagnon, R.F. and Kaye, M. *Uremia Invest*, 8 (1), pp. 17-23 (1984). As part of a study to evaluate the safety and efficacy of dialyzer reuse, a comparative study of two methods of dialyzer reprocessing, manual and automated, was conducted. Five stable end-stage renal disease patients on center hemodialysis were evaluated as to hematological and metabolic parameters throughout two series of three consecutive dialyses using first new and then reused dialyzers reprocessed according to each of the two methods. It would be reasonable to conclude from these results that among the various differences between the two dialyzer reprocessing methods, restoration of the original level of biocompatibility of the reused dialyzer's membrane is related to the concentration of the cleansing agent.

Nursing aspects of dialyzer reuse. Baldasseroni, A. *J Nephrol Nurs*, 1 (1), pp. 17-9 (Jul-Aug 1984).

Leukopenia with different regenerated haemodialysis membranes. Ksiazek, A., Soko-Lowska, G., Marczewski, K. and Solski J. *Int Urol Nephrol*, 16 (1), pp. 61-7 (1984). The white blood cell count (WBC) decreases during haemodialysis and was investigated as a function of different dialysis membranes. Each of them was used four times, applying different sterilization methods. The results indicate differences in biocompatibility between cuprophan and PAN membranes, independent of the sterilization method employed.

Anaphylatoxin formation during hemodialysis: comparison of new and re-used dialyzers. Chenoweth, D.E., Cheung, A.K., Ward, D.M. and Henderson, L.W. *Kidney Int*, 24 (6) pp. 770-4 (Dec 1983). Hemodialysis of 11 end stage renal failure patients with new cuprophan hollow fiber dialyzers produced significant leukopenia as well as increased plasma levels of

both C3a and C5a antigens during the initial phases of the procedure. These observations suggest that C3b deposition on the cellulosic membrane surface during first use markedly diminishes the complement-activating potential of cuprophan dialyzers when they are subsequently reused.

Formaldehyde kinetics in reused dialyzers. Gotch, F.A. and Keen, M.L. *Trans Am Soc Artif Intern Organs*, 29 pp. 396-401 (1983).

Kidney dialysis: ambient formaldehyde levels. Smith, K.A. Jr, Williams, P.L., Middendorf, P.J. and Zakraysek, N. *Am Ind Hyg Assoc J*, 45 (1), pp. 48-50 (Jan 1984). Ambient levels of formaldehyde in kidney dialysis units were discussed. Five kidney dialysis clinics were surveyed and air sampling was performed in all major work areas. Formaldehyde levels were found to be below the TLV of 1.0 part per million (ppm) in all samples and the mean ambient level was below 0.5 ppm. Feasible engineering controls that would further reduce or eliminate potential employee exposures were identified.

Microbiologic evaluation of a new glutaraldehyde-based disinfectant for hemodialysis systems. Petersen, N.J., Carson, L.A., Doto, I.L., Aguero, S.M. and Favero, M.S. *Trans Am Soc Artif Intern Organs*, 28 pp. 287-90 (1982). Development of anti-N-like antibodies during formaldehyde reuse in spite of adequate predialysis rinsing. Vanholder, R., Noens, L., DeSmet, R. and Ringoir, S. *Am J Kidney Dis* Jun 1988, 11 (6) pp. 477-80. Five of 50 patients (10%) became positive for anti-N-like antibodies 6 to 14 months after the start of formaldehyde reuse, indicating that even a careful control of effluent formaldehyde concentration cannot prevent the occurrence of this abnormality.

Cuprophan reuse and intradialytic changes of lung diffusion capacity and blood gases. Vanholder, R.C., Pauwels, R.A., Vandenbogaerde, J.F., Lamont, H.H., Van der Straeten, M.E. and Ringoir, S.M. *Kidney Int*, 32 (1), pp. 117-22 (Jul 1987). Reuse of cuprophan dialyzers significantly attenuated the fall in leukocyte counts and the rise in C3a des Arg seen during first use dialysis. Drop in arterial paO2 normally seen with Cuprophan dialysis was not seen when the dialyzer was reused.

Dialyzer performance over prolonged reuse. Gagnon, R.F. and Kaye, M. *Clin Nephrol*, 24 (1), pp. 21-7 (Jul 1985). Studies were performed in patients on maintenance hemodialysis to evaluate the role of prolonged dialyzer reuse in the management of end-stage renal disease. The data obtained demonstrate that membrane permeability to small solutes (urea, creatinine, phosphate) is maintained up to thirty dialyzer uses. In-vitro studies confirmed this observation and established that clearances of larger solutes (vitamin B12) are also maintained over similar extensive dialyzer reuse. Thus, these results clearly demonstrate that prolonged dialyzer reuse in end-stage renal disease patients constitutes a stable form of renal replacement therapy provided adequate dialyzer reprocessing is applied.

Biocompatibility of dialysis membranes: effects of chronic complement activation. Hakim, R.M., Fearon, D.T., Lazarus, J.M. *Kidney Int*, 26 (2), pp. 194-200 (Aug 1984). Reuse decreases the capacity of the cuprophane membrane to activate complement but does not significantly alter the capacity of cellulose acetate membranes. The extent of complement activation paralleled the ability of these membranes to induce neutropenia. Recurrent dialysis with new cuprophane and cellulose acetate membranes leads to a decrease in pre-dialysis and "rebound leukocytosis" neutrophil count, as well as a more intense activation of complement and an enhanced endogenous clearance of products of complement activation. The clinical sequelae of recurrent complement activation are discussed.

Formaldehyde-related antibodies in hemodialysis patients. Sandler, S.G., Sharon, R., Bush, M., Stroup, M. and Sabo, B. *Transfusion*, 19 (6), pp. 682-7 (Nov-Dec 1979). Sera from patients dialyzed with disposable membranes neither had anti-N-like activity nor agglutinated formaldehyde-treated red blood cells. These findings are consistent with the hypothesis that anti-N-like reactions of hemodialysis patients' sera represent cross reactions of formaldehyde related antibodies with N antigens of normal red blood cells.

Haemolysis due to formaldehyde-induced anti-N-like antibodies in haemodialysis patients. Fassbinder, W., Frei, U. and Koch, K.M. *Klin Wochenschr*, 57 (13), pp. 673-9 (Jul 3, 1979). During reuse of formaldehyde sterilized Kiil-dialysers, red cell survival was significantly reduced in patients with anti-N-like positive sera, when compared with 19 antibody negative control patients. Replacement of formaldehyde sterilized dialysers by ethylene-oxide sterilized disposable dialysers resulted in a significant increase in hematocrit. This improvement took place, although antibody titres declined only slowly. The data demonstrate that formaldehyde sterilisation of dialysers may cause antibody-mediated haemolysis contribut-

ing to the extent of renal anaemia. This immunohaemolysis may be corrected, in spite of continuing antibody persistance, when formaldehyde exposure is totally avoided, or possibly when minimized.

Proceedings of the National Workshop on Reuse of Consumables in Hemodialysis. Sadler, J.H. [ed]. Kidney Disease Coalition: Washington, DC (300 pp.).

Hemodialyzer Reuse: Issues & Solutions (an AAMI Analysis and Review). Association for the Advancement of Medical Instrumentation; Arlington, VA, (76 pp.) (1985). A review of dialyzer reuse including cleaning, disinfection, and associated chemical hazards, quality control, and practical considerations.

Occupational Exposure to Formaldehyde. 29 CFR Parts 1910 and 1926. *Federal Register* (December 4, 1987).

Highlights of ASN Special Workshop on Reuse. Rice-Coplin, K. and Vlchek, D. *Dial & Transplant*, p. 140 (Mar 1987). Discussion of several topical issues: alcide degredation of dialyzer membranes, sinking of formaldehyde with subsequent rebound, absence of evidence regarding formaldehyde's carcinogenicity, effect of sodium hypochlorite on biocompatability factor associated with reuse.

Effect of chemical germicides on the integrity of hemodialyzer membranes. Bland, L.A., Favero, M.S., Oxborrow, G.S., Aguero, S.M., Searcy, B.P. and Danielson, J.W. *ASAIO Trans*, 34 (3), p. 172-5 (Jul-Sep 1988). Epidemiologic investigations of bacteremia in dialysis patients by the Centers for Disease Control (CDC) identified an association with the use of dialyzers disinfected with a specific chemical germicide. A collaborative study by the CDC and the Food and Drug Administration (FDA) was conducted to determine the effect of dialyzer disinfectants on five types of dialyzer membranes: three cellulosic (Cuprophan, cellulose acetate, cuprammonium rayon); and two synthetic (polysulfone, polyacrylonitrile). The disinfectants tested were 4% formaldehyde; Renalin; Cidex Dialyzer; Sporicidin HO; Warexin; and RenNew-D. Water was the control. These results and those obtained from epidemiologic studies suggest that membrane integrity testing (e.g. an air-leak test) should be an integral part of dialyzer reprocessing.

Effect of multiple use of dialyzers on intradialytic symptoms. Bok, D.V., Pascual, L., Herberger, C., Sawyer, R. and Levin, N.W. *Proc Clin Dial Transplant Forum*, 10, pp. 92-9 (1980).

Multiple use of dialyzers: safety and efficacy. Kant, K.S., Pollak, V.E., Cathey, M., Goetz, D. and Berlin, R. *Kidney Int*, 19 (5), pp. 728-38 (May 1981). The practice of multiple use of dialyzers was examined over a 15-month period on all 104 patients in a chronic maintenance hemodialysis facility. The incidence of complications during dialysis, of complications that might be related to infection, and the rate of hospitalization was not greater in the unit practicing multiple use as compared with the rates in the unit practicing single use. Events possibly associated with infection did not occur more frequently during dialyses in which the dialyzer had been used between 2 and 20 times than they did with the initial use of the dialyzer. With successive dialyzer use, there was no significant change in the ability to remove fluid or in the dialysance of urea and creatinine. The neutropenia that characteristically occurs early in dialysis was substantially less with reused dialyzers than with their initial use. Under the operating conditions described, the authors conclude that multiple dialyzer use over a 15-month period is safe, efficacious, and is not associated with an increased rate of infection, of morbidity, or of mortality.

Formation of anti-N-like antibodies in dialysis patients: effect of different methods of dialyzer rinsing to remove formaldehyde. Lewis, K.J., Dewar, P.J., Ward, M.K. and Kerr, D.N. *Clin Nephrol*, 5 (1), pp. 39-43 (Jan 1981). Use of formalin to sterilize dialyzers is known to be responsible for the formation of anti-N-like antibody in long-term hemodialysis patients. Patients dialyzed as in-patients using formalin were found to be completely free of anti-N-like antibody, while among those on home dialysis, there was a high prevalence (31%) and incidence. The hospital patients were found to be receiving concentrations of formaldehyde less than 1 microgram/ml while those on home dialysis received 3-13 micrograms/ml. This is offered as an explanation for the absence of anti-N-antibody in patients using formalin-sterilized dialyzers.

Relationship between formaldehyde-related antibodies and cross-reacting anti-N-like antibodies in patients undergoing chronic haemodialysis. Sharon, R. *J Clin Pathol*, 34 (1), pp. 41-3 (Jan 1981). An attempt was made to determine the sequence of events leading to the production of two distinct antibodies in patients with chronic renal failure who regularly undergo haemodialysis with formaldehyde reused dialyzers. The production of anti-formaldehyde red cells started about six months after the beginning of haemodialysis treatment. Only when the titre of

these antibodies reached 64 or 128 another, apparently cross-reacting, antibody appeared which reacted like an anti-N antibody. A strong direct antiglobulin reaction was found to be positive for formalin-treated red cells after five minutes of contact with specific antibody, indicating a high affinity of the antibody of the formalin-altered red cell.

Effect of multiple use of dialyzers on hepatitis B incidence in patients and staff. Favero, M.S., Deane, N., Leger, R.T. and Sosin, A.E. *JAMA*, 245 (2), pp. 166-7 (Jan 9, 1981). Data pertaining to incidence of hepatitis B from a 1976 Center for Disease Control Study were matched with responses from a Renal Physicians Association survey on dialyzer reuse in the United States. Incidence of infection of staff having at least one HBsAg positive patient was 2.9% in centers practicing reuse *vs.* 3.6% in centers practicing single use. Nearly all (95%) staff who became HBsAg positive were associated with centers having at least one HBsAg-positive patient. The practice of reusing dialyzers does not appear to be associated with increased risk of hepatitis B infection among patients and staff.

Effect of dialyzer reprocessing methods on complement activation and hemodialyzer-related symptoms. Dumler, F., Zasuwa, G. and Levin, N.W. *Artif Organs*, 11 (2), pp. 128-31 (Apr 1987). The effects of different dialyzer processing methods and of reuse on complement activation and dialyzer-related symptoms were studied in 96 maintenance hemodialysis patients. The percentage of patients without symptoms during dialysis was significantly greater with reused dialyzers than with new dialyzers. The severity of total symptoms correlated significantly ($p=0.0004$) with complement activation. The results suggest that total symptoms during dialysis are correlated with the degree of complement activation. However, trends in the data pertaining to chest pain suggest that factors other than complement activation may be important in the pathogenesis of some dialyzer-related symptoms.

U.S.GOVERNMENT PRINTING OFFICE:1991-517-023/29029

FDA 87-4217	Proceedings of the First International Conference of Medical Devices Regulatory Authorities (ICMDRA) - June 2-6, 1986 (PB 88-123005/AS, $25.95).
FDA 87-4218	Have a New Medical Device? (brochure).
FDA 87-4221	Regulatory Requirements for Devices for the Handicapped (PB 88-123013/AS, $12.95).
FDA 87-4222	An Introduction to Medical Device Regulations (pamphlet).
FDA 87-4223	Classifying Your Medical Devices (brochure).
FDA 87-4224	In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions (PB 88-121801/AS, $14.95).
FDA 88-4160	Import and Export - Regulatory Requirements for Medical Devices (August 1988)(GPO 017-012-00336-2, $2.25) (PB 89-121859/AS, $13.95).
FDA 88-4225	Review and Summary of Hemodialysis System Investigative Reports from California, the District of Columbia, Massachusetts and Ohio (PB 88-121793/AS, $19.95).
FDA 88-4226	Medical Device Reporting Questions and Answers (February 1988) (PB 88-192737/AS, $14.95).
FDA 88-4227	Export of Medical Devices: A Workshop Manual (September 1988) (GPO 017-012-00338-9, $10.00) (PB 89-119663/AS, $28.95).
FDA 88-4228	Import of Medical Devices: A Workshop Manual (September 1988) (Supersedes FDA 83-4167) (GPO 017-012-00337-1, $8.50) (PB 89-119671/AS, $21.95).
FDA 88-4229	Applications of DNA Probes for the Diagnosis of Human Infectious Diseases: An Overview (September 1988) (PB 89-120497/AS, $15.95).
FDA 89-4158	Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices (November 1988) (GPO 017-012-00342-7, $3.75) (PB 89-145312/AS, $15.95).
FDA 89-4159	Investigational Device Exemptions - Regulatory Requirements for Medical Devices (May 1989) (Supersedes FDA 83-4159) (GPO 017-012-00346-0, $5.00) (PB 90-128927, $23.00).
FDA 89-4165	Regulatory Requirements for Medical Devices - A Workshop Manual - Fourth Edition (May 1989) (Supersedes FDA 85-4165) (GPO 017-012-00344-3, $18.00) (PB 89-215388/AS, $36.95).
FDA 89-4203	Labeling - Regulatory Requirements for Medical Devices (May 1989) (Supersedes FDA 86-4203) (GPO 017-012-00345-1, $2.75) (PB 90-131418/AS, $17.00).
FDA 89-4231	Nursing and Technology: Moving Into the 21st Century - Conference Proceedings - May 16-18, 1988 - Annapolis, MD (April 1989) (GPO 017-015-00237-3, $6.00) (PB 90-100710/AS, $21.95).
FDA 89-4232	Yorick: The CDRH Bionic Skeleton (pamphlet).
FDA 89-4234	A Manual on Water Treatment for Hemodialysis (July 1989) (PB 90-121211/AS, $31.00).
FDA 90-4219	Medical Devices Standards Activities Report (Supersedes FDA 87-4219) (PB 90-180134/AS, $23.00).
FDA 90-4235	Device Recalls: A Study of Quality Problems (January 1990) (PB 90-181272/AS, $15.00).
FDA 90-4237	The Device Priority Model: Development and Applications (October 1989) (PB 90-165937/AS, $17.00).
FDA 90-4238	Replacement and Repair of the Visual System: I. Visual Prosthetics II. Retinal Transplants - A Review (October 1989) (PB 90-181298/AS, $17.00).
FDA 90-4239	Condoms and Sexually Transmitted Diseases - Especially AIDS (booklet).
FDA 90-4240	AIDS-Information for the Dialysis Patient (pamphlet).
FDA 90-4241	AIDS-Information for the Dialysis Health Professional (pamphlet).

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, Maryland 20857