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AAMI Dialysis Monograph Series

Current Concepts in Hemodialyzer Reprocessing

2nd Edition

Association for the Advancement of Medical Instrumentation

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AAMI Monograph

HDR-1998
2nd edition

Current Concepts in Hemodialyzer Reprocessing

A Monograph based on presentations given at the AAMI Annual Meeting, June 1992, Anaheim, California, AAMI Annual Meeting May, 1995, Anaheim,; California, and AAMI Annual Meeting, June 1997, Washington, D.C.

Abstract: This monograph covers the reprocessing of hemodialyzers, including a brief history, the monitoring of patients and dialyzers, anticoagulation strategies, effects of reprocessing on solute clearances, personnel qualifications and training, the monitoring and prevention of disease transmission in reuse facilities, common pitfalls of reuse programs, continuous quality improvement, and Health Care Financing Administration regulation.

Keywords: anticoagulation, clearance, HCFA, hemodialysis, reuse, ultrafiltration

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Foreword

The Association for the Advancement of Medical Instrumentation (AAMI) is perhaps most widely known for its development of standards and recommended practices for medical devices, including *Hemodialysis Systems* (ANSI/AAMI RD5-1992, 2nd ed.) and *Reuse of Hemodialyzers* (ANSI/AAMI RD47-1993, 2nd ed.). The revision of the second editions of RD5 and RD47 (in progress) will incorporate new information that has been widely accepted in the dialysis field since the publication of the last edition of the two standards. These and other voluntary standards developed by AAMI reflect the collective expertise of health care professionals, representatives of industry, and government officials and must undergo a formal and lengthy national consensus approval process before they are released.

At the same time, standards are not intended to replace professional judgment and, although reviewed and revised periodically (every 5 years), they are static documents applied to a dynamic field. In short, standards are truly useful only when relied on in conjunction with other sources of information and guidance, knowledge about specific situations, and a framework of professional experience.

In this regard, AAMI has annually sponsored two courses—on water quality for dialysis and on dialyzer reprocessing—for more than 15 years. Directed primarily to doctors, nurses, and technicians who specialize in nephrology, the overall goal of the courses is to help dialysis professionals stay current so that they are better able to apply consensus recommendations to real-life situations. Without ignoring the basics, these courses emphasize changes over the previous year, or seen on the horizon, in technology, relevant government requirements and recommendations, and applicable AAMI standards.

The monographs contained in this publication are based on select presentations from courses held in 1992, 1995, and 1997. For AAMI's CD-ROM version, the monographs are provided in two separate files.

Water Quality for Dialysis, the first of the monographs, contains eight papers and addresses the microbiologic qualities of water for hemodialysis, aspects of pre- and post-treatment reverse osmosis membrane technology, monitoring of hemodialysis water treatment systems, and FDA regulation of water purification systems for hemodialysis.

Current Concepts in Hemodialyzer Reprocessing, with nine papers, covers the history of reprocessing, microbiologic considerations, monitoring and anticoagulation strategies, personnel and quality assurance issues, and AAMI guidelines for HCFA compliance.

Comments on this publication are welcome and should be sent to Technical Programs, AAMI, 3330 Washington Boulevard, Suite 400, Arlington, VA 22201. For information concerning future dialysis courses, contact the same department.

NOTE—Chapters of this publication were written by individual experts and reflect the authors' personal views and expertise. Although based on 1992, 1995, and 1997 presentations, it should be noted that authors had an opportunity in 1998 to review and update their edited papers, prior to publication of this document.

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CONTENTS

Page

ABOUT THE CONTRIBUTORS vi

Overview of the History of Dialyzer Reprocessing 1
by Douglas A. Luehmann

Monitoring Strategies for Reuse Patients and Dialyzers 4
by Bruce Farrow, BS

Anticoagulation Strategies for Dialyzer Reprocessing 6
by Jerome Beck

Dialyzer Reprocessing and Solute Clearances 11
by John K. Leypoldt, PhD and Alfred K. Cheung, MD

Personnel Training and Qualifications 18
by Douglas A. Luehmann

Monitoring and Prevention of Disease Transmission in Dialyzer Reuse Facilities 23
by Matthew J. Arduino, MS, DrPH

Common Pitfalls of Dialyzer Reuse Programs 33
by Douglas L. Vlchek, BA, CHT

Continuous Quality Improvement for Dialysis Programs 37
by Anthony Messana, BS

HCFA Standards For Dialyzer Reprocessing 42
by Judith Kari

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ABOUT THE CONTRIBUTORS

Matthew J. Arduino, MS, DrPH, is Acting Chief, Dialysis and Medical Devices Section, Hospital Environment Laboratory Branch, Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention. He received his BS degree in biology from College of Mount Saint Vincent, his MS in microbiology from New York Medical College, and his MPH and DrPH degrees (parasitology and laboratory practice) from the University of North Carolina at Chapel Hill. Dr. Arduino has received a Unit Commendation for his work on allergic reactions in hemodialysis patients (CDC-ATSDR, 1991) and a Group Award for Program Operations for outstanding achievements in the investigation of the L-tryptophan-induced eosinophilia-myalgia syndrome epidemic (CDC-ATSDR, 1991). Dr. Arduino's scientific interests include hospital-acquired infections, dialysis-associated diseases, and tuberculosis and other mycobacterial diseases. He has authored and co-authored 50 papers and two book chapters.

Jerome Beck is the Director of Operations at RENAL WEST in Mesa, Arizona. He has previously held the positions of Staff Development Coordinator, Technical Director, and Facility Administrator. Mr. Beck holds a BS in business administration, has 21 years of dialysis experience, and is a certified Hemodialysis Technician. He is a former Western Region Vice President of the National Association of Nephrology Technicians/Technologists (NANT), and he has served on the Board of Directors of the Board of Nephrology Examiners Nursing and Technology (BONENT). He has also served as a member of the ESRD Network Committee and of the Association for the Advancement of Medical Instrumentation's Renal Disease and Detoxification Committee. Mr. Beck is currently serving on the National Nephrology Technology Certification Board (NNTCB).

Judith Kari is a professional staff member of the Health Standards and Quality Bureau within the Health Care Financing Administration. With 25 years of experience in the renal field, Ms. Kari joined the Health Care Financing Administration in 1993. That year she received HCFA's highest award, the Administrator's Citation. In the early 1970's, she worked for the Department of Health and Human Services in implementing the ESRD program after the passage of the law that extended Medicare coverage to renal patients. She also has served as Executive Director of the metropolitan Washington, D.C., ESRD network and more recently as Associate Director of the American Kidney Fund.

Alfred K. Cheung, MD, is a Professor of Medicine and Medical Director of the Kolff Dialysis Unit at the University of Utah and Chief of Dialysis at the Veterans Affairs Medical Center, Salt Lake City. He received training through a fellowship in nephrology from the University of California, San Diego, and currently conducts research on hemodialysis and uremia. He is board certified in Internal Medicine and Nephrology. Dr. Cheung is a member of the Editorial Boards for *Advances in Renal Replacement Therapy and Blood Purification* and serves as Associate Editor of the *Journal of American Society of Nephrology*. In addition, he is President of Region V of the National Kidney Foundation.

Bruce Farrow, BS, is Biomedical Division Administrator at Total Renal Care; at the time of the 1995 AAMI Annual Meeting, he was Director of Technical Services at Renal Treatment Centers, Inc. He attended North Carolina Central University for 2 years and transferred to the University of North Carolina where he received a BS in health science. He has been active in the dialysis industry for the past 20 years, has worked as a patient care technician, and has multiple years of experience in water treatment and reuse.

John (Ken) Leypoldt, PhD, is Research Associate Professor of Medicine and Adjunct Associate Professor of Bioengineering at the University of Utah and the VA Medical Center in Salt Lake City. He received a PhD in bioengineering from the University of California, San Diego, in 1981 and has performed research related to dialysis membrane transport for more than 15 years. He currently serves as the Dialysis and Kinetics Associate Editor for the *American Society for Artificial Internal Organs (ASAIO) Journal.*

Douglas A. Luehmann is the director of operations for GAMBRO© Systems, Inc., a division of GAMBRO© Healthcare and has been in the dialysis field for more than 30 years. He has published several articles on dialysis technology, participated in NIH and FDA-funded contracts, provided water treatment and dialyzer reuse training to ESRD surveyors and been a contributor in the development of the AAMI Reuse of Hemodialyzers Recommended

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Practice and Hemodialysis Systems Standards. Prior to joining GAMBRO Systems in 1997, Mr. Luehmann was the vice president of dialysis products for the Renal Systems division of Minntech Corporation and has also served as the director of technical services and technical quality assurance at the Regional Kidney Disease Program in Minneapolis, MN.

Anthony Messana, BS, is Manager of Policy and Product Economics for EPGEN® marketing at Amgen, Inc. He has 20 years of renal industry experience spanning technical, clinical, and administrative areas. Before coming to Amgen, Mr. Messana was Director of Dialysis Operations at Dialysis Clinics, Inc., where he oversaw more than 100 dialysis facilities serving 7500 patients. He has contributed to AAMI standards on dialyzer reprocessing and was Cochair of the AAMI short courses on dialyzer reprocessing, 1985-1990. He has served as President of the National Renal Administrators Association (1991), as well as on a variety of community and editorial boards. The National Association of Nephrology Technologists has honored him with both the Torch Bearer Award (1993) and the Lifetime Achievement Award (1995).

Douglas L. Vlchek, BA, CHT, is Vice President at GAMBRO© Healthcare, Lakewood, Colorado. He has authored numerous articles on dialysis-related issues and has served on the Board of Nephrology Examiners for Nursing and Technology and the AAMI Renal Disease and Detoxification Committee and Hemodialyzer Reuse Subcommittee. Mr. Vlchek is co-author of the Food and Drug Administration manual, *Quality Assurance Guidelines for Hemodialysis Devices*. He received his bachelor's degree in biology from Case Western Reserve University, where he has also pursued graduate studies in biochemistry.

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Overview of the History of Dialyzer Reprocessing[1]

Douglas A. Luehmann
Dialysis Technical Services, a division of Vivra Renal Care, Inc.[2]

THE EVOLUTION OF DIALYZER REUSE

The earliest reports of dialyzer reprocessing date back almost to the dawn of the beginning of chronic dialysis. The first report described a technique of refrigerating coil dialyzers between uses, which, in the strictest sense, should not be considered reprocessing, I suppose, but it certainly involved dialyzer reuse (Sheldon et al. 1964).

Next, Pollard et al. (1967) described the methods that they had used to reprocess, disinfect, and reuse Kiil dialyzers; this group in Seattle played a pioneering role in the development of home dialysis. Their method of reprocessing Kiil dialyzers, which are plate dialyzers, was actually intended to facilitate the process of reuse for home patients who worked regular day jobs; it wasn't really a matter of reducing costs. At that time, it would have been a rather daunting chore for a patient to disassemble the dialyzer, install new membranes and blood quarts, perform leak tests, and then fill the dialyzer with formaldehyde (which was then the commonly used disinfectant). Using the method developed by the Pollard group, home patients could reuse dialyzers twice a week, once during the work week and again on Saturday or Sunday.

Gotch (1969) was the first to report reuse of hollow-fiber dialyzers, although the publication did not provide details of the reprocessing method used. Early automated reprocessing systems began to appear in the 1970s; soon thereafter, reports describing the reprocessing of hollow-fiber dialyzers were published. DePalma (1974) provided the first description of an automated method for restoring both coil-plate and hollow-fiber dialyzers. Ahmad (1975) followed with another report on the use of an automated system for the reprocessing of coil-plate dialyzers. Yet another automated system for the reprocessing of coil-plate and hollow-fiber dialyzers was described in Hardy (1976).

In the modern era, beginning in the early 1980s, the five automated devices most commonly used for dialyzer reprocessing have been Compudial® models KPI1 and KP12, the Echo® (manufactured by Mesa Laboratories), the Lixivitron® (manufactured by United Medical Products/Harco), the Renatron® (manufactured by Renal Systems/Minntech Corp), and the Seratronics DRS4® (manufactured by Fresenius). Of these, the Compudial® models and the Lixivitron® are no longer commercially available, but the remaining three account for probably 60% of dialyzer reprocessing performed in the United States today via an automated system.

There is quite a lot of interest in dialyzer reprocessing in Europe today as well. Although, in Europe, only about 10% of dialyzers are reused (still far behind the extent of reuse in the United States), there has been a real proliferation in the development of automated systems in recent years. At least seven systems have been introduced in Europe, and all but two are produced in Germany, where dialyzer reprocessing is practiced principally in private clinics (which are in the minority). Reuse is not commonly practiced in Germany, but a number of Germans think that it is prudent to be developing technology for reprocessing dialyzers. I believe that Europe will expand its use of reprocessing to match that of the United States, but that this expansion will take place a decade or more later, reflecting the fact that the reimbursement rate with which we have struggled in this country (which went into effect in the 1980s) is only now beginning to place economic pressure on Europe.

Based on the data collected annually by the Centers for Disease Control and Prevention (CDC), it appears that 2261 of 2808 U.S. dialysis facilities are now practicing dialyzer reuse (CDC 1996). When the CDC began collecting data, there were only about 400 centers practicing reuse. Hence, there has been a steady upward trend in participation in reuse by U.S. dialysis centers. One can see similar trends by examining the extent of reuse among dialysis patients; however, these numbers really refer to patients who have received their treatments in centers that reprocess and do

[1] Presented at "Dialyzer Reprocessing," a short course held on 23 May 1995 in conjunction with the 1995 AAMI Annual Meeting, Anaheim, California.
[2] At the time this paper was presented, Mr. Luehmann represented Renal Systems, a division of Minntech Corporation.

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not reflect actual numbers of patients on reuse. In 1993, there were approximately 180,000 patients being treated in U.S. dialysis facilities, of whom 143,000 (almost 79%) were in centers that reprocess dialyzers. By far, dialyzer reprocessing in the United States is the rule, not the exception.

TRENDS IN GERMICIDE USE

In regard to the germicide used to disinfect dialyzers, dialyzers were reprocessed almost exclusively with formaldehyde in 1983. Over the years, there has been a downward trend in the use of formaldehyde, while the use of Renalin, a peracetic acid-based chemical made by Renal Systems, has increased. Currently, about 51% of dialysis centers that reprocess use Renalin, about 40% use formaldehyde, and about 8% use glutaraldehyde. In the past couple of years, there has been an interest in a new, heat-based process that does not use a chemical.

INCIDENCE OF PYROGEN REACTIONS

According to other CDC survey data, there was a statistically significant difference, during the years 1989 to 1992, in the number of incidents of pyrogen reactions reported by centers reusing dialyzers vs. the number of pyrogen reactions at centers that did not reuse dialyzers. In 1993, that difference disappeared, reflecting (a) improved quality of the water used in reprocessing procedures both for making up germicide and cleansing dialyzers, (b) changes in CDC's monitoring technique (i.e., how the data pertaining to pyrogen reactions were defined and collected), and (c) the increased use of high-flux dialyzers. It is apparent that, in addition to the decrease of incidents of pyrogen reactions reported by centers that reuse, there was a sharp increase in the incidents of pyrogen reactions reported by centers that do not reuse.

STANDARDS

In the early 1980s, the National Kidney Foundation (NKF) published an interim standard for the reuse of dialyzers [NKF, 1981]. This fairly brief document essentially outlined safe reuse practices that centers intending to reuse dialyzers could follow for guidance. A revision of the document was published in 1984, after an outbreak of mycobacteria infections in a Louisiana center that was attributed to the use of formaldehyde at a concentration insufficient to kill the organism (Brown, et al. 1982). The new edition of the NKF standard essentially consisted only of the recommendation (based on a CDC investigation of the Louisiana incident) that formaldehyde should be used at room temperature in a concentration of 4%.

In 1986, the Association for the Advancement of Medical Instrumentation (AAMI) issued the first edition of a standard for dialyzer reprocessing (AAMI 1986). This document was quite extensive and provided extremely detailed recommendations concerning reprocessing methods, environmental monitoring, quality control, and other aspects of dialyzer reprocessing. In 1991, AAMI issued an interpretation of certain provisions of the standard in order to address how dialysis centers could monitor the clearance performance of dialyzers without necessarily going through the rather demanding validation protocols set forth in the original standard. A second edition of the standard was issued in 1993. This more user-friendly document clarified a great many issues, particularly in regard to monitoring outcomes of reuse practices.

REGULATION OF DIALYZER REPROCESSING

In 1987, the Health Care Financing Administration (HCFA) adopted by reference the 1986 AAMI standard on dialyzer reprocessing, thus giving a voluntary standard the full force of law or regulation. Subsequently, HCFA developed instructions and interpretive guidelines for surveyors and began the process of inspecting dialysis facilities for compliance with the AAMI standard. In 1994, HCFA issued a proposed rule that essentially called for comment on the adoption of the water-quality revisions of the AAMI hemodialysis systems standard (AAMI 1993b) and of the new edition of the AAMI dialyzer reprocessing standard (AAMI 1993a). This rule has not yet become final, with the consequence that HCFA surveyors are still conducting facility audits according to the 1986 AAMI standard instead of the more recent version, which, in many respects, reflects a significant improvement of the original standard.

The Food and Drug Administration (FDA) has developed a *Guidance on Hemodialyzer Reuse Labeling,* which requires "manufacturers of hemodialyzers who distribute to facilities known to reuse that manufacturer's product ..."

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to provide adequate instructions for safe and effective reuse of the device. This document was put into effect February 1997.

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Monitoring Strategies for Reuse Patients and Dialyzers[1]

Bruce Farrow, BS
Total Renal Care[2]

INTRODUCTION

The purpose of patient and dialyzer monitoring is to recognize problems that can be attributed to reprocessing activities and, if problems are found, to take appropriate steps to remedy them.

PATIENT MONITORING

For patients, monitoring should include the measuring of temperature pre- and post-dialysis. If fever (a temperature higher than 100°F [37.8°C]) and/or chills are present, then a pyrogen reaction should be promptly reported and investigated (AAMI 1993b). In suspected cases of pyrogen reaction or bacteremia, the patient's blood should be cultured, and the water used to constitute the germicidal solution should be tested against AAMI's water-quality guidelines (AAMI 1993a). (This document notes that such water should have a bacterial colony count of less than 200 per milliliter [ml] or a bacterial lipopolysaccharide count of less than 1 nanogram [ng]/ml.) The procedures used to monitor and disinfect the water system and to disinfect and sterilize dialyzers, as well as the germicide concentration and dialyzer storage conditions, should also be verified.

Patients should be monitored for other unexplained symptoms as well, such as allergic reactions or pain in the blood-access arm at the beginning of the dialysis treatment. These symptoms could be due to problems associated with either new or reprocessed dialyzers and should be reported properly to the responsible physician. Among the possible causes that should be investigated are the procedures used to remove germicide from reprocessed dialyzers and the procedures used to remove manufacturing residuals from new dialyzers. Hypersensitivity of patients to materials that could be present in new dialyzers is often referred to as "first-use syndrome."

The clinical staff and physicians should be particularly attentive to the occurrence of allergic reactions, because repeated exposure to the causative agent may lead to increasingly severe, even fatal, consequences. To prevent future exposure to an agent suspected of causing an allergic reaction, care should be taken to ensure that all possible sources of the agent are eliminated.

Whenever a patient has a reaction that is thought to be due to reprocessing, one should complete and return to the physician for investigation a "Reprocessed Dialyzer Complaint Report" form. The regulations of the Health Care Financing Administration (HCFA) recommend that operators stop reuse when significant bacterial or pyrogen reactions or other unexplained symptoms are thought to be related to reprocessing; operations cannot resume until the issues are resolved. If one suspects that a patient problem is associated with the reprocessing equipment or supplies identified on the complaint report form, a copy of the form, along with the results of any evaluations performed at the facility, should be sent to the equipment or supply manufacturer for investigation. (The reporting of device-related patient illnesses or injuries to the manufacturer is required by the Safe Medical Devices Act of 1990.)

Patients should be monitored not only for adverse reactions (that can include pyrogenic/septicemic reactions and reactions to chemicals used in reuse), but also for clinical results, i.e. KT/V and URR's, also albumins. In particular, sequential pre- and post-dialysis blood urea nitrogen (BUN) measurements should be taken. If the clinical results do not meet the expectations of the dialysis prescription, adjustments should be made, i.e. blood flow, dialysate, dialyzer charge and increased time.

[1] Presented at "Dialyzer Reprocessing," a short course held on 23 May 1995 in conjunction with the 1995 AAMI Annual Meeting in Anaheim, California.
[2] At the time this paper was presented, Farrow represented Renal Treatment Centers, Inc., Berwyn, Pennsylvania.

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MONITORING DIALYZER FAILURES

The principal types of dialyzer failures that could occur during clinical use are blood leaks and unexplained changes in ultrafiltration characteristics. Such problems could be associated with either new or reprocessed dialyzers. If a patient's clinical condition deteriorates or if there is variability in routine dialysis procedures (e.g., heparinization, ultrafiltration, transfusion requirements), all practices, including reuse, should be investigated.

QUALITY ASSURANCE

Quality assurance (QA) and quality control (QC) activities involve conducting periodic audits, investigating adverse patient reactions and/or dialyzer failures, and participating in the resolution of problems. The findings of QA/QC personnel, supervisors, and other key personnel should include trend analyses to indicate the frequency of particular problems and to detect changes in incidence rates.

The implementation of reuse manuals, training materials, and other written procedures should be reviewed and verified annually. In addition, personnel records should be reviewed for documentation of reuse training and verification of job descriptions. Semiannually, supply information and water system disinfection procedures should be reviewed. Quarterly, complaint investigation files should be reviewed and trend analyses performed. In addition, it should be verified that personnel are wearing the appropriate protective gear during dialyzer handling and reprocessing procedures and that water-quality requirements are being met. Testing for compliance with regulatory limits on occupational exposure to toxic fumes should be performed at least monthly for chemical agents.

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Anticoagulation Strategies for Dialyzer Reprocessing[1]

Jerome Beck
RENAL WEST, Phoenix, Arizona

INTRODUCTION

I do not view heparin therapy—or, to use the broader term, anticoagulation therapy—as a reuse issue, but rather as a true dialysis technique that can vastly affect patient outcomes. Obviously, inadequate anticoagulation can cause problems with residual blood clotting within the dialyzers. As a consequence, patients lose blood and are harmed not only by lowered hematocrit but also by reduced dialysis efficacy through loss of dialyzer surface area. Thus, anticoagulation therapy should be thought of as a quality-of-dialysis issue regardless of whether the facility reuses.

At Renal West, what we have found to be most helpful in addressing the issue is communicating to our staff the importance of proper heparin therapy to their patients. We are not approaching this therapy as a means of increasing the number of dialyzer uses at our facilities, but rather as a means of optimizing dialysis treatment. At one point, the most common reason for dialyzer discard in our reuse program was volume loss due to blood clotting. As a dialyzer's volume decreases, it becomes less and less effective. This decrease occurs in the course of a patient's treatment. Every time there is a low-volume dialyzer failure, one can guess that the patient being treated with that dialyzer received, to some degree, inadequate treatment. Therefore, the greater the frequency of volume failure, the greater the frequency of lowered adequacy.

Again, the key to our success lies in focusing on heparin therapy not as a financial issue but as a quality-of-dialysis issue, in recognition of the fact that proper heparinization minimizes blood loss and thus maximizes dialysis adequacy to the prescription that the physician has ordered.

COMPLEXITY OF HEPARIN

Heparin therapy is a very complex subject for three reasons:

a) *Heparin itself:* Heparin varies in molecular weight and, hence, in level of activity. While the pharmaceutical companies have striven to standardize their products into conventional units of activity, there is still much variability from lot to lot, as much as 10%.
b) *Anticoagulation testing:* Several blood-clot tests can be used to aid in determining the amount of heparin required. Unfortunately, there is much variability from test to test; and even the results of the same test can vary, depending on the reagents used and, more importantly, on the quality of the procedure employed by the staff. Very strict adherence to procedure is extremely critical. Otherwise, clot times can vary significantly even for the same patient.
c) *Patient response:* The response to heparin therapy varies from patient to patient. Over time, even an individual patient's response can change significantly. There is no easy way to determine the appropriate prescription; it cannot be based simply on patient age, sex, weight, or body surface area. Studies performed in surgical units indicate that, from patient to patient, there can be as much as a threefold difference in response to anticoagulation and as much as a fourfold difference in the elimination of heparin over time.

Clearly, then, heparin therapy can be complicated.

PROPERTIES AND ACTIONS OF HEPARIN

Heparin is an anionic mucopolysaccharide. Variations in its molecular weight cause the variations in its activity level. There are two principal sources of heparin: pork intestine and beef lung.

Antithrombin-3 is the blood component that counteracts the clotting tendency of the blood. Heparin increases the activity level of antithrombin-3, which helps promote anticoagulation. The half-life of heparin ranges from 30 to 120 minutes, with a total duration of 4 to 6 hours. These values are very patient-dependent. Some patients eliminate

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heparin very quickly, while others have high heparin activity for extended periods of time. Sensitivity also varies patient to patient.

Although proper heparin therapy is critical to quality patient outcomes, it is important not to abuse it. We must be very aware of the fact that heparin therapy can give rise to several complications. The complication that is probably the most obvious is prolonged, vascular-site bleeding. Other problems include hemotoma, ecchymosis, nosebleeds, and the worsening of already existing bleeding tendencies. Finally, there seems to be some relationship between chronic heparin therapy and osteoporosis.

ASSESSMENT OF HEPARIN NEEDS

Several patient factors may increase heparin demand. First, if the patient's hematocrit rises, it may be necessary to consider using higher levels of heparin. Second, fever presents an increased risk of clotting, so the heparin dose may have to be adjusted. Similarly, thromboses and various gram-negative infections can cause an increase in the clotting tendency and, again, create the need for higher heparin levels. Other conditions that may increase heparin demand include diabetic nephropathy, myocardial infarction, cancer, and various liver diseases.

In terms of treatment factors, lower blood-flow rates and longer treatment times typically create higher heparin needs. Any blood or lipid infusion during treatment can also necessitate an increase in heparin. The type of dialyzer often has an impact, although probably minimal. It is imperative that clinical staff be taught to monitor the circuit for clotting during the course of treatment. At Renal West, we periodically inject a saline bolus of about 100 to 200 ccs to enable us to visualize clearly the entire extracorporeal circuit and identify any clotting that may be occurring. We employ this procedure primarily on new patients as we establish their heparin dose.

There are times, of course, when heparin levels should be reduced. Generally, the lower the hematocrit, the less heparin is required. It is important to examine very carefully the patient's risk factors. Any bleeding event, a history of bleeding problems, or recent surgery generally will result in reduced heparin needs. As the quality of patient access increases, allowing higher blood flow rates, it is possible to reduce heparin demand. Shorter treatment times, as well as frequent saline rinses, can reduce heparin requirements.

It is critical to be aware of the medications that patients are taking, especially when patients have difficulty communicating their medical status. In our nursing-home patients, for example, who are somewhat incapacitated, we have seen on occasion sudden, significant changes in clotting with a heparin regimen that had previously been successful — only to find that, unbeknownst to us, coumadin had been prescribed. Other medications, such as ibuprofen, also affect clotting and, thus, the required heparin level.

How is intradialytic clotting assessed? The most widely used approach is some type of clotting time. Clot times are a valuable tool, although many facilities have abandoned them over the last couple of years because of the Clinical Laboratory Improvement Amendments (CLIA). Visual inspection of the extracorporeal circuit is imperative and is easy to perform by means of the saline flushes mentioned earlier. If saline flushes are not used, one can look for darkening within various portions of the dialyzer and blood tines. Extracorporeal circuit pressure measurements are also good indicators. Finally, clotting can be detected after the dialysis treatment when reprocessing personnel are flushing and cleaning the dialyzer. Communication between reprocessing personnel and clinical personnel is critical.

HEPARINIZATION METHODS

For most patients (i.e., for patients who possess no known bleeding risk), routine systemic heparinization is recommended. The ideal intradialytic clotting time is one and a half to two times the baseline clotting time. Some clinicians do not recommend such high clotting times. However, we have found that clotting times as high as double the baseline are very effective and safe. At the end of treatment, there should be some residual anticoagulation remaining, and the clotting time often recommended is 1.4 times the baseline.

There are two ways to perform routine heparinization. First, there is intermittent bolusing. A pretreatment bolus is given 3 to 5 minutes before dialysis begins, and additional boluses are given intermittently during treatment as a means of maintaining anticoagulation. The second method is continuous infusion. Here again, a pretreatment bolus is given 3 to 5 minutes in advance. Then, heparin is continuously infused throughout the entire treatment or at least

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