

# CJASN

## CJASN's **Role of the Medical Director Series**

*Providing an invaluable resource for practicing nephrologists and nephrology trainees*

A guide to one of the most important, challenging, and rewarding aspects of the nephrologist's professional career, that of the dialysis clinic medical director, is available within this comprehensive 9-part series available now in a user-friendly compiled pdf file.

**Series Editors:**

Jeffrey L. Hymes, MD  
Robert Provenzano, MD

**Deputy Editor:**

Paul M. Palevsky, MD, FASN

**Editor-in-Chief:**

Gary C. Curhan, MD, ScD, FASN

# CJASN

Clinical Journal of the American Society of Nephrology

## Role of the Medical Director

- Article 1** **Introduction: Role of the Medical Director Series**  
*Robert Provenzano and Jeffrey L. Hymes*
- Article 2** **The Evolving Role of the Medical Director of a Dialysis Facility**  
*Franklin W. Maddux and Allen R. Nissenson*
- Article 3** **The Medical Director and Quality Requirements in the Dialysis Facility**  
*Brigitte Schiller*
- Article 4** **Maintaining Safety in the Dialysis Facility**  
*Alan S. Kliger*
- Article 5** **Infection Prevention and the Medical Director: Uncharted Territory**  
*Toros Kapoian, Klemens B. Meyer, and Douglas S. Johnson*
- Article 6** **What Medical Directors Need to Know about Dialysis Facility Water Management**  
*Ted Kasparek and Oscar E. Rodriguez*
- Article 7** **The Medical Director in Integrated Clinical Care Models**  
*Thomas F. Parker III and George R. Aronoff*
- Article 8** **Managing Disruptive Behavior by Patients and Physicians: A Responsibility of the Dialysis Facility Medical Director**  
*Edward R. Jones and Richard S. Goldman*
- Article 9** **Legal Issues for the Medical Director**  
*William G. Trulove*
- Article 10** **Medical Director Responsibilities to the ESRD Network**  
*Peter B. DeOreo and Jay B. Wish*

# CJASN

Clinical Journal of the American Society of Nephrology

## Editors

---

### Editor-in-Chief

Gary C. Curhan, MD, ScD, FASN  
*Boston, MA*

### Deputy Editors

Kirsten L. Johansen, MD  
*San Francisco, CA*

Paul M. Palevsky, MD, FASN  
*Pittsburgh, PA*

## Associate Editors

---

Michael Allon, MD  
*Birmingham, AL*

Jeffrey C. Fink, MD, MS, FASN  
*Baltimore, MD*

Linda F. Fried, MD, MPH, FASN  
*Pittsburgh, PA*

David S. Goldfarb, MD, FASN  
*New York, NY*

Donald E. Hricik, MD  
*Cleveland, OH*

Mark M. Mitsnefes, MD  
*Cincinnati, OH*

Ann M. O'Hare, MD  
*Seattle, WA*

Mark A. Perazella, MD, FASN  
*New Haven, CT*

Vlado Perkovic, MBBS, PhD, FASN, FRACP  
*Sydney, Australia*

Katherine R. Tuttle, MD, FACP, FASN  
*Spokane, WA*

Sushrut S. Waikar, MD  
*Boston, MA*

## Section Editors

---

### Attending Rounds Series Editor

Mitchell H. Rosner, MD, FASN  
*Charlottesville, VA*

### Education Series Editor

Suzanne Watnick, MD  
*Portland, OR*

### Ethics Series Editor

Alvin H. Moss, MD, FACP  
*Morgantown, WV*

### Public Policy Series Editor

Alan S. Kliger, MD  
*New Haven, CT*

### Role of the Medical Director Series Co-Editors

Jeffrey L. Hymes, MD  
*Nashville, TN*

Robert Provenzano, MD  
*Detroit, MI*

## Statistical Editors

---

Ronit Katz, DPhil  
*Seattle, WA*

Robert A. Short, PhD  
*Spokane, WA*

## Editor-in-Chief, Emeritus

---

William M. Bennett, MD, FASN  
*Portland, OR*

## Managing Editor

---

Shari Leventhal  
*Washington, DC*

# CJASN

Clinical Journal of the American Society of Nephrology

## Editorial Board

Rajiv Agarwal  
*Indianapolis, Indiana*

Ziyad Al-Aly  
*Saint Louis, Missouri*

Charles Alpers  
*Seattle, Washington*

Sandra Amaral  
*Philadelphia, Pennsylvania*

Jerry Appel  
*New York, New York*

Arif Asif  
*Miami, Florida*

Mohamed Atta  
*Baltimore, Maryland*

Joanne Bargman  
*Toronto, ON, Canada*

Brendan Barrett  
*St. John's, NL, Canada*

Srinivasan Beddhu  
*Salt Lake City, Utah*

Jeffrey Berns  
*Philadelphia, PA*

Geoffrey Block  
*Denver, Colorado*

W. Kline Bolton  
*Charlottesville, Virginia*

Andrew Bomback  
*New York, New York*

Ursula Brewster  
*New Haven, Connecticut*

Patrick Brophy  
*Iowa City, Iowa*

Emmanuel Burdman  
*São Paulo, Brazil*

Kerri Cavanaugh  
*Nashville, Tennessee*

Micah Chan  
*Madison, Wisconsin*

Anil Chandraker  
*Boston, Massachusetts*

David Charytan  
*Boston, Massachusetts*

Michael Choi  
*Baltimore, Maryland*

Michel Chonchol  
*Denver, Colorado*

Steven Coca  
*New Haven, Connecticut*

Andrew Davenport  
*London, United Kingdom*

Ian de Boer  
*Seattle, Washington*

Bradley Dixon  
*Iowa City, Iowa*

Lance Dworkin  
*Providence, Rhode Island*

Jeffrey Fadrowski  
*Baltimore, Maryland*

Derek Fine  
*Baltimore, Maryland*

Kevin Finkel  
*Houston, Texas*

Steven Fishbane  
*Mineola, New York*

John Forman  
*Boston, Massachusetts*

Lui Forni  
*Worthing, United Kingdom*

Barry Freedman  
*Winston Salem, North Carolina*

Masafumi Fukagawa  
*Kanagawa, Japan*

Susan Furth  
*Philadelphia, PA*

Martin Gallagher  
*Sydney, Australia*

Maurizio Gallieni  
*Milan, Italy*

Ronald Gansevoort  
*Groningen, Netherlands*

Amit Garg  
*London, ON, Canada*

Michael Germain  
*Springfield, Massachusetts*

Eric Gibney  
*Atlanta, Georgia*

John Gill  
*Vancouver, BC, Canada*

David Goldsmith  
*London, United Kingdom*

Stuart Goldstein  
*Cincinnati, Ohio*

Barbara Greco  
*Springfield, Massachusetts*

Orlando Gutierrez  
*Birmingham, Alabama*

Yoshio Hall  
*Seattle, Washington*

Lee Hamm  
*New Orleans, Louisiana*

Ita Heilberg  
*São Paulo, Brazil*

Brenda Hemmelgarn  
*Calgary, AB, Canada*

Jonathan Himmelfarb  
*Seattle, Washington*

Eric Hoste  
*Gent, Belgium*

Chi-yuan Hsu  
*San Francisco, California*

T. Alp Ikizler  
*Nashville, Tennessee*

Tamara Isakova  
*Chicago, Illinois*

Meg Jardine  
*Sydney, Australia*

Michelle Josephson  
*Chicago, Illinois*

Bryce Kiberd  
*Halifax, BC, Canada*

Greg Knoll  
*Ottawa, ON, Canada*

Jay Koynier  
*Chicago, Illinois*

Holly Kramer  
*Maywood, Illinois*

Manjula Kurella Tamura  
*Palo Alto, California*

Hiddo Lambers Heerspink  
*Groningen, Netherlands*

Craig Langman  
*Chicago, Illinois*

James Lash  
*Chicago, Illinois*

Eleanor Lederer  
*Louisville, Kentucky*

Andrew Lewington  
*Leeds, United Kingdom*

Orfeas Liangos  
*Coburg, Germany*

Fernando Líaño  
*Madrid, Spain*

John Lieske  
*Rochester, Minnesota*

Kathleen Liu  
*San Francisco, California*

Randy Luciano  
*New Haven, Connecticut*

Jicheng Lv  
*Beijing, China*

Mark Marshall  
*Auckland, New Zealand*

William McClellan  
*Atlanta, Georgia*

Anita Mehrotra  
*New York, New York*

Rajnish Mehrotra  
*Seattle, Washington*

Michal Melamed  
*Bronx, New York*

Sharon Moe  
*Indianapolis, Indiana*

Barbara Murphy  
*New York, New York*

Nader Najafian  
*Boston, Massachusetts*

Andrew Narva  
*Bethesda, Maryland*

Sankar Navaneethan  
*Cleveland, Ohio*

Alicia Neu  
*Baltimore, Maryland*

Thomas Nickolas  
*New York, New York*

Toshiharu Ninomiya  
*Fukuoka, Japan*

Rainer Oberbauer  
*Vienna, Austria*

Gregorio Obrador  
*Mexico*

Runolfur Palsson  
*Reykjavik, Iceland*

Mandip Panesar  
*Buffalo, New York*

Neesh Pannu  
*Edmonton, Canada*

Rulan Parekh  
*Baltimore, Maryland*

Uptal Patel  
*Durham, North Carolina*

Aldo Peixoto  
*West Haven, Connecticut*

Anthony Portale  
*San Francisco, California*

Jai Radhakrishnan  
*New York, New York*

Mahboob Rahman  
*Cleveland, Ohio*

Dominic Raj  
*Washington, District of Columbia*

Peter Reese  
*Philadelphia, Pennsylvania*

Giuseppe Remuzzi  
*Bergamo, Italy*

Mark Rosenberg  
*Minneapolis, Minnesota*

Andrew Rule  
*Rochester, Minnesota*

Jeffrey Saland  
*New York, New York*

Jane Schell  
*Pittsburgh, Pennsylvania*

Bernd Schröppel  
*Ulm, Germany*

Stephen Seliger  
*Baltimore, Maryland*

Michael Shlipak  
*San Francisco, California*

Edward Siew  
*Nashville, Tennessee*

Theodore Steinman  
*Boston, Massachusetts*

Peter Stenvinkel  
*Stockholm, Sweden*

Harold Szerlip  
*Augusta, Georgia*

Eric Taylor  
*Boston, Massachusetts*

Ashita Tolwani  
*Birmingham, Alabama*

James Tumlin  
*Chattanooga, Tennessee*

Mark Unruh  
*Albuquerque, New Mexico*

Raymond Vanholder  
*Gent, Belgium*

Anitha Vijayan  
*St. Louis, Missouri*

Ron Wald  
*Toronto, ON, Canada*

Michael Walsh  
*Hamilton, ON, Canada*

Matthew Weir  
*Baltimore, Maryland*

Steven Weisbord  
*Pittsburgh, Pennsylvania*

Jessica Weiss  
*Portland, Oregon*

Adam Whaley-Connell  
*Columbia, Missouri*

Colin White  
*Vancouver, BC, Canada*

Mark Williams  
*Boston, Massachusetts*

Alexander Wiseman  
*Aurora, Colorado*

Jay Wish  
*Indianapolis, IN*

Myles Wolf  
*Chicago, Illinois*

Jerry Yee  
*Detroit, Michigan*

Bessie Young  
*Seattle, Washington*

Eric Young  
*Ann Arbor, Michigan*

Carmine Zoccali  
*Reggio Calabria, Italy*

**Executive Director**

Tod Ibrahim

**Director of Communications**

Robert Henkel

**Managing Editor**

Shari Leventhal

The American Society of Nephrology (ASN) marks 50 years of leading the fight against kidney diseases in 2016. Throughout the year, ASN will recognize kidney health advances from the past half century and look forward to new innovations in kidney care. Celebrations will culminate at ASN Kidney Week 2016, November 15–20, 2016, at McCormick Place in Chicago, IL.

[www.cjasn.org](http://www.cjasn.org)

Submit your manuscript online through Manuscript Central at <http://mc.manuscriptcentral.com/cjasn>.

**Contacting CJASN**

Correspondence regarding editorial matters should be addressed to the Editorial Office.

**Editorial Office**

Clinical Journal of the American Society of Nephrology  
1510 H Street, NW, Suite 800  
Washington, DC 20005  
Phone: 202-503-7804; Fax: 202-478-5078  
E-mail: [sleventhal@cjasn.org](mailto:sleventhal@cjasn.org)

**Contacting ASN**

Correspondence concerning business matters should be addressed to the Publishing Office.

**Publishing Office**

American Society of Nephrology  
1510 H Street, NW, Suite 800  
Washington, DC 20005  
Phone: 202-640-4660; Fax: 202-637-9793  
E-mail: [email@asn-online.org](mailto:email@asn-online.org)

**Membership Queries**

For information on American Society of Nephrology membership, contact Pamela Gordon at 202-640-4668; E-mail: [pgordon@asn-online.org](mailto:pgordon@asn-online.org)

**Subscription Services**

ASN Journal Subscriptions  
1510 H Street NW, Suite 800  
Washington, DC 20005  
Phone: 202-557-8360; Fax: 202-403-3615  
E-mail: [bhenkel@asn-online.org](mailto:bhenkel@asn-online.org)

**Commercial Reprints/ePrints**

Hope Robinson  
Sheridan Content Services  
The Sheridan Press  
450 Fame Avenue  
Hanover, Pennsylvania 17331  
Phone: 800-635-7181, ext. 8065  
Fax: 717-633-8929  
E-mail: [hrobinson@tsp.sheridan.com](mailto:hrobinson@tsp.sheridan.com)

**Indexing Services**

The Journal is indexed by NIH NLM's PubMed MEDLINE; Elsevier's Scopus; and Thomson Reuters' Science Citation Index Expanded (Web of Science), Journal Citation Reports - Science Edition, Research Alert, and Current Contents/Clinical Medicine.

**Display Advertising**

The Walchli Tauber Group  
2225 Old Emmorton Road, Suite 201  
Bel Air, MD 21015  
Mobile: 443-252-0571  
Phone: 443-512-8899 \*104  
E-mail: [kim.boyd@wt-group.com](mailto:kim.boyd@wt-group.com)

**Classified Advertising**

The Walchli Tauber Group  
2225 Old Emmorton Road, Suite 201  
Bel Air, MD 21015  
Phone: 443-512-8899 \*106  
E-mail: [rhonda.truitt@wt-group.com](mailto:rhonda.truitt@wt-group.com)

**Change of Address**

The publisher must be notified 60 days in advance. Journals undeliverable because of incorrect address will be destroyed. Duplicate copies may be obtained, if available, from the Publisher at the regular price of a single issue.

**Disclaimer**

The statements and opinions contained in the articles of *The Clinical Journal of the American Society of Nephrology* are solely those of the authors and not of the American Society of Nephrology or the editorial policy of the editors. The appearance of advertisements in the Journal is not a warranty, endorsement, or approval of the products or services advertised or of their effectiveness, quality, or safety. The American Society of Nephrology disclaims responsibility for any injury to persons or property resulting from any ideas or products referred to in the articles or advertisements.

The Editor-in-Chief, Deputy, Associate, and Series Editors, as well as the Editorial Board disclose potential conflicts on an annual basis. This information is available on the CJASN website at [www.cjasn.org](http://www.cjasn.org).

**POSTMASTER:** Send changes of address to Customer Service, *CJASN Clinical Journal of the American Society of Nephrology*, 1510 H Street, NW, Suite 800, Washington, DC 20005. *CJASN Clinical Journal of the American Society of Nephrology*, ISSN 1555-9041 (Online: 1555-905X), is an official journal of the American Society of Nephrology and is published monthly by the American Society of Nephrology. Periodicals postage at Washington, DC, and at additional mailing offices. Subscription rates: domestic individual \$438; international individual, \$588; domestic institutional, \$970; international institutional, \$1120; single copy, \$75. To order, call 504-942-0902. Subscription prices subject to change. Annual dues include \$33 for journal subscription. Publications mail agreement No. 40624074. Return undeliverable Canadian addresses to PO Box 503 RPO West Beaver Creek Richmond Hill ON L4B 4R6. Copyright © 2016 by the American Society of Nephrology.

∞ This paper meets the requirements of ANSI/NISO Z39.48-1992 (Permanence of Paper), effective with January 2006, Vol. 1, No. 1.

## Introduction: Role of the Medical Director Series

Robert Provenzano\* and Jeffrey L. Hymes<sup>†</sup>

*Clin J Am Soc Nephrol* 10: 325, 2015. doi: 10.2215/CJN.11811214

Nephrology has been a leader in the delivery of high-quality metric- and value-driven care for many years. Some of the reasons for this derive from the unique history and payment system for the care of patients with ESRD. Early in the ESRD program and continuing today, the Renal Network System focused on quality and safety. Simultaneously, the US Centers for Medicare and Medicaid Services (CMS) and its regulatory requirements drove improved outcomes. The US Renal Data System data set defined observational benchmarks, and the ability of dialysis organizations to execute processes focused on improving quality of care, helped move our subspecialty forward. The role of the medical director as a focal point in facility-driven quality care has been key to this evolution. In our opinion, this has been a unique feature of renal medicine compared with other specialties.

The roles and responsibilities of medical directors have changed and increased significantly since 1972, when Medicare entitlement was extended to those with kidney failure, irrespective of age (1). In October 2008, the CMS reissued the Conditions for Coverage (CfC) updating and clarifying the role of the medical director for the first time in 30 years (2,3). This update not only helped crystalize the role but expanded its importance as medicine evolves from a volume- to value-based system. Today, with >600,000 patients under the care of nephrologists, the role of the medical director has become even more critical in the management of this complex patient cohort (4).

Medical directors no longer practice in isolation but are integral members of the larger team of renal providers and are empowered by data and tools to drive improved renal outcomes. In this issue of *CJASN*, we begin a series on the role of the dialysis facility medical director. This series brings together content and experiential experts to provide a broad-based practical compendium for all medical directors, both experienced as well as novice. This series will serve as a reference and repository of the expertise of our colleagues, many of whom have helped build and shape the field of nephrology.

In this series, the authors practically interpret the CfC, and add their experience and expertise to better define the role and responsibilities of medical directors. In this issue, Drs. Maddux and Nissenson, who serve as the chief medical officers of the two largest dialysis providers in the United States, provide an overview of the evolving role of the dialysis facility medical

director. In subsequent issues, experts in patient safety and quality, water treatment, and infection control will propel these subjects to the expectations of 21st century renal care. The broader responsibility of a single facility in an integrated renal care model will also be explored, defining the pivotal role of the medical director in bridging the fragmented, facility, renal clinic or office, and hospital environments in the world of integrated renal care. Discussions of the vexing problem of dealing with challenging patients and colleagues, the legal implications of being a medical director, and the medical director's relationship to the regional ESRD Networks, will complete the series.

In this series, the authors have created a guide to one of the most important, challenging, and rewarding aspects of the nephrologist's professional career, that of the dialysis clinic medical director. This is a critical, expanding, and exciting role. The success of the subspecialty of nephrology depends not only on properly executing the basic "blocking and tackling" as articulated in this series, but also on rising to the next level of performance required of true leaders in the field of renal medicine.

### Disclosures

R.P. is employed by and is a shareholder of DaVita Healthcare Partners and is also a shareholder of Vasc-Alert LLC, Nephroceuticals LLC, and Roo LLC. J.L.H. is chief medical officer of Fresenius Medical Services and serves on the Renal Physicians Association's Board of Directors and the Nephroceuticals LLC Scientific Advisory Board.

### References

1. Social Security Administration: Social Security Amendments of 1972: Public Law 92-603. *Fed Regist* 75: 1329–1493, 1972
2. US Centers for Medicare and Medicaid Services: 42 CFR 494: Conditions for Coverage for End-Stage Renal Disease Facilities. *Fed Regist* 73: 20475–20484, 2008
3. US Centers for Medicare and Medicaid Services: Interpretive guidance for conditions for coverage. Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>. Accessed December 5, 2014
4. US Renal Data System: *2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2012

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

\*DaVita Inc, Detroit, Michigan; and  
<sup>†</sup>Fresenius Medical Care North America, Nashville, Tennessee

### Correspondence:

Dr. Robert Provenzano, DaVita Inc, 22201 Moross Road, Suite 150, Detroit, MI 48236-2100. Email: [robert.provenzano@davita.com](mailto:robert.provenzano@davita.com)

## The Evolving Role of the Medical Director of a Dialysis Facility

Franklin W. Maddux\* and Allen R. Nissenson†

### Abstract

The medical director has been a part of the fabric of Medicare's ESRD program since entitlement was extended under Section 2991 of Public Law 92-603, passed on October 30, 1972, and implemented with the Conditions for Coverage that set out rules for administration and oversight of the care provided in the dialysis facility. The role of the medical director has progressively increased over time to effectively extend to the physicians serving in this role both the responsibility and accountability for the performance and reliability related to the care provided in the dialysis facility. This commentary provides context to the nature and expected competencies and behaviors of these medical director roles that remain central to the delivery of high-quality, safe, and efficient delivery of RRT, which has become much more intensive as the dialysis industry has matured.

*Clin J Am Soc Nephrol* 10: 326–330, 2015. doi: 10.2215/CJN.04920514

### History of the Role of the Medical Director in ESRD Care

The Medicare program was 7 years old when entitlement was extended in 1972 to those with disabilities independent of age. The definition of “disabled” included those with CKD who required dialysis or a kidney transplant for survival—they “shall be deemed disabled” for purposes of Medicare parts A and B (1). What was thought to be a small, socially redeeming program, has grown to >600,000 patients with increasingly complex chronic comorbid conditions, and a total cost of >\$40 billion. Currently, 1.3% of all Medicare beneficiaries are covered under the ESRD Program and consume nearly 8% of all Medicare dollars.

With the implementation of the entitlement in 1973, there was gentle growth in outpatient dialysis facilities. These were part of academic institutions or in the community, and had clinical oversight provided by nephrologists, who participated in administration of the facility (“medical director”) as well as provided individual patient care (“attending nephrologist”). As the program began to grow, it became clear that regulatory oversight by the US Centers for Medicare and Medicaid Services (CMS), then the Health Care Financing Administration (HCFA), needed to be codified. Thus, the initial Conditions for Coverage (CfC) were issued to govern the operation of dialysis facilities.

The initial CfC mandated that every facility have a physician as medical director whose responsibilities included creating, reviewing, and updating facility policies and procedures; ensuring appropriate modality education and selection for all patients; overseeing training of staff; and ensuring safe and effective dialysis treatments. The physician director was to be board eligible or certified in internal medicine or pediatrics and had to have at least 12 months of experience caring for patients on dialysis. The same nephrologists were

delivering direct patient care and participating on the governing body to ensure that the facility was running properly. This proved confusing for some nephrologists who could not separate the patient care role from the administrative role as medical director. Some physicians seemed to treat the medical directorship as an “honorary” position without setting aside specific administrative time to accomplish the job. Of note, even the HCFA had a lack of clarity about the medical director role. When facilities were found deficient during routine surveys, the facility (not the medical director) was cited even if the area of deficiency was a direct medical director responsibility.

As the dialysis industry consolidated during the 1990s, nephrologists were contracting with dialysis companies to provide medical director services. This contractual relationship came with more explicit expectations of the duties of the medical director and rudimentary systems of accountability to monitor delivery of these duties. In 2002, the US Department of Health and Human Services Office of Inspector General (OIG) issued a report titled “Clinical Performance Measures for Dialysis Facilities: Lessons Learned by the Major Dialysis Corporations and Implications for Medicare” (2). Among a number of recommendations to the CMS in that report to help improve the healthcare outcomes for dialysis patients was that the CfC be revised so that they “require facility medical directors to exert leadership in quality improvement” (2). In 2008, a revised CfC was published that spelled out the responsibilities of the medical director more clearly and completely, as recommended by the OIG report in concert with CfC Interpretive Guidelines to foster correct interpretation of the CfC (3). The medical director is not solely held responsible for every aspect of care provided in the dialysis facility, but is recognized in 53 V-Tag segments of the interpretive

\*Fresenius Medical Care North America, Waltham, Massachusetts; and †DaVita HealthCare Partners, Denver, Colorado

### Correspondence:

Dr. Franklin W. Maddux, Fresenius Medical Care North America, 920 Winter Street, Waltham, MA 02451-1457. Email: frank.maddux@fmc-na.com

guidelines to the CfC (4) (Supplemental Table 1). The facility is still the entity sanctioned by the CMS if a medical director does not carry out his or her responsibilities, although dialysis organizations are developing increasingly specific contracts that delineate medical director expectations and consequences for underperformance. Being a medical director is not an entitlement; rather, it is an essential role to ensure high performance and high reliability in providing care within the dialysis facility.

### Evolution of the Delivery System for ESRD Care

Dialysis facilities were initially developed with a governing body including the facility administrator or chief/head nurse, a medical director, and an interdisciplinary team. The latter consisted of registered nurses, machine technicians, dietitians, and social workers. Before 1990, dialyzers were commonly reprocessed and few injectable medications were administered during dialysis beyond intravenous antibiotics. By 1990, as the patient population expanded and technical and medication advances were adopted, the system for delivering care changed when many more patients began dialyzing with reprocessed dialyzers, dialysis equipment became more sophisticated with enhanced safety features, and dialyzers and concentrate solutions obviated the severe hypotension seen with earlier-generation therapies. In addition, the widespread availability of intravenous erythropoietin, iron, and vitamin D improved anemia and metabolic bone disease management. With the introduction of erythropoietin and intravenous vitamin D, registered nurses were needed to spend more time administering medications than caring directly for patients, whereas increasing responsibility for placing dialysis needles and setting up and tearing down machines was part of the job of the technician. During this time, the dialysis facility administrators were often not nurses, but business administrators. These changes in the interdisciplinary team along with an increasing acuity of patients have made the role of the medical director increasingly one of senior leadership, coach, and head of the care team and facility medical staff. The medical director role emphasizes enhanced accountability for oversight of a more complex technical and regulatory environment of the modern dialysis facility.

### Perspectives on the Medical Director Role

The medical director of a dialysis facility incorporates both clinical knowledge and administrative capabilities in helping to guide the facility toward high performance and high reliability. There are three primary focus areas with regard to this administrative role, including regulatory requirements, medical practice standards, and operational oversight with the dialysis provider business leadership (5–11). The medical director is not asked to care directly for any given patient; rather, the medical director provides population management and implement processes, methods, and tools for delivering care of the highest quality in a safe and efficient manner.

The CfC and associated interpretive guidelines define areas in which the medical director has distinct responsibility and accountability for overseeing and leading facility performance independent of the ownership or organizational

characteristics of the dialysis facility. These areas of influence include infection control, water and dialysate quality, reuse of dialyzers, physical environment, patient assessment standards, patient plan of care processes, quality assessment and performance improvement, personnel qualifications, and governance of the facility.

Each of the CfC regulated areas is noted in a distinct nomenclature known as the V-Tag (a computer-identified tag in interpretive guidelines to the CfC). For example, infection control references the medical director in two V-Tags, in which the medical director participates in defining the infection control culture and policies and is expected to be responsive to a surveyor when asked about the infection control program and reporting mechanisms. Furthermore, there are 16 V-Tags related to water quality. Each of these recognizes the expectation that the medical director is knowledgeable of the water treatment system installed in order to be sure that the water quality meets the Association for the Advancement of Medical Instrumentation water quality standards for dialysis.

The physical environment, patient assessment, and plan of care areas have three to four V-Tags, each of which relate to the medical director's role in ensuring that emergency equipment and drugs are available and that staff are properly trained. Patient assessment frequencies and content are regulated by the CfC, including ensuring that each patient has a valid dialysis prescription delivered in a safe physical environment. The quality assessment and performance improvement V-Tag recognizes the medical director's role in leading the interdisciplinary team in the measurement, observation, interpretation, and planning for quality care process improvement within the dialysis facility.

There are four V-Tags in which the medical director must provide assessment of clinical and medical staff capability within the dialysis facility, as well as the disciplines surrounding patient care technician (PCT) training. Furthermore, support of governing body rules for staffing and employing technical, PCT, and nursing positions are part of the medical director role. This includes staff education, training and competency assessment of staff, and logistics of admitting patients to facilities.

Finally, the medical director is recognized no less than seven times in V-Tags related to the governance of dialysis facilities, having close communication with the governing body regarding quality assessment and performance improvement, orientation and communication with the medical staff, assurance of compliance to governing body decisions, clear plans for dealing with patient grievances, and decision making on whether any condition with the facility would prohibit the ability to deliver safe treatments (12).

### A Clearer Role

Originally, the medical director role was narrow and focused singularly on the clinical policies and procedures in the dialysis facility. In the early years after the Medicare entitlement, the dialysis facility medical directorship was prestigious and an honor. The revision to the CfC in 2008 became explicit about the expectations of the work involved gauged to accommodate 25% of the medical directors' total work time. This move toward active and engaged executive



leadership was a tremendous change in the responsibility and accountability for medical directors. As the dialysis providers began to consolidate, the medical director became the central authority for observing and molding practice patterns by the full medical staff in their facility, guided by the medical leadership of the dialysis provider organization. Such facility practice patterns are dictated by the clinical and medical needs of the patients, the safe environment of the facility, and a highly integrated reporting and analysis process. The role of the medical director has evolved into a key decision-making component on both the delivery of clinical services and operations at the dialysis facility.

## Skill Sets

### Distinctive Roles for Patient Care and Administration

Most medical directors are also attending physicians with some number of patients being treated at the dialysis facility. One of the great distinctions of the medical director role is that the primary purpose is not the care of any individual patient or clinical circumstance; rather, the medical director manages both the administrative and population management needs of the facility as a whole. The development of a strong clinical staff and the ability to distinguish individual patient care decisions as an attending nephrologist and the administrative role as a medical director in the dialysis facility are challenges that each medical director must master.

### A Need for Facility Population Management Skills

Although not explicitly stated in the CfC, to fulfill the contemporary responsibilities as medical director, the nephrologist is accountable for the health outcomes of a discrete population of patients, those who are receiving care within their dialysis facility (13). If this is done well, the need for emergency department visits, hospitalizations, and costly procedures will be minimized. This concept is not one that nephrologists fully understand or have been exposed to in training. Overall facility measurement of outcomes, generally driven by protocols and algorithms, are key to successful population management, and robust data and analytics are necessary to provide the medical director with the information needed to manage the population. This is one of the most challenging parts of a medical director role because it means working with other physicians in the facility to ensure adoption of standardized care protocols and organized systems of care, always recognizing that the art of medicine is deciding when a protocol should *not* be followed. Finally, true population management requires the medical director to work with the interdisciplinary team, attending nephrologists, and patients to engage patients in their own care, which is essential for driving the best outcomes. The need for discreet population management skills is consistent with the requirement for medical directors to provide a patient-centered safe environment of quality care as articulated by Medicare in its Quality Strategy Document 2014 (14).

### Team Leadership

The medical director acts as the senior clinical leader in a dialysis facility and is responsible for both communicating and listening to the medical staff in determination of those clinical policies to which the whole medical staff will adhere.

Beyond this, the medical director retains a responsibility for the clinical strength of the interdisciplinary team members including clinical nursing staff, PCTs, dieticians, social workers, and any other ancillary staff that interact with the patient population. The medical director should include in his or her purview the operational leadership that has great effect on the patients' experience of care and ultimately quality of life. The close working relationship of this team is frequently the critical factor in developing a high-performing and highly reliable dialysis facility. The medical director must present clear leadership that distinctly sets the tone and culture for all staff that work with patients in the facility and exemplifies the primary goal of delivery of high-quality, safe, and effective RRT.

### Business Acumen

An effective medical director is asked to be more capable of influencing effective operations, culture, staff development, education, and sustainability of the facility. Medical directors should seek and obtain background in basic business principles so that they can understand how to influence good decisions about equipment, standardized processes, and hiring. This knowledge supports the need for developing a sustainable, healthy dialysis facility. Although specifics regarding business competency are not a regulatory requirement of the CfC, such expertise enhances the effectiveness of the medical director. When a medical director does not participate in the business and operational decisions regarding the promotion of safe, effective, and efficient care, the facility will suffer sustainability risk. Therefore, as the senior clinical leader within an individual dialysis facility, the medical director should take an active and engaged role in fostering strategies to improve the facility performance regarding clinical quality, operational excellence, and financial viability.

### Technical Skills and Background

The medical director should have completed a full, comprehensive fellowship in nephrology that includes hands-on care of hemodialysis and peritoneal dialysis patients. It is highly desirable for training to include technical aspects of dialysis in addition to the medical care of dialysis patients. Experience such as setting up dialysis equipment, inserting dialysis needles, monitoring treatments, and shadowing biomedical personnel all are invaluable to a prospective medical director. Finally, an understanding of the regulatory environment in which dialysis facilities operate is essential for a medical director because he or she is responsible for ensuring that all regulatory requirements are met so that high-quality, safe, and efficient dialysis is delivered to all patients at all times (15,16).

### Managing a Medical Staff

One of the most challenging responsibilities of a medical director is overseeing the activities of the medical staff, some members of whom may be part of the medical director's nephrology group and others may be part of competing groups. All consider themselves equals with the medical director, which can create points of conflict. This part of a medical director's role is one of the most challenging, but really involves developing, fostering, and reinforcing a true team mentality among the medical staff

members independent of the practice relationships represented within an individual facility medical staff (17,18). This effort is most effective when the medical director can get the medical staff to have a shared vision and goal for the facility, as well as clarity about the distinctive roles of the medical director and attending nephrologist. This includes robust, frequent, clear communication, and creation of a culture of mutual trust, respect, and adoption of evidenced-based care pathways or protocols.

### Governing Body Leadership

The medical director plays an active role in helping to guide and influence the governing body toward rational choices and correct decisions in the development of a high-performing and highly reliable dialysis facility. The medical director may be the chief executive officer of the facility in some cases, whereas the medical director may simply be a member of the governing body in others. This governing body's role is to recognize both the direct business interests, as well as relationships between the dialysis provider and the clinical care paradigm supported at the facility. The medical director's role includes ensuring that the governing body is aware and effectively addresses ongoing quality improvement processes that lead to effective evidence-based quality improvements in care at the facility. The governing body meetings should be regular and should have both regular routine and topical components to the agenda that include assessment of performance of the facility from financial, operational, and clinical quality standpoints. The governing body must set the tone for development of a strong, highly educated, proficient, and professional staff. The governing body must also adjudicate any conflicts and create a rational observation of the clinical staff ability to deliver safe and effective therapy. In many cases, the medical director is the most senior person at the governing body meeting within the organization and should thus take on a substantial role in providing leadership, direction, and active participation in governing body decisions.

As the Medicare ESRD Program enters its 40th year, now is a good time to reflect on the role of the medical director as well as the value that an effective medical director can bring to patients, medical staff members, the interdisciplinary team, and the organization of which he or she is a part. In the early years of the ESRD entitlement, the medical director worked with the chief nurse to develop and oversee policies and procedures within the facility. This limited role was seen by many nephrologists as largely an entitlement for them—a recognition that they, the doctor, were really in charge and bringing patients to the facility. Although some nephrologists were deeply engaged in other aspects of the administration of the facility, this remained the exception rather than the rule. With the revision of the CfC in 2008, the role of the medical director became much more explicit, with the responsibilities and accountabilities delineated in detail. Although this approach was long overdue, many nephrologists serving as medical directors were not prepared for this set of responsibilities or for the “expected” time commitment of a quarter of their full-time professional effort.

It is now clear that for dialysis patients to receive the safe, effective, and efficient care they need and deserve, each facility must have a fully engaged medical director who understands and carries out the responsibilities of the role

as an enthusiastic leader of a highly functioning team. Both a deep understanding of the technical and regulatory aspects of dialysis delivery as well as an appreciation of the concept and tools for population management are essential. In addition, strong interpersonal communication skills and the ability to manage conflict are essential qualities.

A careful self-examination will reveal that we have not taught the essential skills of being a dialysis facility medical director during the nephrology fellowship. Excellent efforts have been initiated by the Forum of ESRD Networks and the Renal Physicians Association, but these efforts need broader dissemination (19,20). In addition, only recently has the American Society of Nephrology attempted to conduct medical director training courses at its annual meeting. Dialysis organizations have such educational programs specific to their companies, but getting significant participation is a challenge. It is time to come together with industry, academic institutions, and renal organizations to recommend the best methods to train future medical directors.

### Acknowledgments

We thank John Larkin and Jackie Wenzler for assisting in the preparation of this article.

### Disclosures

F.W.M. is employed by Fresenius Medical Care and holds stock in the company. A.R.N. is employed by DaVita Health Care Partners and holds stock in the company.

### References

1. Social Security Amendments of 1972 Section 299I. Available at <http://www.ssa.gov/policy/docs/ssb/v36n3/v36n3p3.pdf>. Accessed September 19, 2014
2. US Department of Health and Human Services Office of Inspector General: Clinical Performance Measures for Dialysis Facilities: Lessons Learned by the Major Dialysis Corporations and Implications for Medicare, 2002. Available at <http://oig.hhs.gov/oei/reports/oei-01-99-00054.pdf>. Accessed August 10, 2014
3. US Centers for Medicare and Medicaid Services: Interpretive Guidance for Conditions for Coverage, 2008. Available at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf>. Accessed August 10, 2014
4. Fresenius Medical Care North America: CfC Medical Director Reference Table. Available at [http://fmcna.com/fmcna/idcplg?IdcService=GET\\_FILE&allowInterrupt=1&RevisionSelectionMethod=LatestReleased&Rendition=Primary&dDocName=PDF\\_3000063951](http://fmcna.com/fmcna/idcplg?IdcService=GET_FILE&allowInterrupt=1&RevisionSelectionMethod=LatestReleased&Rendition=Primary&dDocName=PDF_3000063951). Accessed July 22, 2014.
5. Lacson E Jr, Maddux FW: Intensity of care and better outcomes among hemodialysis patients: A role for the Medical Director. *Semin Dial* 25: 299–302, 2012
6. Spiegel BM: Treatment center characteristics associated with better outcomes: A role for the medical director? *Semin Dial* 25: 296–298, 2012
7. Goldman RS, Latos DL: Dialysis medical directors' role in maintaining quality of care and responsibility for facility-specific patient outcomes: Evolution and current status. *Semin Dial* 25: 286–290, 2012
8. DeOreo PB, Wilson R, Wish JB: Can better understanding and use of treatment center performance feedback improve hemodialysis care? A role for the medical director. *Semin Dial* 25: 290–293, 2012
9. Maddux FW, Maddux DW, Hakim RM: The role of the medical director: Changing with the times. *Semin Dial* 21: 54–57, 2008
10. Klinger AS: The dialysis medical director's role in quality and safety. *Semin Dial* 20: 261–264, 2007

11. Gutman RA: Medical direction of dialysis—a critical leadership role. *Semin Dial* 20: 257–260, 2007
12. Lindenfeld S, Vlcek D: Engaging physicians in continuous quality improvement. *Adv Ren Replace Ther* 8: 120–124, 2001
13. Nissenson AR: Should medical directors assume responsibility for facility-specific outcomes? *Semin Dial* 25: 284–285, 2012
14. Garrick R, Kliger A, Stefanchik B: Patient and facility safety in hemodialysis: Opportunities and strategies to develop a culture of safety. *Clin J Am Soc Nephrol* 7: 680–688, 2012
15. Vaqar S, Murray B, Panesar M: The medical-legal responsibilities of a dialysis unit medical director. *Semin Dial* 27: 472–476, 2014
16. Wish JB: What is expected of a medical director in the Centers for Medicare and Medicaid Services Conditions of Coverage? *Blood Purif* 31: 61–65, 2011
17. DeOreo PB: The medical directorship of renal dialysis facilities under the new Medicare conditions for coverage: Challenges and opportunities. *Blood Purif* 27: 16–21, 2009
18. Deoreo PB: How dialysis is paid for: What the dialysis medical director should know, and why. *Semin Dial* 21: 58–62, 2008
19. US Centers for Medicare and Medicaid Services: About the CMS Quality Strategy, 2014. Available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>. Accessed August 10, 2014
20. Forum of ESRD Networks Medical Advisory Council: Medical Director Toolkit, 2012. Available at <http://esrdnetworks.org/mac-toolkits/download/medical-director-toolkit-2>. Accessed September 19, 2014

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

This article contains supplemental material online at <http://cjasn.asnjournals.org/lookup/suppl/doi:10.2215/CJN.04920514/-/DCSupplemental>.

# The Medical Director and Quality Requirements in the Dialysis Facility

Brigitte Schiller\*†

## Abstract

Four decades after the successful implementation of the ESRD program currently providing life-saving dialysis therapy to >430,000 patients, the definitions of and demands for a high-quality program have evolved and increased at the same time. Through substantial technological advances ESRD care improved, with a predominant focus on the technical aspects of care and the introduction of medications such as erythropoiesis-stimulating agents and active vitamin D for anemia and bone disease management. Despite many advances, the size of the program and the increasingly older and multimorbid patient population have contributed to continuing challenges for providing consistently high-quality care. Medicare's Final Rule of the Conditions for Coverage (April 2008) define the medical director of the dialysis center as the leader of the interdisciplinary team and the person ultimately accountable for quality, safety, and care provided in the center. Knowledge and active leadership with a hands-on approach in the quality assessment and performance improvement process (QAPI) is essential for the achievement of high-quality outcomes in dialysis centers. A collaborative approach between the dialysis provider and medical director is required to optimize outcomes and deliver evidence-based quality care. In 2011 the Centers for Medicare & Medicaid Services introduced a pay-for-performance program—the ESRD quality incentive program (QIP)—with yearly varying quality metrics that result in payment reductions in subsequent years when targets are not achieved during the performance period. Success with the QIP requires a clear understanding of the structure, metrics, and scoring methods. Information on achievement and nonachievement is publicly available, both in facilities (through the facility performance score card) and on public websites (including Medicare's Dialysis Facility Compare). By assuming the leadership role in the quality program of dialysis facilities, the medical director is given an important opportunity to improve patients' lives and effect true change in a patient population dealing with a very challenging chronic disease. This article in the series on the role of the medical director summarizes the medical director's specific role in the quality improvement process in the dialysis facility and the associated requirements and programs, including QAPI and QIP.

*Clin J Am Soc Nephrol* 10: 493–499, 2015. doi: 10.2215/CJN.05810614

\*Satellite Healthcare, San Jose, California, and †Department of Medicine, Division of Nephrology, Stanford University, Palo Alto, California

**Correspondence:**  
Dr. Brigitte Schiller,  
300 Santana Row,  
Suite 300, San Jose,  
CA 95128. Email  
schillerb@  
satellitehealth.com

## Introduction

Air travel didn't get safer by exhorting pilots to please not crash. It got safer by designing planes and air travel systems that support pilots and others to succeed in a very, very complex environment. We can do that in healthcare, too.

—Donald Berwick on the launch of the Partnership for Patients April 12, 2011

It is not enough to do your best; you must know what to do, and then do your best.

—W. Edwards Deming

It is self-evident that both healthcare providers and patients want high-quality healthcare. Quality is a fundamental prerequisite for value in any service area and certainly is of prime importance in medicine, where often that most critical issue, life and death, is at stake. However, the common underlying tapestry in medicine is woven by every individual's personal understanding of what quality care entails. Not surprisingly, the definition of quality, including how to measure it, varies widely.

Since the 1973 implementation of universal access to dialysis care in the United States, many advances in the delivery of ESRD care have been implemented. The initial goal of this program—to allow rehabilitation to a full and active life—has evolved over the ensuing 40-plus years and resulted in a larger than expected program that provided dialysis services to >430,000 patients in 2013 (1). What was initially a primarily home-based therapy became a large industry of center-based dialysis care for increasingly older patients with multiple comorbidities. Delivering a reliably beneficial product (*i.e.*, high-quality care) to a small number of patients with limited evidence-based mandates required a different set-up, one that relied heavily on individuals and their good intentions. As the program grew, the tasks required to ensure quality assurance and quality control transformed.

The role of a medical director before expansion of Medicare payments for dialysis care mainly involved being the treating physician for most if not all the patients in a facility and thus primarily practicing medicine for the individual patient. After passage of the amendments to the Social Security Act in 1973, the

medical director became part of a wider care team that includes nurses, social workers, and dietitians; this Act also mandated a medical director for each facility. The governing body in each facility further reinforced the team approach set forth by Medicare. The nephrologist–medical director took on a managerial role in the facilities, a role that focused on quality outcomes for all patients with ESRD.

Since the implementation of the Medicare ESRD program, rules for participation had always been clearly outlined (2). The conditions for coverage (CfC) effective October 2008, however, made the medical director the ultimate authority responsible for all aspects of quality care delivered in the facility and markedly increased the scope of responsibilities (3). The tasks can be divided into three categories—administrative, medical, and technical oversight—accounting for a managerial position that the Centers for Medicare & Medicaid Services (CMS) estimates to be the equivalent of a quarter-full-time position. The time and responsibility requirement are no small burden for a practicing nephrologist and continue to increase, with ever more challenging clinical situations and quality metrics of increasing complexity.

The CfC outlines the duties (Table 1). The primary role of the medical director with respect to quality is providing leadership for the interdisciplinary team and its role in both individualized patient care and the quality assessment and performance improvement process (QAPI).

ESRD care has been paid at a composite rate composed of dialysis and some laboratory tests since 1983. In 2011, following the passage of the 2008 Medicare Improvements for Patients and Providers Act (MIPPA), a bundled payment that includes the dialysis treatment, injectable drugs, and all ESRD-related laboratory tests, was implemented. The Act allowed for the prospect of oral drugs to be included at a later time. MIPPA mandated the introduction of the ESRD quality incentive program (QIP). The intent of the program is to promote high-quality care in the outpatient dialysis facilities treating patients with ESRD. This pay-for-performance system is unique in the sense that it works through a reduced payment on the facility level, thus linking a portion of the payment directly to facility performance in specific quality metrics. The specific measures included in the QIP are modified and published annually and have increased in number, from initially 3 metrics for 2012 to 11 metrics for payment year 2016 (4). This rapid modification and increase of metrics put additional pressure on providers and facilities that have limited time

available to implement the new metrics; these metrics have often been published only at the end of the year preceding the implementation year.

Nonetheless, the QIP has contributed to considerable improvement in the results achieved across the United States, including decreased percentage of catheters in place for >90 days and increased fistula penetration. Other metrics raise questions about their meaningfulness as a true quality measure likely to affect patient survival and quality of life, the primary goals of high-quality care for patients with ESRD. While the QIP may be regarded primarily as a pay-for-performance measure only for the dialysis provider, it is evident that truly life-changing quality metrics will and indeed already require the active participation of not only the medical director but all referring physicians under the medical director's leadership. Quality measures for the practicing nephrologist may be more tangible in the care of patients with CKD rather than ESRD, resulting in similar wide-ranging reactions (5). However, no matter how one might think about the incentive program and its quality indicators, the QIP is here to stay.

With participation of all stakeholders, the ESRD community has an opportunity to advance ESRD care by working closely together.

#### QAPI

The QAPI is led by the medical director, with an interdisciplinary team composed of, at a minimum, a physician (typically the medical director, who has overall responsibility for the QAPI program at each facility), a registered nurse (typically the clinical manager), a Masters-prepared social worker, and a registered dietitian. This team “must have effective communications and devote sufficient time and attention to produce effective quality assessment and performance improvement activities which positively influence their patients' outcomes” (3). The interdisciplinary team meets quarterly or monthly, depending on state law, and documents all QAPI meetings, activities, and projects.

CfC §494.110 (Condition Quality Assessment and Performance Improvement) reads as outlined in Table 2. This table also summarizes the scope and the metrics included in a standard QAPI program. Surveyors focus on these measures during state surveys.

Part of the QAPI program is the continued performance improvement monitoring and also the expectation for prioritization of improvement activities. Over the past few

**Table 1. Condition for coverage**

494.150 Condition: Responsibilities of the Medical Director		
The dialysis facility must have a Medical Director to be responsible for the delivery of patient care and outcomes in the facility.	The Medical Director is accountable to the governing body for the quality of medical care provided to patients.	Medical Director responsibilities include, but are not limited to, the following: (a) Quality assessment and performance improvement program (b) Staff education, training, and performance (c) Policies and procedures

**Table 2. §494.110 Condition: quality assessment and performance improvement process definition by conditions for coverage and metrics**

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

**QAPI Metrics**

Health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

Adequacy of dialysis

Nutritional status

Mineral metabolism and renal bone disease

Anemia management

Vascular access

Medical injuries and medical errors identification

Hemodialyzer reuse program, if the facility reuses hemodialyzers

Patient satisfaction and grievances

Infection control

Analyze and document infections to identify trends, establish baseline information on infection incidence

Develop recommendations and action plans to minimize infection transmission, promote immunization

Take actions to reduce future incidents

Obtained from reference 3. CMS, Centers for Medicare & Medicaid Services; QAPI, quality assessment and performance improvement process.

years, because of a focused effort to emphasize the data-driven, target-centered quality and care delivery model, a mindset of achieving the target numbers has become increasingly prevalent in the facilities. While a desire to reach all target metrics is commendable, efforts to reach these goals need to be tempered with the larger picture in mind. The medical director's leadership role is important in helping centers to prioritize improvement projects and in directing efforts to identify and address systemic issues. It is critical to the success of the QAPI program that true quality issues affecting many patients are differentiated from a deviation due to single-patient outliers. The focus should be on the entire group of patients, with a strategy of making changes so that most patients get better care, not just the "outliers." The intent of quality improvement is not to solve the issue of the very sick patient who does not meet the target. The individual patient issue is addressed through direct patient care. Quality improvement instead concentrates on trends, processes, infrastructure, access, and adherence to care as the cause for not achieving quality outcomes in a group of patients (*i.e.*, patients in a dialysis center).

A hemodialysis center with a high percentage of central venous catheters in place for >90 days thus has two issues. One concerns the "outlier" (*i.e.*, the individual patient with a catheter in place). This is a patient issue requiring intervention by the nephrologist and care team to place a permanent access, preferably a fistula. The QAPI process looks at the cause of this issue. What needs to happen to prevent patients from having a hemodialysis catheter? What needs to be done to achieve permanent access in patients with a catheter in a timely matter? Is this a patient issue, a referral issue, or an access-to-surgery issue? Do patients understand the risk associated with a catheter?

The answers to these questions allow the facility to implement change accordingly to benefit current and future patients receiving care at the center. Thus, the QAPI process embodies one of the ways where the nephrologist as medical director moves from a patient care provider role to a population health management role with responsibility for facility patient care and outcome. Some differences in these roles affecting the nephrologist's tasks are outlined in Table 3.

Attendance at the QAPI meetings is mandated by the medical director and is critical for a successful program. Providers have supplied resources and tools, including QAPI manuals, QAPI training, fishbone (cause-and-effect) templates, and quality specialists, to help implement and maintain a QAPI culture and successful QAPI programs.

While delivering high-quality care is intrinsic to healthcare providers, the QAPI process is often not intuitive even for many well trained and dedicated professionals. A tendency to jump to solutions without asking all the right questions hinders successful execution of a quality program. It is evident that the success of the QAPI process depends on a "needs to improve—get it done" attitude of the whole team. The most common error in the QAPI process is founded on a belief that everything has already been done. Root cause analysis—which determines the most fundamental causes of an adverse event/outcome that has already occurred by systematically assessing the multiple types of possible human, process, organizational, equipment, and other failures—is a prerequisite for quality improvement. Fishbone analysis facilitates this process through its illustrative way of summarizing the causes. With a medical director leading the QAPI meeting and selecting and developing, with the interdisciplinary team, a project to execute, continued improvement

**Table 3. Nephrologist's tasks in patient care versus role as medical director in population health management in the dialysis center**

Domain	Patient Care	Population Health Management
Anemia management	Assess patient for clinical causes of anemia or hemoglobin > 12g/dl  Safety/clinical issue requiring intervention?	Review, monitor and analyze target levels for hemoglobin > 12 g/dl reached in a facility Protocol issue? Adherence to policy and procedure? Staff knowledge—education need? Safety issue?
Infection control	Treat patient with antibiotic according to clinical presentation and microbiology findings CVC requiring permanent access? Evaluate cause for infection and possible intervention to prevent recurrence	Review, monitor, and analyze infection rate in dialysis center  Perform root cause analysis Infection surveillance Infection control policy and procedure Staff/patient and referring physicians adherence to infection control policy and procedure? In-service required?
Patient plan of care	Individual patient assessments and plan of care according to patient's individual needs documented for each patient at mandated intervals	Review referring physicians' compliance with patient care plan documentation, monthly visits and quarterly in-center visits Reach out to physicians who are out of compliance

CVC, central venous catheter.

is seen repeatedly. Creative, alternative venues are explored in situations where a sentiment prevailed that efforts had been exhausted. This changed approach has probably contributed to improvements in many areas of dialysis care, including adequacy and access. Through continued monitoring and tracking of the performance measures, the Plan-Do-Study-Act cycle of quality improvement is set into motion: Set a realistic goal; lay out a plan; execute it; reassess; and, depending on the outcome, modify or implement the process throughout (6) (Table 4). This approach allows the facility to correct any identified problems that threaten the health and safety of patients, as mandated by the CfC.

### QIP

In accordance with section 1881(h) of the MIPPA, added on July 15, 2008, by section 153(c), CMS implemented the ESRD QIP to promote high-quality care by outpatient dialysis facilities treating patients with ESRD starting in January 2012 (7). The QIP is a first-of-its-kind program in Medicare and changes the way CMS reimburses for dialysis treatments of patients with ESRD. Payment is linked to certain performance-quality metrics as pay for performance in a "value-based purchasing" program. However, the QIP represents a withholding rather than a reward for performance payment incentive. Facilities who do not meet certain performance standards are subject to a payment reduction (withholding) of up to 2% in subsequent years, also known as payment years. An overall facility score for applicable measures will determine whether payment should decrease. The scores are publicly reported on

Dialysis Facility Compare (8) and also in the Performance Score Certificate. CMS provides this certificate annually to all centers, both those with perfect scores and those with scores resulting in payment reductions. The certificate must be displayed in the facility for easy review by staff and patients.

It is obvious that a proactive involvement of the medical director is key to achieving the QIP targets. A successful medical director must fully understand the QIP, the underlying metrics, and its scoring system. The ongoing monitoring of target metrics, the reinforcement of staff and physician behavior working toward this goal, and patient engagement and education are essential. The award of certificates for perfect performance relies heavily on strong collaborative efforts between the medical director and the dialysis provider. In a world where consumers use the Internet and social media for product and service choices, it is easy to imagine that patients' choice for their dialysis therapy will be guided by such public ratings. And we would not expect our patients to accept a lower quality rating when trusting their lives to our care.

While the format of the program does not change, the quality metrics, standards, and weighting of the results and formulas are subject to annual changes. Thus, the initial QIP, performance year of 2010 and payment year in 2012, consisted of 3 metrics, while the current QIP, based on 2014 performance for 2016 payment, encompasses 11. The measures initially comprised only clinical metrics, starting with anemia and adequacy measures. Since then a variation has been implemented with clinical metrics, commonly accounting for 75%–90% of the overall score, and reporting measures, representing 10%–25% of the overall score. The measures

**Table 4. Plan-do-study-act: quality improvement cycle**

Project Phases	Steps
Goal: Define a specific, measurable and achievable goal	Decide what you want to change Set a percentage or absolute change target Establish a timeline for completion Better to start small than to over-reach
Plan	What will you do? Who will do it? When will it be done? What are the expectations? What data will be collected?
Do	Carry out the plan Document observations Collect the data
Study	Analyze the data Did the process work? Was it enough? Was the objective met? Is the new process realistic? Are the resources available to implement this new process?
Act	Process worked: Implement the plan Process did not work: Revise the plan or start over with a new plan

have evolved from laboratory results and vascular access distribution to more complex clinical events, such as infections reported *via* the National Healthcare Surveillance Network (9) and patient experiences captured through the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (10).

The actual details of the program are complex, with several program-years potentially affecting the QIP: a payment year, the comparison period, and the performance period. The comparison period is the designated time (often a full year) during which CMS is gathering data on all dialysis facilities. The performance year follows the comparison period and requires the facility to perform at least as well as during the comparison period to avoid payment cuts. CMS assesses the facility’s performance on the basis of the comparison period and calculates a score for each measure, according to the methods detailed each year in a final rule published in the *Federal Register*. These changes clearly indicate CMS’s efforts to align ESRD care outcomes with the desired triple aim of healthcare initiatives to achieve improved patient outcomes and experience of care while containing costs (11).

Examples are given for the payment year of 2015 and 2016 based on the measures achieved in the performance period in 2013 and 2014, currently ongoing (Table 5). The table illustrates the complexities of controlling the details of this annually changing program. The frequent QIP changes and time frames may evoke experiences of the Ghosts of Christmases Past, Present, and Yet to Come from Charles Dickens’ *A Christmas Carol*. Not only is everyone required to consider and execute best practices in the present, but performances of the past and future represent continuous challenges, eventually painting the longitudinal picture of quality achievement of each facility.

However, one has to applaud some of the results emerging since the introduction of the QIP with improvements in some important areas, such as vascular access, results once thought by many to be unachievable in the United States. Thus, Medicare has introduced a transparent program suitable for tracking and positively affecting quality improvements in some domains while maintaining high marks in others, such as adequacy (12).

As nephrologists and other stakeholders discuss the ultimate definition of goals for high-quality kidney care, expressing support for many metrics and questioning others as to their importance in improving patients’ lives, the focus on more clinical measures guided by clinicians is a good step forward. Advancing quality care to improve patient survival, reduce hospitalizations, and improve our patients’ experience with their care are unanimously agreed-upon goals.

Kidney Care Partners, a coalition of patient advocates, dialysis professionals, care providers, and manufacturers, has collaborated since its foundation in 2003 to improve quality of care for patients with CKD. The Kidney Care Partners Strategic Blueprint for Advancing Kidney Care Quality, released in March 2014, outlines the essential areas for improvements and touches on wide-reaching domains ranging from care coordination and disease management to patient engagement, education, and infrastructure changes (13). This will be a roadmap for many coming years, with great potential to affect the way we deliver dialysis care at a time when the discussion about quality care has been reframed (14). Nephrologists are taking the lead in promoting and implementing innovative models of care addressing the primary concerns in ESRD care, including fluid control, longer dialysis times, incorporation of underlying comorbid conditions



Table 5. Quality improvement program for 2015 and 2016		
Payment year	2015	2016
Measure	6 clinical Hb > 12 g/dl VAT measure topic Catheter Fistula Kt/V HD PD Pediatric 4 reporting  NHSN ICH CAHPS Mineral metabolism Anemia management	8 clinical Hb > 12 g/dl VAT measure topic Catheter Fistula Kt/V HD PD Pediatric NHSN bloodstream infections in HD outpatients Hypercalcemia 3 reporting ICH CAHPS Mineral metabolism Anemia management
Performance period	CY 2013	CY 2014
Comparison period	CY 2011 (achievement) CY 2012 (improvement)	CY 2012 (achievement) CY 2013 (improvement) No improvement scoring for NHSN bloodstream infections
Performance standard	National performance rate (CY 2011)	National performance rate (CY 2012) National performance rate (May–December 2012) for hypercalcemia National performance rate (CY 2014) for NHSN
Weighting	Clinical 75%, reporting 25%	Clinical 75%, reporting 25%, hypercalcemia at two thirds of each remaining clinical measure
Maximum performance score	100 points	100 points
Minimum total performance score	60 points	54 points
Payment reduction scale	0.5%–2% with a 0.5% reduction for every 10 points under the minimum total performance score	

Adapted from Centers for Medicare & Medicaid Services ESRD quality improvement project summary for payment year 2012–2016. "Clinical" means that target value needs to be achieved. "Reporting" indicates that no target value was available and credit was given for reporting results only. Hb, hemoglobin; VAT, vascular access type; HD, hemodialysis; PD, peritoneal dialysis; NHSN, National Healthcare System Network (reporting of dialysis-related infection events); ICH CAHPS, In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems; CY, Calendar Year.

into the dialysis prescription, infection control, coordinated care approaches, increased penetration of home dialysis, and better education for our patients (15–17).

These are truly exciting times for nephrologists—and an opportunity for medical directors to show and live true leadership.

### Conclusion (Tip of the Month for Medical Directors)

It cannot be overstated how this is a time of opportunity for all clinicians, medical directors especially, to wield their clinical expertise, intuition, and aspiration to live the core mission of being a physician to affect patient's lives by preventing further adverse events, alleviating suffering, and delivering truly patient-centered care.

Responsibilities and tasks for the medical director of a dialysis center have increased both in number and complexity over the past few years. A leadership position is a privilege requiring hard work and dedication. The stresses of daily routine, the increasing requirement for documentation with ever-changing demands, pay-for-performance programs, and the looming beginnings of healthcare reform may often mitigate the initial motivation to choose this profession.

However, the leadership role of the medical director in a dialysis center opens an incredible opportunity to improve not only individual patient care but also the experience of all patients cared for in a center. Using intuition and the application of knowledge and guidance to all staff and patients, the medical director makes a difference in patients' lives not

through direct patient care but through population health management for all patients at the center.

One might argue that the medical director sets the tone and culture of a dialysis center as the leader who will determine whether quality improvement processes are an integral part of caring for patients or yet another task to check off on an overwhelming list of things to do.

When compassion and love are ingredients of the quality program—or any aspect of healthcare—they may prove not just to require more time and energy. They may also in return give back and both fill the buckets of those who rely on us and miraculously add quality to the physician's life as well (18).

#### Disclosures

B.S. is a salaried employee of Satellite Healthcare, Inc.

#### References

1. US Renal Data Systems: *USRDS Annual Data Report: Atlas of End-Stage Renal Disease in the United States 2013*. Available at [http://www.usrds.org/2013/pdf/v2\\_ch1\\_13.pdf](http://www.usrds.org/2013/pdf/v2_ch1_13.pdf). Accessed June 7, 2014
2. Federal Register, Vol 41, No 108, Thursday June 3, 1976, pp. 22502–22522
3. Department of Health and Human Services: Centers for Medicare & Medicaid Services: 42 CFR Parts 405, 410, 413 et al. Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule. *Fed Regis* 73: 20370–2–484, 2008 Available at <http://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf>. Accessed May 26, 2014
4. National Forum of ESRD Networks: Centers for Medicare & Medicaid Services: Quality Assessment and Performance Improvement. 2010. Available at [http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/99\\_EduResources.html](http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/99_EduResources.html). Accessed July 17, 2014
5. Smith KA, Hayward RA: Performance measurement in chronic kidney disease. *J Am Soc Nephrol* 22: 225–234, 2011
6. Agency for Healthcare Research and Quality. Module 5: Improvement – developing a strategy for diabetes quality improvement. Publication #04-0072. August 2008. Available at <http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/diabguide/diabguidemod5.html>. Accessed May 26, 2014
7. Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program; End-Stage Renal Disease Quality Incentive Program: Final Rule 42 CFR Part 413 *Fed Regist* 76: 628–645, 2011 Available at <http://www.gpo.gov/fdsys/pkg/FR-2011-01-05/pdf/2010-33143.pdf>. Accessed May 26, 2014
8. Medicare.gov. Dialysis Facility Compare. Available at <http://www.medicare.gov/dialysisfacilitycompare/search.html> Accessed July 16, 2014
9. Centers for Disease Control and Prevention: National Healthcare Safety Network (NHSN). Dialysis event surveillance. Available at <http://www.cdc.gov/nhsn/dialysis/dialysis-event.html>. Accessed June 7, 2014
10. In-Center Hemodialysis CAHP Survey. Available at <https://ichcahps.org>. Accessed June 7, 2014
11. Berwick DM, Nolan TW, Whittington J: The triple aim: care, health, and cost. *Health Aff (Millwood)* 27: 759–769, 2008
12. CMS.gov: ESRD Quality Incentive Program Available at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/>. Accessed August 30, 2014
13. Kidney Care Partners: A Strategic Blueprint for Advancing Kidney Care Quality. Washington, DC, 2014 Available at <http://kidney-carepartners.com/images/blueprint.pdf>. Accessed May 26, 2014
14. Nissenson AR: Improving outcomes for ESRD patients: shifting the quality paradigm. *Clin J Am Soc Nephrol* 9: 430–434, 2014
15. Parker TF 3rd, Glasscock RJ, Steinman TI: Conclusions, consensus, and directions for the future. *Clin J Am Soc Nephrol* 4[Suppl 1]: S139–S144, 2009
16. Parker T 3rd, Hakim R, Nissenson AR, Steinman T, Glasscock RJ: Dialysis at a crossroads: 50 years later. *Clin J Am Soc Nephrol* 6: 457–461, 2011
17. Parker TF 3rd, Straube BM, Nissenson A, Hakim RM, Steinman TI, Glasscock RJ: Dialysis at a crossroads—part II: A call for action. *Clin J Am Soc Nephrol* 7: 1026–1032, 2012
18. Press MJ, Judson TJ, Detsky AS: A piece of my mind. Filling buckets. *JAMA* 311: 1859–1860, 2014

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

## Maintaining Safety in the Dialysis Facility

Alan S. Kliger

### Abstract

**Errors in dialysis care can cause harm and death. While dialysis machines are rarely a major cause of morbidity, human factors at the machine interface and suboptimal communication among caregivers are common sources of error. Major causes of potentially reversible adverse outcomes include medication errors, infections, hyperkalemia, access-related errors, and patient falls. Root cause analysis of adverse events and "near misses" can illuminate care processes and show system changes to improve safety. Human factors engineering and simulation exercises have strong potential to define common clinical team purpose, and improve processes of care. Patient observations and their participation in error reduction increase the effectiveness of patient safety efforts.**

*Clin J Am Soc Nephrol* 10: 688–695, 2015. doi: 10.2215/CJN.08960914

Yale University School of Medicine, Yale New Haven Health System, New Haven, Connecticut

### Introduction

In the 15 years since the Institute of Medicine Report *Crossing the Quality Chasm* was published (1), much has been written about improving quality, culture change, process change, and risk reduction. We now recognize that practitioners are human, and like all humans we make mistakes—and sometimes they harm our patients. Yet little evidence has been published showing any real improvement in outcomes that result from our awareness and our efforts to deal with these vulnerabilities. For patients undergoing life-sustaining dialysis in particular, some data and much opinion (2–20) have detailed the increased risk of errors and their unintended consequences. In a survey of dialysis patients, nearly half responded that at times they had concerns for their safety in the dialysis facility (6). These studies have identified several of the highest-risk domains our patients experience and have led to improved processes of care designed to reduce the risk of error and the effect of medical mistakes on our patients. Perhaps most important, in recent years evidence has suggested that some of this attention has improved outcomes for patients with ESRD. Dialysis facility medical directors are responsible for ensuring the quality and safety of care and for fostering a culture of patient safety. It is therefore important that medical directors understand the sources of risk to dialysis patients and champion process improvements to keep their facilities safe.

In this review, I discuss the progress we have started to see in recognizing where errors occur, how they might be reduced or even eliminated, and opportunities to accelerate this process of improvement. The basic elements of a plan to recognize and prevent mistakes in caring for ESRD patients are shown in Table 1.

### Culture of Safety

The Agency for Healthcare Research and Quality (AHRQ) has defined culture of safety as follows (21):

The safety culture of an organization is the product of individual and group values, attitudes, perceptions,

competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

Medical care systems are highly complex, caring for patients with multiple risk factors that predispose to errors—errors of omission, errors of commission, errors in judgment. Other industries, such as the aviation industry and the nuclear power industry, have similar characteristics of complexity and risk. In such organizations, reorganization can improve reliability and safety. High-reliability organizations are defined as those that succeed in avoiding serious safety events in an environment where normal accidents can be expected because of risk factors and complexity. High-reliability organizations operate on five principles (22): (1) reluctance to simplify, (2) preoccupation with failure, (3) deference to expertise, (4) sensitivity to operations, and (5) resilience.

If dialysis facilities are to operate as high-reliability organizations, the medical director must educate and engage the medical and nursing staff, support staff, and patients themselves to accomplish each of these five principles. High-reliability organizations establish and maintain a culture of safety in which all staff members are encouraged to report errors or potentially harmful events in a blame-free environment without fear of punishment. At the same time, a safe organizational culture does require appropriate accountability: Each individual is responsible for his or her own action.

Of the many approaches to accomplish these goals, Crew Resource Management is one tool that has been helpful (23). Developed in the aviation industry, this technique helps physicians and dialysis staff work collaboratively to value safety as a primary goal, develop

### Correspondence:

Dr. Alan S. Kliger, Yale New Haven Health System, 300 George Street, Room 487, New Haven, CT 06510. Email: Alan.Kliger@ynhh.org

**Table 1. Elements of ESRD patient safety improvement**

1. Culture of safety: Create an environment in which it is safe to recognize and report errors for yourself and coworkers  
Dialysis facilities should operate as high-reliability organizations
2. Regulatory protection: Create legislation and regulation protecting voluntary reporters of error
3. Human factors: Identify patterns of interaction at the machine-human interface that may predispose to error
4. Identify major causes of potentially reversible adverse outcomes
  - Medication errors
  - Infections
  - Access-related errors
  - Falls
  - Deaths from RRT complications
5. Perform root cause analyses of adverse events and “near misses”
6. Involve patients in safety efforts
7. Address home hemodialysis issues

specific competencies in safe practice, create patterns of behavior or practice that foster patient safety, and measure the effectiveness of preventive measures. Teams of caregivers learn together to hold patient safety as a top priority and practice in a nonpunitive, accountable, safe environment. Precepts include having a questioning attitude, asking clarifying questions, and being responsible both for one’s own behavior and the behavior of each other. Tools such as safety huddles, read-backs, and checklists help improve communication and minimize the likelihood of errors and harm. The effectiveness of these efforts can be measured by recording the numbers and types of serious safety events and the efforts to prevent similar future occurrences.

Simulation training in vascular access is one example of how these measures have been used in dialysis facilities (24). This training can be a powerful tool to develop procedural skill and improve patient safety. The Accreditation Council for Graduate Medical Education supports simulation training, and expects it to be part of residency training. Simulation training also can go beyond procedural skills and assist teams of caregivers to deliver safer care.

Multidisciplinary training, cofacilitated by aviation and medical experts, teaches physicians, nurses, and other dialysis personnel to work as teams and respond to dialysis access adverse outcomes or emergencies, such as bleeding. This approach differs from the traditional systems of individual-focused training and response, where undesirable outcomes are managed with incident reports, and root cause analyses, which focus on what individuals should do differently. Highly functional teams receive hands-on skills learning under direct supervision, as well as more didactic education about CKD, patient selection algorithms, and best processes to create and maintain vascular access. Multidisciplinary clinicians then learn and practice team interaction in a simulated environment. These communication skills, practiced in a safe simulation environment, are critical to prepare for real-life emergencies and are rarely taught as part of classic renal fellowship or nursing school curricula. Thus, this training of individuals in procedure-based skills, such as ultrasound-guided vascular access cannulation, and team training in managing challenging clinical problems provides a safer and more effective environment for our patients.

### Regulatory Protection

In 2005, President George W. Bush signed into law the Patient Safety and Quality Improvement Act (25). Congress recognized that to create a culture of safety, clinicians and care teams need regulatory protection from discovery for voluntary reporting of safety concerns. The goal of this act is to

improve patient safety by encouraging voluntary and confidential reporting of health care events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services issued the Patient Safety and Quality Improvement Rule (Patient Safety Rule). The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs (Patient Safety Organizations) to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events. This process enables PSOs to more quickly identify patterns of failures and develop strategies to eliminate patient safety risks and hazards.

Many state hospital associations, health care organizations, and individual specialties have developed PSOs, where care teams can share safety experiences, concerns and best practices in a protected environment to improve patient safety.

### Human Factors

Dialysis facilities are complex organizations. Nurses and technicians care for patients, cannulate their vascular access, and connect them to electronically-controlled dialysis machines. Sophisticated equipment purifies water for mixing dialysate. Dialyzers are sometimes reprocessed and sterilized before delivery to the technician or nurse setting up the dialysis equipment. The interaction between dialysis staff, machines, and the environment provides a large opportunity for errors to occur.

Human factors engineering is a discipline designed to identify and address these vulnerabilities (26). Here again, we can learn from the aviation industry (27). Human factors engineering has several applications to improve patient safety.

*Usability testing* examines new systems and equipment under real-world conditions to identify potential safety

problems leading to unintended consequences. This technique has been used to identify common “workarounds”—intentional bypassing of safety policies and procedures by frontline staff seeking presumably more efficient ways to accomplish their tasks. Often, these workarounds unintentionally bypass the safety checks purposefully built into these policies.

*Forcing functions* prevent unintended actions in critical areas by reducing the possibility of selecting dangerous care sequences. An example of this is to prevent the placement of dialysis machines in sterilization mode during routine machine setup.

*Standardization* reduces potential errors as, for example, when dialysis nurses use one dialysis machine with procedures designed for another, or when multiple central venous access devices, each with their own recommended package insert instructions, are used in a dialysis facility.

*Resiliency efforts* help focus clinicians on the detection, avoidance, and mitigation efforts to anticipate unsafe actions before they occur. If harm does occur, resiliency training and tools assist teams to deal effectively with the consequences, improve system function in the future, and move on to care for the next patient. For example, physicians and nurses often feel devastated when they realize that something they did (or neglected to do) caused a patient irreparable harm. This feeling can be overwhelming, can color clinical judgment, and has led some clinicians to stop practicing. Resiliency efforts can channel these self-defeating feelings into positive action to deal with the consequences of the error and to devise improvements in our care systems to make such errors unlikely in the future.

Policies and procedures are developed and taught to dialysis staff. Many of these are specifically designed to prevent errors and keep patients safe. Nonetheless, clinicians sometimes ignore or are unaware of policies and do not follow procedures as prescribed. A study of Pennsylvania dialysis patients reported that failure to follow protocol represented >12% of reported dialysis adverse events (28). A survey of dialysis staff asked which factors they thought most prominently contributed to breaches in patient safety. The number one factor chosen was staff non-adherence to policies and procedures (6). There are many reasons why staff may not follow policies and procedures. Engaging human factors tools can help understand why this is happening in a dialysis facility and suggest mechanisms and tools to correct it. Factors leading to an improved culture of safety in dialysis facilities can be identified (29).

## Major Causes of Potentially Reversible Adverse Outcomes

### Medication Errors

Medication errors are common among dialysis patients (4,30–33), often occurring as errors of omission (28) and upon transitioning between care settings and providers (34–36). In one study, omission of an ordered medication was the most common error, representing 69% of all errors (4). In a national survey of hemodialysis staff and patients, we found that almost half of patients take 6–10 medications daily, yet only “sometimes” discuss all their medications with their doctor (6,37). In the hemodialysis community, medication errors are

reported as the most common patient safety event. A report from Pennsylvania (28) noted:

While medication omissions were the most frequently occurring type of medication error, other medication errors during hemodialysis administration involved heparin infusion mistakes, inadequate handoff of information about patients’ medications during transitions between the hemodialysis unit and other care areas, and miscommunication of medication orders.

In a small study of hemodialysis patients admitted to surgical services at a tertiary care center (38), errors in medication-prescribing were common, including inappropriate analgesic orders of morphine and nonsteroidal anti-inflammatory drugs (63% of patients), and incorrect antibiotic dosing (42%), including inappropriate dose or frequency and one case of a contraindicated antibiotic. For peritoneal dialysis patients, one report of iatrogenic hypoglycemia in patients receiving icodextrin dialysate should be noted (39). This agent, sometimes used in peritoneal dialysis solutions to augment ultrafiltration and fluid removal, is metabolized to maltose, a nonglucose sugar that is poorly excreted in patients with little endogenous kidney function. Nonglucose sugars are measured as “glucose” by some strips and the glucometer devices patients use to monitor their glucose control. In this case, a patient undergoing peritoneal dialysis measured his glucose as “high,” even though the major source of the measured sugar was maltose. He injected insulin to control his high “glucose” and induced profound hypoglycemia; serum glucose in the clinical chemistry laboratory was 29 mg/dl, while simultaneous glucometer testing showed a value of 131 mg/dl.

Several strategies are needed to reduce this remarkably high level of medication error. Electronic medical records, including computerized provider order entry and a clinical decision support system, can help reduce the frequency of drug incompatibilities, medication duplication, and incorrect dosing for dialysis patients (14). However, this will be effective only if the electronic record is patient-centered, where all prescribers access and modify the single medication list that is centered on the patient rather than multiple providers and institutions. Regular and systematic use of medication reconciliation techniques can reduce errors (32,33). Other tools can be “hardwired” into the transitions of care process, such as required medication review, checklists, and sign-offs when patients return to the dialysis facility from other care settings. Human factors engineering can help physicians and others more accurately and consistently communicate about medications at times of patient admission and discharge from the hospital and dialysis facility, as well as other transitions of care. Patients and their families can play a primary role in keeping current medication lists and being proactive in questioning their caregivers about these medications, particularly at times of care transition.

### Infections

Bloodstream and other infections are leading causes of death and hospitalization among hemodialysis patients, second only to cardiovascular disease (40,41). In a registry-based study of dialysis patients from Scotland, health care-associated infection contributed to 9.6% of all deaths (19).

Two specific risk areas deserve attention:

1. *Hand hygiene.* For more than a century, hand washing has been recognized as essential to prevent transmission of disease-causing organisms from caregivers to patients (42). One survey of hand hygiene practices in dialysis facilities found that during a 3-month period, 25% of staff and about 10% of patients reported that staff did not wash or use alcohol-based hand gel before touching or interacting with patients and their dialysis machines (6). While many dialysis facilities have installed alcohol-based gel dispensers at the patients' chairside, there are no published data on the frequency of use of these devices. Beyond establishing policies and installing these devices, dialysis facility operators may find it helpful to engage human factors engineering processes to assure adequate hand hygiene for physicians, nurses, and all others interacting with patients in the dialysis facility. The Centers for Disease Control and Prevention recommend several interventions to improve hand hygiene, including hand hygiene observations and sharing results with clinical staff (15,20,43).

2. *Central venous catheters (CVCs).* In his review of hemodialysis-related bloodstream infections, Camins addresses the history of CVC use for dialysis and its associated increase in bloodstream infections (15). Compared with arteriovenous fistulas, CVCs are associated with a 15- to 33-fold increase in bloodstream infections (44–46) and an increased risk for all-cause mortality (47). While efforts to increase use of arteriovenous fistulas (Centers for Medicare & Medicaid Services Fistula First initiative) have indeed increased fistula use, 80% of patients undergoing long-term hemodialysis use CVCs at initiation of dialysis, and 52% use them after 90 days (41). For patients who must use CVCs, several interventions have proven useful in reducing bloodstream infections. Application of antimicrobial ointments or solutions to the catheter exit site reduces bacteremia (48,49). The unintended consequence of antimicrobial use, emergence of drug-resistant bacteria, must be considered and examined. Mupirocin ointment applied to the nares reduces nasal colonization by *Staphylococcus aureus* and may reduce systemic infections (50). Mupirocin applied directly to the catheter exit site reduces *S. aureus* infections and catheter-related bacteremia (51,52). Of particular interest, thrice-weekly application of honey to the catheter exit site has the same efficacy as mupirocin application (52). Recently, a multi-site study of two CVC-associated bloodstream infection prevention techniques—scrubbing catheter hubs before their use, and treating catheter exit sites with chlorhexidine and alcohol—proved effective in reducing these infections (53).

Care must be taken to assure that any ointment or solution applied to a CVC exit site is compatible with the plastic compound used to manufacture that particular catheter. Some CVCs specify in their package insert instructions for use that the polymers used are broken down by some ointments or solutions and should not be used. Antibiotic and nonantibiotic antimicrobial lock solutions have proven effective in reducing infections (54–57). A standard approach to catheter care, defined by facility policy and verified by practice audits, will likely result in fewer CVC-associated bloodstream infections.

### Access-Related Events

An early descriptive report of errors and adverse events in hemodialysis showed that infiltration of the hemodialysis access and clotting of the hemodialysis circuit was fairly common (4). Infiltrations represented 35% and clotting 22% of all adverse events. These access-related events occurred in approximately one of every 1300 treatments (4). In a survey of hemodialysis patients, 30% reported that over the preceding 3 months, staff tried more than twice to insert needles before seeking assistance (6,37,58). Most staff reported that a policy on difficult cannulation did not exist or that they were not familiar with such a policy. In another study, fistula infiltrations leading to additional interventions occurred at an annualized rate of 5.2% (59). Access needle dislodgment has the potential for life-threatening hemorrhage (60,61), and 5% of surveyed patients reported needle dislodgment before completion of treatment (37). The Veterans Affairs National Center of Patient Safety reported that 40 of 47 bleeding episodes analyzed between 2002 and 2008 were related to venous needle dislodgment (6,62). Prolonged bleeding after dialysis is also common (6,28,58,62,63). Reducing the frequency of these events requires adherence to the safety policies and procedures in dialysis facilities, supported by the human factors engineering tools discussed above.

### Patient Falls

Falls among dialysis patients are common and often result in injury. In one study, nearly half of dialysis patients older than age 65 years fell during a 1-year observation period, and 19% sustained injuries (64). In another study, 3% of all dialysis patients fell and sustained a bone fracture, and the overall fall rate was 1.18 falls/patient per year (65). This rate is substantially higher than in the nondialysis elderly population. Falls were common at home and were more common in the first half of the interdialytic cycle. The Renal Physicians Association survey of patients found that approximately 5% reported a fall in the previous 3 months (37). Factors associated with falls include age, diabetes, motor strength, visual acuity, previous falls, and medications (including antidepressants) (33–39). Strategies to reduce the risk of falls include staff education concerning fall risk, fall-risk assessment, gait assistance, use of in-floor weight scales, and reducing clutter (64–70).

### Dialysis Equipment Factors

Dialysis membrane bio-incompatibility, roller pump-induced hemolysis, and errors in reprocessing dialyzers have in the past caused harm. A recent report suggested that the use of electron-beam sterilized dialyzer membranes is associated with significant thrombocytopenia following dialysis (71). The report stemmed from a root cause analysis (RCA) and underscores the potential utility of this technique in examining unexpected outcomes (72). Impure water used to prepare dialysate can be a source of morbidity (73,74).

### Deaths from complications of RRT

A retrospective Scottish study of mortality among all patients treated with RRT showed that only 2.1% of deaths were directly ascribed to complications of RRT (19). In an additional 3.5% of deaths, while complications of RRT were not the direct cause of death, RRT factors that may

have contributed to death were identified. Death rate due to complications of RRT was 1.35 deaths/1000 RRT patients per year. Death from hemorrhage from vascular access was very uncommon, occurring at the same frequency as death related to treatment-related accident. Death from hyperkalemia was 6-fold more common than either of these two causes. Of note, there were no cases of dialysis equipment failure causing death. The causes of potentially preventable complications leading to death were: (1) recognition and treatment of hyperkalemia, (2) medication prescription issues, (3) care after hours, and (4) prevention of infection and management of vascular access. These authors conclude that efforts to improve the safety of RRT should focus on the human factors involved in care rather than focusing only on the technical aspects.

### RCA

RCA is a structured method used to examine serious safety events (75). The Joint Commission has mandated the use of RCA to examine sentinel events since 1997, and many states require RCA after any serious safety event. Whether care errors result in patient harm or not (precursor events), a systematic analysis of factors that might lead to errors often uncovers several opportunities to improve systems of care and reduces the likelihood of future error. These in-depth analyses examine institutional and regulatory factors, organizational and management policies and procedures, the work environment, the function of the care team, staffing, specific task functions, and patient-specific factors.

For example, a dialysis facility seeks to understand the causes of an event in which blood loss from a dislodged venous needle was not detected promptly and led to substantial blood loss. The RCA team examined policies and procedures, interviewed the nurse, technician, physician caring for that patient, charge nurse, and medical director. The RCA team considered people, procedures, equipment, and organizational structure and constructed a “fishbone diagram” describing the components of process for each category. They created a process map, carefully describing each step in the process of cannulating this patient, operating the dialysis machine, and monitoring the vascular access and blood flow.

The team found multiple places in this map where improved processes may make needle dislodgments less likely to occur. They found that the needle had not been secured in a safe fashion. The nurse had received adequate training but did not strictly follow facility policy. The unit was short-staffed that day and the nurse was called away to see another patient reporting pain at the time he was completing the cannulation. The patient had covered the access site because she felt the room temperature was cold, and no staff had observed or corrected this. The dialysis machine did sound an alarm, but a stressed staff hearing frequent machine alarms did not respond promptly to the alarm. The charge nurse believed that the facility’s mandate to make shift changes more efficient focused staff more on efficiency than on safety.

The RCA team made several recommendations, including better education for staff and patients, creating a checklist for cannulation, and charge nurse rounding to assure access visibility and integrity. They also recommended more structured shift-change policies and supported a study to examine

“alarm fatigue” to determine best solutions to this problem. While some RCA recommendations are easy to effect, others may be more challenging and deserve attention from medical directors and facility operators (76).

### Patient Involvement in Safety Efforts

In 2003, a 17-year-old girl died after receiving a heart and lung transplant from a donor with an incompatible blood type. Several system failures that resulted in this tragic mistake were found. Following the nationally publicized tragedy, the patient’s mother worked with the medical center to establish a patient safety program. Patient and family participation in studying and promoting patient safety in medical care is a new and often unfamiliar role for patients. Studies of the patient-related factors and caregiver factors show the barriers to its widespread use (77).

The Joint Commission requires that patients be encouraged to take an active role in their own care. The Centers for Medicare & Medicaid Services and the ESRD Networks encourage patient engagement, and many quality assurance and performance improvement committees include patient participants. Patients often report errors that were not otherwise detected (78). Patient-reported safety events are actionable (79). Patients are critical partners in establishing an institutional culture of safety (80). Care should be taken, however, when patients participate in studying and acting on error detection and reduction. In a survey of parents of hospitalized children, nearly two thirds felt personally responsible for ensuring their child received safe care (81). Thus, the care team must remain sensitive to the needs of patients and families while working together to make care safer.

### Particular Issues in Home Dialysis Safety

A recent report of procedure-related serious adverse events among home hemodialysis patients found a mortality rate of 0.06 events/1000 dialysis treatments (16). Fatal mistakes can cause exsanguination (82). While life-threatening adverse events among home hemodialysis patients may be rare, home dialysis presents particular challenges to patient safety that require systematic attention from the care team (83). Unobserved adverse safety events, such as hypotension, confusion, edema, hypoglycemia, hyperkalemia, and drug reactions (18), require special precautions and protocols. Potentially fatal errors involving the vascular access are of particular concern for home hemodialysis. Appropriate use of vascular clamps, vascular catheter closure devices, one-way valves, and patient education about the risks of bleeding and air embolization must be completed, tested, and reviewed at intervals. Communication plans between patients at home and training dialysis centers require protocols of ongoing monitoring for these critical risk factors. Technological assistance from devices such as BP cuffs, scales, and dialysis machines that transmit data to dialysis centers and caregivers can play important roles in keeping home peritoneal and hemodialysis patients safe.

### Summary

Errors in dialysis care can cause harm and death. Medical directors of dialysis facilities are responsible for fostering a culture of safety and for creating and supporting policies

and practices that reduce errors and improve patient safety. In the past 15 years, we have learned where the major risks lie and have made some progress toward reducing these errors. Dialysis machines are rarely the major cause of morbidity. Underlying disease and patient factors, such as age, disability, hyperkalemia, diabetes, and vascular instability, may increase the risk of adverse, unintended outcomes. Dialysis patients commonly use multiple medications, and medication errors are common, including missed doses, drug incompatibilities, and mistakes in transferring care from one clinical setting to another (e.g., from dialysis unit to hospital and back again). Patient falls are common and may cause fractures and other morbidity. Better risk assessment, patient assistance protocols, and environmental improvements can reduce this risk. Infections are a common cause of morbidity and mortality. Techniques to improve hand hygiene, reduce central venous catheter use, and improve adherence to sterile technique when these devices are handled reduce the incidence of infections. While vascular access infiltrations and clotting are common, these rarely result in death. Care protocols to detect and treat hyperkalemia, increase appropriate medication use, provide more robust after-hours care, and increase infection prevention may reduce mortality. Dialysis at home requires a special set of precautions to reduce the risks of bleeding, air embolism, and unobserved complications. Finally, communication lapses among caregivers and between patients and caregivers are a major source of errors and adverse outcomes. Techniques such as crew resource management and deployment of tools such as RCA may improve communication and spotlight system factors that can be fixed to improve patient safety. Patient participation in these processes may enhance error detection and improve the culture of safety.

#### Disclosures

None.

#### References

- Institute of Medicine Committee on Quality of Health Care in America: *Crossing the Quality Chasm: A New Health System for the 21st Century*, Washington, DC, National Academies Press, 2001
- Klinger AS, Diamond LH: Patient safety in end-stage renal disease: How do we create a safe environment? *Adv Ren Replace Ther* 8: 131–137, 2001
- Klinger AS: Patient safety in the dialysis facility. *Blood Purif* 24: 19–21, 2006
- Holley JL: A descriptive report of errors and adverse events in chronic hemodialysis units. *Nephrol News Issues* 20: 57–58, 60–61, 63 passim, 2006
- Ward RA, Ronco C: Improvements in technology: A path to safer and more effective hemodialysis. *Blood Purif* 27: 6–10, 2009
- Garrick R, Klinger A, Stefanchik B: Patient and facility safety in hemodialysis: Opportunities and strategies to develop a culture of safety. *Clin J Am Soc Nephrol* 7: 680–688, 2012
- Ellingson KD, Palekar RS, Lucero CA, Kurkjian KM, Chai SJ, Schlossberg DS, Vincenti DM, Fink JC, Davies-Cole JO, Magri JM, Arduino MJ, Patel PR: Vascular access hemorrhages contribute to deaths among hemodialysis patients. *Kidney Int* 82: 686–692, 2012
- McIntyre CW, Rosansky SJ: Starting dialysis is dangerous: How do we balance the risk? *Kidney Int* 82: 382–387, 2012
- Saibu R, Mitchell P, Alleyne J, Blackman J, DeConcilio K, Joseph A, Salifu MO: Dialysis line separation: Maximizing patient safety through education and visibility of access site for patients on hemodialysis. *Nephrol Nurs J* 38: 515–519, 526, 2011
- Thomas A: Patient safety in hemodialysis care delivery—a commentary. *CANNT J* 21: 24–25, 2011
- Lodi CA, Vasta A, Hegbrant MA, Bosch JP, Paolini F, Garzotto F, Ronco C: Multidisciplinary evaluation for severity of hazards applied to hemodialysis devices: an original risk analysis method. *Clin J Am Soc Nephrol* 5: 2004–2017, 2010
- Kallen AJ, Arduino MJ, Patel PR: Preventing infections in patients undergoing hemodialysis. *Expert Rev Anti Infect Ther* 8: 643–655, 2010
- Barraclough KA, Hawley CM, Playford EG, Johnson DW: Prevention of access-related infection in dialysis. *Expert Rev Anti Infect Ther* 7: 1185–1200, 2009
- Chang J, Ronco C, Rosner MH: Computerized decision support systems: Improving patient safety in nephrology. *Nat Rev Nephrol* 7: 348–355, 2011
- Camins BC: Prevention and treatment of hemodialysis-related bloodstream infections. *Semin Dial* 26: 476–481, 2013
- Wong B, Zimmerman D, Reintjes F, Courtney M, Klarenbach S, Dowling G, Pauly RP: Procedure-related serious adverse events among home hemodialysis patients: a quality assurance perspective. *Am J Kidney Dis* 63: 251–258, 2014
- Alquist M, Bosch JP, Barth C, Combe C, Daugirdas JT, Hegbrant JB, Martin G, McIntyre CW, O'Donoghue DJ, Rodriguez HJ, Santoro A, Tattersall JE, Vantard G, Van Wyck DB, Canaud B: Knowing what we do and doing what we should: Quality assurance in hemodialysis. *Nephron Clin Pract* 126: 135–143, 2014
- Weir MR, Fink JC: Safety of medical therapy in patients with chronic kidney disease and end-stage renal disease. *Curr Opin Nephrol Hypertens* 23: 306–313, 2014
- Bray BD, Boyd J, Daly C, Doyle A, Donaldson K, Fox JG, Innes A, Khan I, Mackinnon B, Peel RK, Shilliday I, Simpson K, Stewart GA, Traynor JP, Metcalfe W; Scottish Renal Registry (SRR): How safe is renal replacement therapy? A national study of mortality and adverse events contributing to the death of renal replacement therapy recipients. *Nephrol Dial Transplant* 29: 681–687, 2014
- Patel PR, Yi SH, Booth S, Bren V, Downham G, Hess S, Kelley K, Lincoln M, Morrisette K, Lindberg C, Jernigan JA, Kallen AJ: Bloodstream infection rates in outpatient hemodialysis facilities participating in a collaborative prevention effort: A quality improvement report. *Am J Kidney Dis* 62: 322–330, 2013
- Organising for Safety: Third Report of the ACSNI (Advisory Committee on the Safety of Nuclear Installations) Study Group on Human Factors*. Health and Safety Commission (of Great Britain), Sudbury, England, HSE Books, 1993
- Weick K, Sutcliffe K: *Managing the Unexpected. Resilient Performance in the Age of Uncertainty*, 2nd Ed., San Francisco, John Wiley & Sons, Inc., 2007
- Maynard MT, Marshall D, Dean MD: Crew resource management and teamwork training in health care: A review of the literature and recommendations for how to leverage such interventions to enhance patient safety. *Adv Health Care Manag* 13: 59–91, 2012
- Davidson IJ, Lok C, Dolmatch B, Gallieni M, Nolen B, Pittiruti M, Ross J, Slakey D: Virtual reality: Emerging role of simulation training in vascular access. *Semin Nephrol* 32: 572–581, 2012
- Agency for Healthcare Research and Quality: Patient Safety Organization Program. Available at: <https://www.pso.ahrq.gov/legislation>. Accessed September 8, 2014
- Agency for Healthcare Research and Quality: Patient safety primers. Available at: <http://psnet.ahrq.gov/primer.aspx?primerID=20>. Accessed September 8, 2014
- Kerber CW: Changing our culture: Adopting the military aviation safety system. *J Neurointerv Surg* 6: 332–341, 2014
- Pennsylvania Patient Safety Advisory: Hemodialysis administration: Strategies to ensure safe patient care. *Pa Patient Saf Advis* 7: 87–96, 2010 Available at: [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7\(3\)/Pages/87.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7(3)/Pages/87.aspx). Accessed September 8, 2014
- Di Benedetto A, Pelliccia F, Moretti M, d'Orsi W, Starace F, Scatizzi L, Parisotto MT, Marcelli D: What causes an improved safety climate among the staff of a dialysis unit? Report of an evaluation in a large network. *J Nephrol* 24: 604–612, 2011
- Weighing the options, making the choice: *ESRD Network #12 Patient Newsletter* 3:1, Spring 2003. Available at: [http://www.mymedicalneighborhood.com/community/pat\\_newsletters/weighing\\_the\\_options.pdf](http://www.mymedicalneighborhood.com/community/pat_newsletters/weighing_the_options.pdf). Accessed September 8, 2014



31. Dager WE: What are the important drug use errors in dialysis patients? Pharmacokinetic and pharmacodynamic principles. *Semin Dial* 23: 466–469, 2010
32. St Peter WL: Improving medication safety in chronic kidney disease patients on dialysis through medication reconciliation. *Adv Chronic Kidney Dis* 17: 413–419, 2010
33. Ledger S, Choma G: Medication reconciliation in hemodialysis patients. *CANNT J* 18: 41–43, 2008
34. Seliger SL, Zhan M, Hsu VD, Walker LD, Fink JC: Chronic kidney disease adversely influences patient safety. *J Am Soc Nephrol* 19: 2414–2419, 2008
35. Chapin E, Zhan M, Hsu VD, Seliger SL, Walker LD, Fink JC: Adverse safety events in chronic kidney disease: the frequency of “multiple hits”. *Clin J Am Soc Nephrol* 5: 95–101, 2010
36. Hug BL, Witkowski DJ, Sox CM, Keohane CA, Seger DL, Yoon C, Matheny ME, Bates DW: Occurrence of adverse, often preventable, events in community hospitals involving nephrotoxic drugs or those excreted by the kidney. *Kidney Int* 76: 1192–1198, 2009
37. Renal Physicians Association: Health and safety survey to improve patient safety in end stage renal disease: Report of findings from ESRD patient survey, 2007. Available at: <http://www.kidneypatientsafety.org/about.aspx> Accessed September 8, 2014
38. Harel Z, Wald R, Liu JJ, Bell CM: Lapses in safety in end-stage renal disease patients admitted to surgical services. *Hemodial Int* 16: 286–293, 2012
39. Sloan JA: Dialysis patient safety: Safeguards to prevent iatrogenic hypoglycemia in patients receiving icodextrin. *Am J Kidney Dis* 60: 514–516, 2012
40. Centers for Disease Control and Prevention: Dialysis Data Reports. Available at: <http://www.cdc.gov/dialysis/monitoring/Data-reports.html>. Accessed September 8, 2014
41. U.S. Renal Data System: *USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2013
42. Boyce JM, Pittet D; Healthcare Infection Control Practices Advisory Committee. Society for Healthcare Epidemiology of America. Association for Professionals in Infection Control. Infectious Diseases Society of America. Hand Hygiene Task Force: Guideline for Hand Hygiene in Health-Care Settings: recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *Infect Control Hosp Epidemiol*. Dec; 23(12 Suppl):S3–40, 2002
43. Centers for Disease Control and Prevention (CDC): Reducing bloodstream infections in an outpatient hemodialysis center—New Jersey, 2008–2011. *MMWR Morb Mortal Wkly Rep* 61: 169–173, 2012
44. Taylor G, Gravel D, Johnston L, Embil J, Holton D, Paton S; Canadian Hospital Epidemiology Committee. Canadian Nosocomial Infection Surveillance Program: Prospective surveillance for primary bloodstream infections occurring in Canadian hemodialysis units. *Infect Control Hosp Epidemiol* 23: 716–720, 2002
45. Taylor G, Gravel D, Johnston L, Embil J, Holton D, Paton S; Canadian Nosocomial Infection Surveillance Program; Canadian Hospital Epidemiology Committee: Incidence of bloodstream infection in multicenter inception cohorts of hemodialysis patients. *Am J Infect Control* 32: 155–160, 2004
46. Stevenson KB, Hannah EL, Lowder CA, Adcox MJ, Davidson RL, Mallea MC, Narasimhan N, Wagnild JP: Epidemiology of hemodialysis vascular access infections from longitudinal infection surveillance data: Predicting the impact of NKF-DOQI clinical practice guidelines for vascular access. *Am J Kidney Dis* 39: 549–555, 2002
47. Ravani P, Palmer SC, Oliver MJ, Quinn RR, MacRae JM, Tai DJ, Pannu NI, Thomas C, Hemmelgarn BR, Craig JC, Manns B, Tonelli M, Strippoli GF, James MT: Associations between hemodialysis access type and clinical outcomes: A systematic review. *J Am Soc Nephrol* 24: 465–473, 2013
48. Levin A, Mason AJ, Jindal KK, Fong IW, Goldstein MB: Prevention of hemodialysis subclavian vein catheter infections by topical povidone-iodine. *Kidney Int* 40: 934–938, 1991
49. Lok CE, Stanley KE, Hux JE, Richardson R, Tobe SW, Conly J: Hemodialysis infection prevention with polysporin ointment. *J Am Soc Nephrol* 14: 169–179, 2003
50. van Rijen M, Bonten M, Wenzel R, Kluytmans J: Mupirocin ointment for preventing Staphylococcus aureus infections in nasal carriers. *Cochrane Database Syst Rev* (4): CD006216, 2008
51. Sesso R, Barbosa D, Leme IL, Sader H, Canziani ME, Manfredi S, Draibe S, Pignatari AC: Staphylococcus aureus prophylaxis in hemodialysis patients using central venous catheter: Effect of mupirocin ointment. *J Am Soc Nephrol* 9: 1085–1092, 1998
52. Johnson DW, van Eps C, Mudge DW, Wiggins KJ, Armstrong K, Hawley CM, Campbell SB, Isbel NM, Nimmo GR, Gibbs H: Randomized, controlled trial of topical exit-site application of honey (Medihoney) versus mupirocin for the prevention of catheter-associated infections in hemodialysis patients. *J Am Soc Nephrol* 16: 1456–1462, 2005
53. Rosenblum A, Wang W, Ball LK, Latham C, Maddux FW, Lacson E Jr: Hemodialysis catheter care strategies: A cluster-randomized quality improvement initiative. *Am J Kidney Dis* 63: 259–267, 2014
54. Yahav D, Rozen-Zvi B, Gafer-Gvili A, Leibovici L, Gafer U, Paul M: Antimicrobial lock solutions for the prevention of infections associated with intravascular catheters in patients undergoing hemodialysis: Systematic review and meta-analysis of randomized, controlled trials. *Clin Infect Dis* 47: 83–93, 2008
55. Labriola L, Crott R, Jadoul M: Preventing haemodialysis catheter-related bacteraemia with an antimicrobial lock solution: A meta-analysis of prospective randomized trials. *Nephrol Dial Transplant* 23: 1666–1672, 2008
56. Maki DG, Ash SR, Winger RK, Lavin P; AZEPTIC Trial Investigators: A novel antimicrobial and antithrombotic lock solution for hemodialysis catheters: A multi-center, controlled, randomized trial. *Crit Care Med* 39: 613–620, 2011
57. Boyce JM: Prevention of central line-associated bloodstream infections in hemodialysis patients. *Infect Control Hosp Epidemiol* 33: 936–944, 2012
58. Renal Physicians Association: Report on the findings from the ESRD professional survey. Rockville, MD, Renal Physicians Association, 2007. Available at: [http://www.kidneypatientsafety.org/uploadedFiles/HSSProfessionalSurveyReport\\_FNL\\_3-21-07.pdf](http://www.kidneypatientsafety.org/uploadedFiles/HSSProfessionalSurveyReport_FNL_3-21-07.pdf). Accessed September 8, 2014
59. Lee T, Barker J, Allon M: Needle infiltration of arteriovenous fistulae in hemodialysis: Risk factors and consequences. *Am J Kidney Dis* 47: 1020–1026, 2006
60. ECRI Institute: Hazard report: Undetected venous needle dislodgment during hemodialysis can be fatal. *Health Devices* 32: 325–326, 2003
61. Zeigler SA: Prevent dangerous hemodialysis catheter disconnections. *Nursing* 37: 70, 2007
62. Veteran Affairs announces that redsense alarm will be mandatory on patients by November 1, 2010. PR Newswire. August 25, 2010. Available at: <http://www.prnewswire.com/news-releases/veteran-affairs-announces-that-redsense-alarm-will-be-mandatory-on-patients-by-november-1-2010-101462114.html>. Accessed September 8, 2014
63. DeVivo R: National ESRD Patient Safety Initiative. Phase II report. A partnership between The Renal Physicians Association, the Forum of End Stage Renal Disease Networks, and the National Patient Safety Foundation. December 2001. Available at: <http://www.renalmd.org/WorkArea/DownloadAsset.aspx?id=515>. Accessed September 8, 2014
64. Cook WL, Tomlinson G, Donaldson M, Markowitz SN, Naglie G, Sobolev B, Jassal SV: Falls and fall-related injuries in older dialysis patients. *Clin J Am Soc Nephrol* 1: 1197–1204, 2006
65. Desmet C, Beguin C, Swine C, Jadoul M; Université Catholique de Louvain Collaborative Group: Falls in hemodialysis patients: Prospective study of incidence, risk factors, and complications. *Am J Kidney Dis* 45: 148–153, 2005
66. Roberts RG, Kenny RA, Brierley EJ: Are elderly haemodialysis patients at risk of falls and postural hypotension? *Int Urol Nephrol* 35: 415–421, 2003
67. Roberts R, Jeffrey C, Carlisle G, Brierley E: Prospective investigation of the incidence of falls, dizziness and syncope in haemodialysis patients. *Int Urol Nephrol* 39: 275–279, 2007
68. Morse JM: Enhancing the safety of hospitalization by reducing patient falls. *Am J Infect Control* 30: 376–380, 2002
69. Heung M, Adamowski T, Segal JH, Malani PN: A successful approach to fall prevention in an outpatient hemodialysis center. *Clin J Am Soc Nephrol* 5: 1775–1779, 2010

70. Abdel-Rahman EM, Turgut F, Turkmen K, Balogun RA: Falls in elderly hemodialysis patients. *QJM* 104: 829–838, 2011
  71. Kiaii M, Djurdjev O, Farah M, Levin A, Jung B, MacRae J: Use of electron-beam sterilized hemodialysis membranes and risk of thrombocytopenia. *JAMA* 306: 1679–1687, 2011
  72. Himmelfarb J: Optimizing patient safety during hemodialysis. *JAMA* 306: 1707–1708, 2011
  73. Coulliette AD, Arduino MJ: Hemodialysis and water quality. *Semin Dial* 26: 427–438, 2013
  74. Fendley DA, Ward RA: Dialysate quality: New standards require a new approach to compliance. *Semin Dial* 25: 510–515, 2012
  75. Agency for Healthcare Research and Quality; AHRQ PSNet. Patient safety primers: root cause analysis. Available at: <http://psnet.ahrq.gov/primer.aspx?primerID=10> Accessed September 8, 2014
  76. Wrigstad J, Bergström J, Gustafson P: Mind the gap between recommendation and implementation-principles and lessons in the aftermath of incident investigations: A semi-quantitative and qualitative study of factors leading to the successful implementation of recommendations. *BMJ Open* 4: e005326, 2014
  77. Longtin Y, Sax H, Leape LL, Sheridan SE, Donaldson L, Pittet D: Patient participation: Current knowledge and applicability to patient safety. *Mayo Clin Proc* 85: 53–62, 2010
  78. Weingart SN, Pagovich O, Sands DZ, Li JM, Aronson MD, Davis RB, Bates DW, Phillips RS: What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J Gen Intern Med* 20: 830–836, 2005
  79. Ginsberg JS, Zhan M, Diamantidis CJ, Woods C, Chen J, Fink JC: Patient-reported and actionable safety events in CKD. *J Am Soc Nephrol* 25: 1564–1573, 2014
  80. Agency for Healthcare Research and Quality; AHRQ PSNet. Patient safety primers: The role of the patient in safety. Available at: <http://psnet.ahrq.gov/primer.aspx?primerID=17>. Accessed September 8, 2014
  81. Tarini BA, Lozano P, Christakis DA: Afraid in the hospital: Parental concern for errors during a child's hospitalization. *J Hosp Med* 4: 521–527, 2009
  82. Allcock K, Jagannathan B, Hood CJ, Marshall MR: Exsanguination of a home hemodialysis patient as a result of misconnected blood-lines during the wash back procedure: a case report. *BMC Nephrol* 13: 28, 2012
  83. Hawley CM, Jeffries J, Nearhos J, Van Eps C: Complications of home hemodialysis. *Hemodial Int* 12[Suppl 1]: S21–S25, 2008
- Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

# Infection Prevention and the Medical Director: Uncharted Territory

Toros Kapoian,<sup>\*†</sup> Klemens B. Meyer,<sup>\*§</sup> and Douglas S. Johnson<sup>||</sup>

## Abstract

**Infections continue to be a major cause of disease and contributor to death in patients on dialysis. Despite our knowledge and acceptance that hemodialysis catheters should be avoided and eliminated, most patients who begin dialysis initiate treatment through a central vein hemodialysis catheter. Dialysis Medical Directors must be the instrument through which our industry changes. We must lead the charge to educate our dialysis staff and our dialysis patients. We must also educate ourselves so that we not only know that our facility policies are consistent with the best evidence available, but we must also know where local and federal regulations differ. When these differences impact on patient care, we must speak out and have these regulations changed. But it is not enough to know the rules and write them. We must lead by example and show our patients, our nephrology colleagues and our dialysis staff that we always follow these same policies. We need to practice what we preach and be willing and available to redirect those individuals who have difficulty following the rules. In order to effectively change process meaningful data must be collected, analyzed and acted upon. Dialysis Medical Directors must direct and lead the quality improvement process. We hope this review provides Dialysis Medical Directors with the necessary tools to effectively drive this process and improve care.**

*Clin J Am Soc Nephrol* 10: 863–874, 2015. doi: 10.2215/CJN.06050614

## Introduction

Health care–associated infections are among the most important preventable causes of dialysis morbidity and mortality (1). Among patients undergoing hemodialysis, hospitalizations for infection have increased 43% since 1993, although the overall hospitalization rate and total hospital days have declined (2). Mortality due to infection peaks in the second month after starting dialysis, at 43 deaths/1000 patient-years, and falls to 19.4 deaths/1000 patient-years after 1 year (2). Since 2000, prevalent hemodialysis (HD) patient mortality rates have declined by 21%. Nonetheless, only half of all patients who begin HD are still living 3 years later (2), and infections cause or contribute to many of these deaths.

## Medical Directors: Responsibilities and Importance as Role Models

The dialysis community and dialysis facility medical directors must do better. According to the Centers for Medicare & Medicaid Services (CMS) 2008 Conditions for Coverage (CfC) §494.150 Condition: Responsibilities of the Medical Director, “the dialysis facility must have a medical director . . . to be responsible for the delivery of patient care and outcomes in the facility. The medical director is accountable to the governing body for the quality of medical care provided to patients” (3). Table 1 outlines the responsibilities set forth in the CfC.

To optimize an infection prevention program, dialysis facilities must change their culture. Culture change requires dedicated and committed leadership, which

the medical director must provide. This is not an easy task, especially in light of the many other priorities competing for medical directors’ time. To do this well, medical directors need to make infection prevention a priority. They must ensure that their dialysis providers set up evidence-based quality assessment and performance improvement (QAPI) systems and must lead the team, not only attend the QAPI meetings. Medical directors are uniquely positioned to guide and support the dialysis clinic’s infection prevention team. Their understanding of epidemiology, microbiology, and pathophysiology, and their professional authority, carry with them the responsibility to champion this quality improvement activity. They need to be involved at every level: educating patients and staff, evaluating adherence to policies and procedures, ensuring that the QAPI process is optimized according to the needs of their clinic, and working with their local administrator and their dialysis provider to ensure that appropriate resources are available to run their program.

Medical directors can think about infection prevention principles in two broad program areas: those regarding patient care and those regarding the facility and its staff. Patient-related issues include those involving the HD access (minimizing the use of catheters, using the Centers for Disease Control and Prevention [CDC] “scrub the hub” protocol, and caring for the arteriovenous access) and immunization issues (screening and vaccination). Dialysis clinic–related issues include hand hygiene, environmental disinfection, cleaning and disinfection of dialysis equipment, modified contact precautions, isolating and

<sup>\*</sup>Associate Professor of Medicine, Rutgers–Robert Wood Johnson Medical School, Department of Medicine, Division of Nephrology New Brunswick, New Jersey; <sup>†</sup>Medical Director, Dialysis Clinic, Inc., North Brunswick, New Jersey; <sup>‡</sup>Professor of Medicine, Division of Nephrology, Tufts University School of Medicine, Medford, Massachusetts; <sup>§</sup>Director, Dialysis Services, Tufts Medical Center, Boston, Massachusetts; and <sup>||</sup>Vice-Chairman of the Board, Dialysis Clinic Inc., Nashville, Tennessee

## Correspondence:

Dr. Douglas S. Johnson, Dialysis Clinic, Inc., 1633 Church Street, Suite 500 Nashville, TN 37203. Email: doug.johnson@dcinc.org

**Table 1. Centers for Medicare & Medicaid Services Conditions for Coverage § 494.150 Condition: Responsibilities of the Medical Director**

Medical director responsibilities include, but are not limited to, the following:	
(a)	Quality assessment and performance improvement program (QAPI)
(b)	Staff education, training and performance
(c)	Policies and procedures. The medical director must: <ul style="list-style-type: none"> <li>(1) Participate in the development, periodic review and approval of a “patient care policies and procedures manual” for the facility; and</li> <li>(2) Ensure that—</li> </ul>
(i)	All policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and nonphysician providers; and
(ii)	The interdisciplinary team adheres to the discharge and transfer policies and procedures specified in § 494.180 (f)

cohorting patients, and antibiotic stewardship. This review contains data elements and tools that we have found to be effective. We hope that other medical directors will similarly benefit and use this information to drive the infection prevention process effectively and influence their dialysis providers to adopt programs that have been shown to improve care.

### Patient-Related Issues

#### Hemodialysis Access

**Minimize Use of Dialysis Catheters.** Cuffed and non-cuffed catheters are 15 and 21 times more likely to become infected, respectively, than arteriovenous fistulae (4). In 2011, 81% of incident patients began HD using a catheter (1). Although patients who had been under the care of a nephrologist for more than a year were more likely to begin treatment using a fistula, 41% still start hemodialysis using a catheter only (2). The prognosis of patients with CKD stage 4 and early stage 5 is uncertain; many die before reaching dialysis, and these numbers may grow in the

wake of the Initiating Dialysis Early and Late (IDEAL) study and supporting observational data (5). Nonetheless, medical directors and staff nephrologists alike have an infection prevention opportunity to improve their own practice in preparing patients for dialysis, along with a public health opportunity in educating internists, family practitioners and the other subspecialists with whom they work. Predictive instruments are available to estimate the likelihood that a patient will survive to dialysis (6). Patients should be educated about their dialysis access and what they can do to avoid infections (CDC’s “Dialysis Patient Pocket Guide”) (7).

Perhaps the most important process to decrease the risk of catheter-related infections is to have a system in place to have permanent accesses placed as soon as possible and to have catheters removed as quickly as possible. Incident patients beginning HD with catheters should be closely monitored and counseled about their risks. Medical directors should ensure that their dialysis clinic staff assists these patients with the necessary steps (e.g., vessel mapping, access surgery appointments) to have a permanent access

Patient Name	Nephrologist	Surgeon	Date Patient Education	Date Care Plan Meeting	Date Vessel Mapping	Date Surgical Consult	Date Access Placement	Post-Op Access Evaluation	4-Week Access Evaluation	Surgical ReEvaluation If Needed	Date One Needle Cannulation	Date Two Needle Cannulation	Date Catheter Removal

**Figure 1. | Example of a dialysis catheter removal tracking tool.** Adapted from references 9,10.

inserted and catheter removed. Medical directors must also ensure that the dialysis clinic has systems in place to track dialysis catheter infections. One such tool is the Fistula First infection tracking log (8). Medical directors must also ensure that the steps required for catheter removal are followed systematically (Figure 1) (9,10). Given their overwhelmingly high rates of infection, noncuffed catheters should be avoided.

**Implement the CDC “Scrub the Hub” Protocol.** The CDC recommends using a “scrub the hub” protocol as a method to reduce the likelihood of bloodstream infection in patients receiving HD *via* a central venous catheter (11). The procedure involves using one of several acceptable antiseptics, including >0.5% chlorhexidine gluconate (CHG) with alcohol, 70% alcohol, or 10% povidone-iodine. After application, the solution should be allowed to dry completely to impart maximal effect. The effect might be enhanced if an antiseptic pad is used rather than a swab or other delivery system because a pad can conform to the surface irregularities of the catheter. Particular attention should be paid to the catheter hub and its connecting limb, both of which are “scrubbed” starting at the catheter hub (with caps removed) and ensuring that the threads are cleaned of any residual debris or blood. The scrubbing action then continues to move along the catheter limb in a direction toward the patient and away from the open threaded end of the hub. If vascular access related infection or the blood stream infection rates are unacceptably high, medical directors should review clinic policies and practice and recommend changes as indicated.

**Care of the Fistula or Graft and Skin Preparation for Dialysis.** Patients should learn the CDC’s “6 Tips for Preventing Dialysis Infections” (Supplemental Material): (1) Take care

of your dialysis access site at home. Avoid scratching or picking it; (2) know the steps your health care providers should take when using your dialysis access for treatment; (3) wash your hands often, especially before and after dialysis treatment; (4) know the signs and symptoms of infection and what to do if you think you might have an infection; (5) know what to do if you have any problem with your dialysis access site; (6) wash or cleanse your dialysis access site before treatment (7). The importance of patient hand and arm washing deserves continuing emphasis (12).

The skin overlying a fistula or graft may be prepared for cannulation using povidone iodine, CHG, sodium hypochlorite, or alcohol. Table 2 compares their characteristics (13–19). The CDC recommends using “an alcohol-based chlorhexidine (>0.5%) solution as the first line skin antiseptic agent for central line insertion and during dressing changes” (18). Some studies suggest that CHG is more effective than other agents (20–25), but this finding is not definitive; the choice of agent is less important than strict adherence to the procedure of its application (20). CHG is particularly attractive in the dialysis setting because it dries so quickly. CHG may be used for skin preparation before catheter insertion, during catheter exit site care, and during catheter limb/hub care. Unfortunately, many patients and facilities limit its use because of adverse reactions ascribed to CHG. The rate of true allergic reactions to CHG is <5% (26,27). If facilities experience higher rates, episodes of generalized skin irritation are probably being classified as true allergic reactions (see Table 3) (28). In patients suspected of having a reaction to CHG, rechallenge with CHG on a nonaccess site may be warranted. Medical directors need to know how vascular accesses are

**Table 2. Comparison of topical skin disinfectants available for use in dialysis**

Product	Availability	Other Supplies Needed	Application Time (Reference)	Dry Time (Reference)
Chlorhexidine: Dry site <sup>a</sup>	Swab/pad (>0.5%)	None	30 sec (13)	30 sec (13)
Chlorhexidine: moist site <sup>b</sup>	Swab/pad (>0.5%)	None	2 min (13)	1 min (13)
PVP-I <sup>c</sup>	10% PVP-I swab/pad	None	2–3 min (14)	2 min (15,16)
	10% PVP-I solution	Gauze	2–3 min (14)	2 min (15,16)
Alcohol	70% swab/pad	None	1 min (14)	Cannulate immediately (14)
	70% solution	Gauze	1 min (14)	Cannulate immediately (14)
Sodium hypochlorite (NaOCl) <sup>d</sup>	0.114% solution	Gauze	Not specified (17) <sup>e</sup>	2 min (17)

PVP-I, povidone iodine.

<sup>a</sup>Dry sites: sites not occluded by skin or other surfaces and with free access to air circulation, such as the forearm, chest wall, and neck (13).

<sup>b</sup>Moist sites: sites occluded by skin or other surfaces and without free access to air circulation, such as the axilla, groin, and abdominal wall under a large pannus of skin (13).

<sup>c</sup>Preferably with alcohol (18).

<sup>d</sup>Sodium hypochlorite 0.55% is also approved for catheter hub care. Carefully wrap each port in gauze that is freshly saturated with NaOCl. Leave each port wrapped for at least 1 minute. Remove gauze and initiate hemodialysis (19).

<sup>e</sup>Saturate a 4×4 pad with NaOCl and cleanse the exit site starting at the center and moving in a circular motion outward to a radius of at least 2 inches from the center. Repeat with a new NaOCl-saturated 4×4 pad.

**Table 3. Possible causes of chlorhexidine-associated skin irritation**

Site rubbed too vigorously  
 Site covered before CHG completely dried  
 Formulation contains more than 2% CHG  
 Tape/ tape residue interaction with alcohol and CHG

CHG, chlorhexidine gluconate. Information obtained from reference 28.

managed in their clinics. They should review the choice of topical disinfectant, design a protocol for skin disinfection that adheres to guidelines, ensure that patients are not experiencing an increased incidence of adverse events, and ensure that patients and dialysis staff are following policy. Any areas of concern should be reviewed and addressed in QAPI.

### Immunization and Screening Issues

**Routine Screening.** The CMS 2008 CfC adopt the CDC 2001 recommendations regarding screening for hepatitis B virus (HBV) infection and immunity. Following these recommendations, individual by individual, for a large population of patients is a complex enterprise. Medical directors should consider developing a program of regular audits and review these findings in QAPI. HBV surface antigen may occasionally appear as a false-positive test result following influenza and hepatitis B immunizations (29,30). Testing for HBV surface antigen within 4 weeks of immunization for hepatitis B increases the risk for a false-positive result (31). The presence of rheumatoid factor may produce false-negative results (32,33). The availability of nucleic acid testing may be helpful in selected cases but may also create further uncertainty (34).

HBV seroconversions, a major problem in the early 1970s, have become a rare event in dialysis facilities, but hepatitis C virus (HCV) transmission remains an important problem. The CDC 2001 recommendations included screening for HCV antibody every 6 months in patients lacking antibody and thus free of infection. Notably, CMS did not adopt hepatitis C screening in the 2008 CfC, giving the dialysis medical directors and governing bodies a choice of what approach to adopt. If a policy of less than universal screening is adopted, it may be prudent to consider the CDC's more recent recommendation for universal screening among individuals born between 1945 and 1965. Whatever level of screening for hepatitis C is adopted, it is prudent also to include universal testing of alanine aminotransferase in monthly blood

work and to investigate unexplained elevations. Both HBV and HCV are reportable, and seroconversions should also prompt a thorough internal root cause analysis (35).

Although the 2008 CfC do not speak to screening for tuberculosis (TB), the interpretive guidelines for surveyors require that dialysis facilities record the history of tuberculosis testing; page 190 of the Interpretive Guidance column of the document quotes a CDC recommendation that dialysis patients "[b]e tested at least once for baseline tuberculin skin test (TST) results and re-screened if TB exposure is detected. Chest x-rays may be used for individuals for whom the TST is not an option" (36). IFN- $\gamma$  release assays have sensitivities similar to that of TSTs (37) and may be better than chest radiography. Although their optimal role in a TB prevention strategy has not been established, they can be used as an adjunct to TST in certain circumstances, such as in patients or employees who have previously been treated with bacillus Calmette-Guérin (38). Because dialysis patients are at increased risk for progression of latent infection to active TB, their identification is an important part of targeted testing for TB infection and treatment. According to the CDC, "patients with ESRD who need chronic dialysis should have at least one test for *M. tuberculosis* infection to determine the need for treatment. Annual re-screening is indicated if ongoing exposure of ESRD patients to *M. tuberculosis* is probable" (39). Medical directors should review their clinic's TB infection control program annually. The CDC's TB risk assessment worksheet (40) is a helpful tool.

**Vaccination.** HBV vaccination is recommended for all susceptible patients undergoing long-term dialysis. In general, vaccinating patients with CKD before dialysis initiation produces higher antibody titers and seroprotection rates than vaccinating patients who have already begun dialysis (41). Vaccination, coupled with environmental controls, is the best method for preventing the spread of HBV within the dialysis clinic. Medical directors must ensure that their clinics have programs in place to monitor the administration of hepatitis B vaccine to all patients. Figure 2 is an example of a hepatitis B tracking form. These results should be reviewed in QAPI. Medical directors must also ensure that the clinic does not assign staff who are susceptible to HBV infection to care for patients who are HBV surface antigen positive. Furthermore, a nurse or technician participating in the treatment of a HBV surface antigen-positive patient cannot provide simultaneous care to patients who do not have adequate titers (>10 international units) of HBV surface antibody. Medical directors should spot-check staff assignments to ensure that these rules are being followed. Special attention should be given to the temporary staffing coverage that occurs

Month	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
# Patients that are Hep B surface antigen positive												
# Patients that are Hep B surface antigen negative												
# Patients that are Hep B surface antibody positive												
# Patients that are Hep B surface antibody negative												
# Patients that are receiving Hep B vaccine series												
# Patients refusing Hep B vaccination												
# Patients that are non-converters												

**Figure 2.** | Example of a hepatitis B vaccination tracking form used in some Dialysis Clinic, Inc. clinics.

during meal and shift breaks when these rules may be more likely to be violated. The sensitivity of available HBV surface antigen assays is increasing, and it may behoove medical directors to ask their laboratory which assay it uses (42).

Routine annual influenza vaccination is recommended for all persons aged 6 months and older. Until recently, all patients received a trivalent vaccine that was designed to protect against two strains of influenza A and one strain of influenza B. Epidemics of influenza B occur every several years in patients of all ages and are much more difficult to predict than influenza A strains. In 2013 a quadrivalent influenza vaccine containing two strains of influenza A and two strains of influenza B was made available (43). It is hoped that the newer quadrivalent products will provide additional influenza protection. Older adults have decreased antibody response to influenza vaccination (44). Studies performed in patients aged 65 years and older have shown that high-dose vaccines containing four times the standard amount of antigen elicited a substantially higher immune response (45–47). Although no controlled trials have assessed these vaccines in the HD population, newer formulations (quadrivalent and high-dose) can be considered for use in the HD population. Although vaccine effectiveness varies from year to year, depending on the match between the vaccine strains and the strains that turn out to be prevalent, it is reasonable to estimate that vaccination may reduce the risk of death from influenza by 50% (48–50). Patients may casually decline vaccination without fully understanding its small risks and substantial benefits. Because vaccination is performed on behalf not only of the individual being immunized but also the public, it is appropriate for medical directors to personally speak with any patients who have declined vaccine to try to persuade them to change their minds.

By the very nature of their work, health care workers (HCWs) are at increased risk for contracting influenza and for transmitting it to their dialysis patients, a group at high risk for morbidity and mortality from influenza. Although some voluntary HCW vaccination programs have achieved sufficiently high vaccination rates, there is now a trend toward mandating universal influenza vaccination of HCWs, with individuals who are not able to receive the vaccine because of medical contraindications or who decline vaccination being required to wear masks while working with patients during the influenza season. This movement is supported by many professional societies, including the American College of Immunization Practices (ACIP), the Infectious Diseases Society of America, the Society for

Healthcare Epidemiology of America, the Pediatric Infectious Diseases Society, and others. According to the CDC, only 72% of HCWs reported being vaccinated against influenza for the 2012–2013 season (51). Although this represents an increase from the previous year (67%), it is far lower than rates seen for physicians (92%) or HCWs (97%) in settings with mandatory vaccination requirements. In view of the fragility of dialysis patients, medical directors should consider universal influenza vaccination; the fact that an increasing number of major medical centers require this of their employees may make it more acceptable. Medical directors should consider whether patients who decline or are unable to receive vaccination should also be subject to the requirement to wear a mask during influenza season.

*Streptococcus pneumoniae* (pneumococcus) is a leading cause of serious illness in adults. Adults with high-risk medical conditions are at increased risk for invasive pneumococcal disease. The ACIP now recommends that dialysis patients be vaccinated with both the PPSV23 vaccine (Pneumovax, traditionally used in adults) as well as the PCV13 vaccine (traditionally used in children, marketed as Prevnar) (52). This recommendation comes from 2010 data showing that half of the cases of invasive pneumococcal disease among immunocompromised adults were caused by pneumococcal serotypes contained in the PCV13 vaccine and another almost quarter of the cases were caused by serotypes contained in the PPSV23 vaccine. In pneumococcal vaccine-naïve patients, ACIP recommends that adults aged 19 years and older who have not previously received PCV13 or PPSV23 should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later. Subsequent doses of PPSV23 should follow the current PPSV23 recommendations. In patients who were previously vaccinated with PPSV23, ACIP recommends that adults aged 19 years and older should be vaccinated with PCV13 at least 1 year after the last PPSV23 dose was received. For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23. Medical directors should review the clinic's policies regarding pneumococcal vaccination to see whether they have been modified according to ACIP recommendations.

## Dialysis Clinic-Specific Issues

### Hand Hygiene

Hand hygiene is the cornerstone of infection prevention. Medical directors must ensure the proper use of hand-washing sinks and waterless hand sanitizers, by setting an

**Table 4. Hand hygiene opportunities in dialysis**

<p>Before and after entering the dialysis treatment area          Before and after touching a patient or their belongings          Before injecting or infusing a medication          Before cannulating a fistula/graft or accessing a catheter          After touching blood, body fluids, mucous membranes, wound dressings, or dialysis fluids (<i>e.g.</i>, spent dialysate)          After touching medical equipment or other items at the dialysis station          After removing gloves</p>
---

Adapted from references 53,54.

example, publically asking other physicians and staff to comply, and requiring random audits of staff adherence to appropriate hand hygiene opportunities (Table 4) (53,54). Proper use of soap, paper towels, and hand sanitizer should be audited regularly. Examples of audit tools are available from the World Health Organization (55) and the CDC (56). Results of these audits should be reviewed at the monthly clinic QAPI meeting. As clinic leaders, it is essential that medical directors clean their hands before and after contact with each patient, and work to ensure that other nephrologists in the clinic follow suit (57,58). They should insist that policies and procedures require that when the patient is suspected or documented to have *Clostridium difficile* infection, soap and water must be used at all times (59): alcohol-based hand-sanitizers do not kill the spores (60,61). Hand washing is not trivial: staff must demonstrate proper methods for hand washing and use of waterless hand sanitizer. The World Health Organization's "Hand Hygiene: Why, How & When?" brochure (62) is a helpful resource.

HCWs must wear gloves and other personal protective equipment (PPE) (see the CDC "Sequence for Donning and Removing Personal Protective Equipment" poster [63]) when engaged in any activity that may result in contact with blood or body fluids (Table 5) (53). If staff cannot properly perform hand hygiene or use PPE, medical directors must ensure that programs are put in place to correct

these issues. Assuring hand-cleaning competence or PPE use could be appropriate quality improvement projects.

### Environmental Disinfection

Proper cleaning and disinfection reduce the risk of spreading infections. Cleaning involves the use of water, a detergent, and friction to remove surface dirt and protein-containing materials and to prepare the surface for disinfection. Disinfection reduces the number of microorganisms and is optimized when applied to a clean surface. Surfaces that are not cleaned allow microorganisms to "hide" from the disinfectant within the layers of dirt and protein. Medical directors should ensure that the clinic is using an Environmental Protection Agency-registered hospital-grade disinfectant (64) and following the manufacturer's instructions for dilution and contact time (65). To prevent contamination of the stock solution, the solution should be changed frequently, and used disinfection cloths should not be submerged in the solution. Bleach is the most commonly used disinfectant in dialysis units. If bleach is being used, medical directors should ensure that it is Environmental Protection Agency-registered hospital-grade bleach (65). They should also ensure that their clinic correctly prepares the diluted solution and that each batch is dated and timed.

Particular attention should be paid to high-touch areas and all aspects of the dialysis station, including BP cuffs, television controls and remote control devices, machine

**Table 5. Association for Professionals in Infection Control and Epidemiology recommendations for personal protective equipment use during hemodialysis procedures**

Task	Gloves	Face Protection	Gowns
<b>Pretreatment</b>			
Setting up the machine	X		
Handling clean dialyzer	X		
Checking for residual bleach	X		
Checking for conductivity and pH	X		
Vital signs	X		
Patient assessment	X		
Catheter care, including dressing change	X	X	X
Cannulation	X	X	X
Laboratory draw	X	X	X
<b>During treatment</b>			
Initiation of treatment	X	X	X
Needle adjustment	X	X	X
Reverse lines	X	X	X
Line and/or dialyzer change	X	X	X
Silence alarms	X		
Routine vital signs check/ documentation	X		
Machine recirculation	X	X	X
Urinal/bedpan handling	X	X	X
<b>After treatment</b>			
Laboratory draw	X	X	X
Termination of treatment	X	X	X
Pulling needles/holding sites	X	X	X
Stripping of the machine	X	X	X
Incidental blood spill	X	X	X
Sharps disposal	X	X	X
Surface disinfection of machine and patient care areas	X	X	X
Cleaning contaminated equipment	X	X	X

Information obtained from reference 53.



surfaces, dialysate waste buckets, intravenous poles, and other surfaces where patients store personal belongings. The CDC’s “Checklist: Dialysis Station Routine Disinfection” (66) can help medical directors and their clinics organize this process. Any visible soil must be cleaned before disinfection. Medical directors should ensure that sufficient disinfectant be applied to environmental surfaces with sufficient contact time. The dialysis chair may be difficult to clean adequately. Torn or damaged surfaces should be repaired immediately. All surfaces, including the crevices between the sides and back of the chair, should be adequately cleaned and disinfected. Dialysis chairs should be thoroughly cleaned to remove debris that may be caught in the seams and crevices. They should not be power-washed. All devices for which the manufacturer makes recommendations about cleaning must be cleaned in accordance with those recommendations. Medical directors should periodically observe staff practice during turnover. Dialysis staff should wait for the previous patient to exit the dialysis station before they begin cleaning and disinfecting for the next patient.

If medical directors are involved in the construction of a dialysis clinic, they should ensure that the chosen surfaces are smooth, nonporous, easy to clean, and compatible with hospital-grade cleaners and disinfectants. A cleaning schedule is needed for all items and areas. Medical directors should periodically walk through and inspect the clinic. They should ensure that any worn, stained, torn, or cracked items are replaced. Cloth furnishings and carpeting are not recommended in patient care areas, and if these are chosen, medical directors should ensure that the clinic has a process to keep these items clean and maintained.

**Dialysis Equipment**

Nondisposable equipment used in the dialysis clinic must be disinfected according to the manufacturer’s directions for use. These include dialysis machines, water treatment and distribution systems, acid and bicarbonate jugs, mixing and distributing systems, dialyzers and dialyzer reprocessing equipment, oxygen tanks and oxygen concentrators, centrifuges, pipettes and other laboratory equipment, BP cuffs, stethoscopes, and vascular clamps. Equipment differs between manufacturers. For example, some dialysis

machines have a waste handling option, while other have a priming bucket. Each requires different procedures to prevent the spread of potentially infectious material. Nondisposable items that are taken into a patient’s HD station must be dedicated for single-patient use or disinfected before being used on another patient. Items that cannot be disinfected should be dedicated for single-patient use (53).

The Association for the Advancement of Medical Instrumentation (AAMI) standards state that dialysis water samples must be collected throughout the distribution loop, including where the water enters a mixing tank, where a dialysis machine connects to the water distribution loop, and from a point in the distal segment of the loop. Samples must be assayed within 4 hours of collection or immediately refrigerated. Samples must be sent for culture and endotoxin with water treatment disinfection conducted if an action level is exceeded. Although the AAMI standards were revised in 2009, the CMS 2008 Cfc only require dialysis facilities to comply with the 2006 standards (67,68) (Table 6). Ultrapure dialysis fluid, not required by regulation, requires a dialysate total viable microbial count <0.1 colony-forming units/ml and endotoxin levels less than 0.03 EU/ml (67). Medical directors should review and sign (as evidence that they have reviewed) their clinic’s culture and endotoxin results during QAPI. These data should be examined for trends, with corrective action plans initiated as appropriate.

**Modified Contact Precautions**

Multidrug-resistant organisms (MDROs) are microorganisms, usually bacteria, that are resistant to one or more classes of antimicrobial agents (Table 7) (69). These pathogens can be gram-positive (such as resistant *Staphylococcus aureus*), gram-negative (such as  $\beta$ -lactamase-producing *Pseudomonas aeruginosa*), or fungal (resistant *Candida* species). Patients who are colonized or infected with an MDRO require special attention to prevent the spread of these microorganisms to others. The first case of methicillin-resistant *S. aureus* (MRSA) was identified in the United Kingdom in 1961 (70). Since then, controlling the spread of MRSA has become a health care priority. This is especially true in dialysis patients, whose rate of invasive MRSA infections is

**Table 6. AAMI recommendations for water and dialysate**

Source	AAMI 13959:2009		AAMI RD62:2006 (CMS)	
	Action Level	Standard	Action Level	Standard
<b>Water</b>				
Culture	50 CFU/ml	100 CFU/ml	50 CFU/ml	200 CFU/ml
Endotoxin	0.125 EU/ml	0.25 EU/ml	1 EU/ml	2 EU/ml
<b>Dialysate</b>				
Culture	50 CFU/ml	100 CFU/ml	50 CFU/ml	200 CFU/ml
Endotoxin	0.125 EU/ml	0.25 EU/ml	1 EU/ml	2 EU/ml
<b>Bicarbonate</b>				
Culture	50 CFU/ml	100 CFU/ml	50 CFU/ml	200 CFU/ml

AAMI, Association for the Advancement of Medical Instrumentation; CMS, Centers for Medicare & Medicaid Services; CFU, colony-forming units; EU, endotoxin units. Information obtained from references 67,68.

**Table 7. Centers for Disease Control and Prevention antibiotic resistance threats in the United States****Urgent threats<sup>a</sup>***Clostridium difficile*

Carbapenem-resistant Enterobacteriaceae

Drug-resistant *Neisseria gonorrhoeae***Serious threats<sup>b</sup>**Multidrug-resistant *Acinetobacter* speciesDrug-resistant *Campylobacter* speciesFluconazole-resistant *Candida* species (fungus)Extended spectrum  $\beta$ -lactamase-producing

Enterobacteriaceae

Vancomycin-resistant *Enterococcus* speciesMultidrug-resistant *Pseudomonas aeruginosa*Drug-resistant nontyphoidal *Salmonella* speciesDrug-resistant *Salmonella typhi*Drug-resistant *Shigella* speciesMethicillin-resistant *Staphylococcus aureus*Drug-resistant *Streptococcus pneumoniae*

Drug-resistant tuberculosis

**Concerning threats<sup>a</sup>**Vancomycin-resistant *S. aureus*Erythromycin-resistant group A *Streptococcus* species

Information obtained from reference 69.

<sup>a</sup>This organism is an immediate public health threat that requires urgent and aggressive action.<sup>b</sup>This organism is a serious concern and requires prompt and sustained action to ensure that the problem does not grow.<sup>c</sup>This bacterium is concerning, and careful monitoring and prevention actions are needed.

100 times higher than that in the general population (71). The major determinant of the rise in MDROs is patient-to-patient transmission, usually by HCW hands. Unlike hospitals or other skilled nursing facilities, most dialysis units do not have the ability to isolate these patients. Given these constraints, additional precautions for patients at increased risk for transmitting infection are warranted. These “modified contact precautions” (Table 8) include use of a dedicated

**Table 8. Modified contact precautions****Whom to isolate**

1. Patients who have infected blood or body fluids that are not contained

- a. *Draining wounds*

- b. *Fecal incontinence*

2. Patients with MDROs

**How to isolate**

1. Dialysis staff should wear a separate, dedicated gown when providing care

2. The gown should not be worn when caring for other patients

3. Patients should be dialyzed at a station with as few adjacent stations as possible

- a. *This could be at the end or in the corner of the unit*

MDRO, multidrug-resistant organism. Adapted from reference 72.

gown over clothing in caring for patients with MDRO infections and removal of this gown when finished (72). Patients with MDROs should be dialyzed at an end-station or in the corner of the dialysis unit to minimize the number of adjacent stations. Medical directors should be aware of all patients with MDRO infections who are undergoing dialysis. They should consider the use of these modified contact precautions if the rates of MDRO infections in their clinic are unacceptably high.

**Isolating and Cohorting Patients**

The only patients whom regulation requires that dialysis facilities treat in isolation are those who test positive for the HBV surface antigen. Dialysis nurses and technicians treating these patients may not at the same time treat a susceptible patient, one who lacks surface antibody. Incident patients who have not yet been shown, by a recent result, to test negative should be isolated using the same policies and procedures—such as dedicated equipment, dedicated gowns for staff, terminal disinfection of the dialysis machine after treatment—but not receive dialysis in the HBV isolation room. Given the low prevalence of HBV surface antigen positivity, the incident patient is statistically more likely to be surface antigen negative, and administering dialysis to them in the HBV isolation room puts them at risk of acquiring HBV infection. In the absence of an adequate titer of HBV surface antibody, it is logical to require a negative HBV surface antigen result within the past 30 days in prevalent patients. In the presence of a documented history of adequate antibody titers, it might seem reasonable to accept an incident patient who had an older negative antigen result drawn more than 30 days earlier. However, the CDC “Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients” states: “among hemodialysis patients who respond to the vaccine, protection against HBV is not maintained when antibody titers fall below protective levels” (73). Therefore, medical directors who wish that their clinic accept an incident patient lacking adequate antibody titers and a negative hepatitis B surface antigen result within the past month should personally review the serologic data or should order isolation until new results are available.

Dialysis clinics that were built before February 9, 2009, or have been granted a waiver may have an isolation “area” rather than isolation “room.” In such cases, the ESRD Program Interpretative Guidance states that the “area used for HBV surface antigen positive patients must be separated from other stations by a space equivalent to the width of one hemodialysis station” (74). In clinics with an isolation area, medical directors should strongly encourage their dialysis provider to create an isolation room, which is the better method for managing patients with HBV surface antigen.

Experience in facilities having a high prevalence of HCV shows that cohorting or isolation of patients with HCV is associated with a reduction in seroconversions of susceptible patients (75–77). It is not known whether the effect would be similar in a clinic that carefully observes all CDC recommendations for infection prevention. In any event, no United States authority has recommended isolation or cohorting of HCV-positive patients. Medical directors should review all newly identified cases of HBV and

	Penicillin	Cefazolin	Methicillin	Clindamycin	Erythromycin	Tetracycline	TMP-SMX	Ciprofloxacin	Levofloxacin	Vancomycin	Linezolid	Ceftriaxone	Cefotaxime
<i>Enterococcus faecalis</i>	95		72	3	15	22	55	67	71	99	98	12	
<i>Enterococcus faecium</i>	40				9	43		25	35	40	97		
<i>Enterococcus</i> species – VRE	22				5	31		2	5		96		
<i>Enterococcus</i> species	86		80	4	17	29	54	64	67	90	99	10	
<i>Staphylococcus aureus</i>	8	55	42	79	22	99	99	60	69	99	99	44	36
<i>Staphylococcus aureus</i> - MRSA	0	0		83	11	97	98	53	46	99	99	0	0
<i>Staphylococcus aureus</i> – MSSA	15	99	99	80	54	95	99	88	85	99	99	99	99
<i>Staphylococcus coagulase negative</i>	12	52	48	66	37	77	65	59	62	99	99	62	47
<i>Staphylococcus epidermidis</i>	8	36	30	69	28	80	45	60	55	99	99	47	42
<i>Staphylococcus agalactiae</i> (Group B)	99	98		56	52	14			98	99	100	99	99
<i>Streptococcus pneumoniae</i>	57			67	48	67	59		98	99	100	92	83

**Figure 3. | Sample antibiogram.** Numbers represent the percentage of isolates susceptible to the specified antibiotic. VRE, vancomycin-resistant *Enterococcus*; MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-sensitive *Staphylococcus aureus*.

HCV infection and consider whether evidence shows a breach in infection prevention practice.

As noted above, patients with MDROs as well as those infected with or suspected of having *C. difficile* should undergo dialysis at an end-station or in the corner of the dialysis unit to minimize the number of adjacent stations.

**Antibiotic Stewardship**

The rising prevalence of MRSA has been accompanied by the increased use of vancomycin. The pharmacokinetic profile of vancomycin has made it the antibiotic of choice for suspected gram-positive bacterial infections in the dialysis population. Unfortunately, the common and often indiscriminant use of vancomycin has led to resistance. In 1997, the CDC reported the first *S. aureus* strains exhibiting reduced susceptibility to vancomycin. These vancomycin-intermediate *S. aureus* specimens were isolated from peritoneal dialysis patients in Michigan and New Jersey (78). In 2002, the first case of vancomycin-resistant *S. aureus* was identified in an HD patient (79). That same year the CDC launched its "Campaign to Prevent Antimicrobial Resistance." This initiative focuses on the use of narrow-spectrum yet effective antimicrobial treatment of documented infections by identifying the organism and susceptibilities to optimally target treatment and limiting use of broad-spectrum antimicrobials.

Medical directors should ensure that processes are in place to track microbiologic culture results, resistant organisms, and antibiotic administration. Most laboratories that process microbiologic samples routinely perform antimicrobial susceptibility testing for bacterial pathogens, and aggregate these cumulative susceptibility testing results into a summary table, or antibiogram (Figure 3). The antibiogram can

be used as the community reference guide to determine local microorganism resistance patterns. A member of the dialysis unit infection prevention team should collaborate with the local laboratory to regularly update the antibiogram. Medical directors should review the dialysis unit’s culture results, patterns of antimicrobial resistance, use of empirical antimicrobial agents, and the appropriateness of antimicrobial administration.

**Putting It All Together**

**Creating an Infection Prevention Program**

Establishing an infection prevention committee is the first step in preventing the spread of infection within a dialysis unit. This review and the referenced audit tools should provide the elements to start a comprehensive infection prevention program. Many of the items may be familiar to medical directors but not to other members of the infection prevention team. At a minimum, this committee should include the medical director (serving as its leader), the nurse manager of the dialysis clinic, and a member of the biomedical department. The committee should develop and review policies as well as monitor the dialysis clinic for infections and practice patterns that might lead to the spread of infection.

The first task of the infection prevention committee should be to conduct a generalized infection prevention audit using a tool such as is provided by the CDC (80). This audit will highlight the areas of concern within the dialysis unit. The CMS Surveyor Laminar on infection control and isolation offers another point of departure (81). Any of the elements listed in the patient-specific and dialysis clinic-specific areas, such as hand hygiene and review of dialysis

**Table 9. Centers for Medicare & Medicaid Conditions for Coverage quality assessment and performance improvement requirements**

**The facility must:**

1. Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence
2. Develop recommendations and action plans to minimize infection transmission and promote immunization
3. Take actions to reduce future incidents

Information obtained from reference 82.

charts for vaccination records, can be appropriate audits performed by the infection prevention committee. These audits and the findings of the infection prevention committee should be presented at the dialysis clinic's QAPI meetings (Table 9) and to the governing authority (82). Although not mandated, the medical director may find it helpful to engage the services of a consultant infection preventionist. The expertise of these professionals in infection control and prevention can be invaluable. A collaborative relationship can help medical directors determine the status of their dialysis clinic and optimize their infection prevention program.

## Conclusion

Health care–associated infections are a common yet preventable cause of dialysis morbidity and mortality. Medical directors are key leaders in infection prevention and are an important resource to implement programs to monitor and improve infection prevention practices at all levels within the dialysis clinic. Medical directors should help develop and review protocols guiding practice for tasks such as the care of patients with MDRO infections and universal vaccination to help avoid preventable health care–associated infections. They should also institute policies regarding hand hygiene, environmental and dialysis equipment disinfection, and other processes of care that will allow the clinic to optimize care for their dialysis patients.

More important, medical directors serve as role models both to clinic staff and to other health care practitioners. Medical directors must set the policy standards and lead by example. They are under the scrutiny of patients, colleagues, and dialysis staff who see whether they wash their hands, wear gloves, and disinfect their stethoscopes between patients. How can medical directors expect their patients to wash their access with soap and water before cannulation, sanitize their hands after holding their sites at the end of treatment, or consent to influenza vaccination if they and other practitioners are not following the rules themselves? Medical directors should send a consistent message to the entire dialysis community, including other practitioners, that these elements are not trivial. When other nephrologists or healthcare practitioners do not follow policies, it is the medical director who must let them know, firmly but respectfully, that this behavior will not be tolerated in the dialysis clinic. Medical directors are entrusted with the lives of all the patients that dialyze in their clinics and must protect all of them at all times.

## Acknowledgments

The opinions or views expressed in this manuscript are those of the authors and do not necessarily reflect the opinions of Dialysis Clinic, Inc.

## Disclosures

D.J. is the Vice Chairman of the Board for Dialysis Clinic, Inc. T.K. is an employee of Dialysis Clinic, Inc. K.M. receives salary support from Dialysis Clinic, Inc.

## References

- Patel PR, ed: Understanding and preventing infectious complications in dialysis. *Semin Dial* 26: 375–530, 2013
- U.S. Renal Data System: *USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2013
- Centers for Medicare & Medicaid Services: 42 CFR Parts 405, 410, 413. Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule. *Federal Register* Available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/downloads/esrdfinalrule0415.pdf>. Accessed July 12, 2014
- Tokars JI, Miller ER, Stein G: New national surveillance system for hemodialysis-associated infections: initial results. *Am J Infect Control* 30: 288–295, 2002
- Cooper BA, Branley P, Bulfone L, Collins JF, Craig JC, Fraenkel MB, Harris A, Johnson DW, Kesselhut J, Li JJ, Luxton G, Pilmore A, Tiller DJ, Harris DC, Pollock CA; IDEAL Study: A randomized, controlled trial of early versus late initiation of dialysis. *N Engl J Med* 363: 609–619, 2010
- Tangri N, Stevens LA, Griffith J, Tighiouart H, Djurdjev O, Naimark D, Levin A, Levey AS: A predictive model for progression of chronic kidney disease to kidney failure. *JAMA* 305: 1553–1559, 2011
- Centers for Disease Control and Prevention: Dialysis patient pocket guide. Available at: <http://www.cdc.gov/dialysis/PDFs/Dialysis-Patient-PocketGuide.pdf>. Accessed April 4, 2014
- Change Concept 9: Infection tracking log. Available at: <http://esrdncc.org/ffcl/change-concepts/change-concept-9/>. Accessed December 26, 2014
- FFBI Monitoring the newly placed AV fistula for maturation algorithm. Available at: <http://esrdncc.org/ffcl/change-concepts/change-concept-1/vascular-access-coordinator-resource-manual/>. Accessed December 26, 2014
- Change Concept 7: Central venous catheter tracking tool. Available at: <http://esrdncc.org/navigating-your-esrd-journey/lifeline-for-a-lifetime/access-planning/professional-resources-for-access-planning/step1/>. Accessed December 26, 2014
- Centers for Disease Control and Prevention: Central venous catheter hub cleaning prior to accessing. 2009. Available at: <http://www.cdc.gov/dialysis/PDFs/collaborative/Protocol-Hub-Cleaning-FINAL-3-12.pdf>. Accessed December 26, 2014
- Walworth L; ESRD Network of New England. Dialysis patients speak preventing infections 2012. Available at: <https://www.youtube.com/watch?v=4Jiy6RdwPC8>. Accessed May 28, 2014
- ChlorPrep product label. El Paso, TX, CareFusion, April 2013
- National Kidney Foundation: KDOQI clinical practice guidelines and clinical practice recommendations for 2006 updates: Hemodialysis adequacy, peritoneal dialysis adequacy and vascular access. *Am J Kidney Disease* 48(suppl 1): S1–S322, 2006.
- Hemani ML, Lepor H: Skin preparation for the prevention of surgical site infection: Which agent is best? *Rev Urol* 11: 190–195, 2009
- Moureau NL, Dawson RB: Keeping needleless connectors clean, part 1. *Nursing* 40: 18–19, 2010
- ExSept Plus product information. Gaithersburg, MD, Angelini Pharma, Inc., October 2014
- Centers for Disease Control and Prevention: CDC approach to BSI prevention in dialysis facilities (i.e., the core interventions for dialysis bloodstream infection [BSI] prevention). Available at: <http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html>. Accessed July 23, 2014
- Alcavis 50 product information. Gaithersburg, MD, Angelini Pharma, Inc, June 2014
- Centers for Disease Control and Prevention: Guidelines for the prevention of intravascular catheter-related infections, 2011. Available at: <http://www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf>. Accessed May 28, 2014
- Onder AM, Chandar J, Billings A, Diaz R, Francoeur D, Abitbol C, Zilleruelo G: Chlorhexidine-based antiseptic solutions effectively reduce catheter-related bacteremia. *Pediatr Nephrol* 24: 1741–1747, 2009
- Darouiche RO, Wall MJ Jr, Itani KM, Otterson MF, Webb AL, Carrick MM, Miller HJ, Awad SS, Crosby CT, Mosier MC, Alsharif A, Berger DH: Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. *N Engl J Med* 362: 18–26, 2010

23. Vallés J, Fernández I, Alcaraz D, Chacón E, Cazorla A, Canals M, Mariscal D, Fontanals D, Morón A: Prospective randomized trial of 3 antiseptic solutions for prevention of catheter colonization in an intensive care unit for adult patients. *Infect Control Hosp Epidemiol* 29: 847–853, 2008
24. Mimoz O, Villeminey S, Ragot S, Dahyot-Fizelier C, Laksiri L, Petitpas F, Debaene B: Chlorhexidine-based antiseptic solution vs alcohol-based povidone-iodine for central venous catheter care. *Arch Intern Med* 167: 2066–2072, 2007
25. O'Grady NP, Alexander M, Burns LA, Dellinger EP, Garland J, Heard SO, Lipsett PA, Masur H, Mermel LA, Pearson ML, Raad II, Randolph AG, Rupp ME, Saint S; Healthcare Infection Control Practices Advisory Committee (HICPAC): Guidelines for the prevention of intravascular catheter-related infections. *Clin Infect Dis* 52: e162–e193, 2011
26. Garvey LH, Krøigaard M, Poulsen LK, Skov PS, Mosbech H, Venemalm L, Degerbeck F, Husum B: IgE-mediated allergy to chlorhexidine. *J Allergy Clin Immunol* 120: 409–415, 2007
27. Beaudouin E, Kanny G, Morisset M, Renaudin JM, Mertes M, Laxenaire MC, Mouton C, Jacson F, Moneret-Vautrin DA: Immediate hypersensitivity to chlorhexidine: Literature review. *Eur Ann Allergy Clin Immunol* 36: 123–126, 2004
28. Kallen AJ, Patel PR, Hess S: Intolerance of chlorhexidine as a skin antiseptic in patients undergoing hemodialysis. *Infect Control Hosp Epidemiol* 32: 1144–1146, 2011
29. Bigham M, Ponnampalam A: Neutralization positive but apparent false-positive hepatitis B surface antigen in a blood donor following influenza vaccination. *Transfus Apheresis Sci* 50: 92–94, 2014
30. Schwarzwald H, Kline NE: False positive hepatitis B surface antigen test caused by hepatitis B vaccine. *Pediatr Infect Dis J* 20: 1101–1102, 2001
31. Onuigbo MA, Nesbit A, Weisenbeck J, Hurlburt J: Hepatitis B surface antigenemia following recombinant Engerix B hepatitis B vaccine in an 81-year-old ESRD patient on hemodialysis. *Ren Fail* 32: 531–532, 2010
32. Xu L, Yu Z, Fan W, Wang X, Xie M, Xu Y, Hu L, Li Y: Negative interference in serum HBsAg ELISA from rheumatoid factors. *PLoS One* 8: e80620, 2013
33. Xu L, Wang X, Ma R, Zeng X, Wu B, Hu L, Li Y: False decrease of HBsAg S/CO values in serum with high-concentration rheumatoid factors. *Clin Biochem* 46: 799–804, 2013
34. Charlewood R, Flanagan P: Ultrio and Ultrio Plus non-discriminating reactives: False reactives or not? *Vox Sang* 104: 7–11, 2013
35. Mbaeyi C, Thompson ND: Hepatitis C virus screening and management of seroconversions in hemodialysis facilities. *Semin Dial* 26: 439–446, 2013
36. Centers for Medicare & Medicaid Services: ESRD Surveyor Training. Interpretive Guidance. Interim final version 1.1. October 3, 2008. Available at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/esrdpgmguidance.pdf>. Accessed May 28, 2014.
37. Pai M, Zwering A, Menzies D: Systematic review: T-cell-based assays for the diagnosis of latent tuberculosis infection: an update. *Ann Intern Med* 149: 177–184, 2008
38. Mazurek GH, Jereb J, Vernon A, LoBue P, Goldberg S, Castro K; IGRA Expert Committee; Centers for Disease Control and Prevention (CDC): Updated guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection—United States, 2010. *MMWR Recomm Rep* 59[RR-5]: 1–25, 2010
39. Jensen PA, Lambert LA, Iademarco MF, Ridzon R; CDC: Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings, 2005. *MMWR Recomm Rep* 54[RR-17]: 1–141, 2005
40. Centers for Disease Control and Prevention: Appendix B: Tuberculosis (TB) risk assessment worksheet. Available at: [http://www.cdc.gov/tb/publications/guidelines/AppendixB\\_092706.pdf](http://www.cdc.gov/tb/publications/guidelines/AppendixB_092706.pdf). Accessed July 24, 2014
41. Fraser GM, Ochana N, Fenyves D, Neumann L, Chazan R, Niv Y, Chaimovitch S: Increasing serum creatinine and age reduce the response to hepatitis B vaccine in renal failure patients. *J Hepatol* 21: 450–454, 1994
42. Martin LA, Stramer SL, Kuhns MC, Schlauder GG: Correlation of improved hepatitis B surface antigen detection limits with hepatitis B virus DNA nucleic acid test yield in blood donations. *Transfusion* 52: 2201–2208, 2012
43. Centers for Disease Control and Prevention (CDC): Prevention and control of seasonal influenza with vaccines. Recommendations of the Advisory Committee on Immunization Practices—United States, 2013–2014. *MMWR Recomm Rep* 62[RR-07]: 1–43, 2013
44. Reber AJ, Chirkova T, Kim JH, Cao W, Biber R, Shay DK, Sambhara S: Immunosenescence and challenges of vaccination against influenza in the aging population. *Aging Dis* 3: 68–90, 2012
45. Couch RB, Winokur P, Brady R, Belshe R, Chen WH, Cate TR, Sigurdardottir B, Hooper A, Graham IL, Edelman R, He F, Nino D, Capellan J, Ruben FL: Safety and immunogenicity of a high dosage trivalent influenza vaccine among elderly subjects. *Vaccine* 25: 7656–7663, 2007
46. Falsey AR, Treanor JJ, Tornieporth N, Capellan J, Gorse GJ: Randomized, double-blind controlled phase 3 trial comparing the immunogenicity of high-dose and standard-dose influenza vaccine in adults 65 years of age and older. *J Infect Dis* 200: 172–180, 2009
47. Keitel WA, Atmar RL, Cate TR, Petersen NJ, Greenberg SB, Ruben F, Couch RB: Safety of high doses of influenza vaccine and effect on antibody responses in elderly persons. *Arch Intern Med* 166: 1121–1127, 2006
48. Simonsen L, Taylor RJ, Viboud C, Miller MA, Jackson LA: Mortality benefits of influenza vaccination in elderly people: an ongoing controversy. *Lancet Infect Dis* 7: 658–666, 2007
49. Vu T, Farish S, Jenkins M, Kelly H: A meta-analysis of effectiveness of influenza vaccine in persons aged 65 years and over living in the community. *Vaccine* 20: 1831–1836, 2002
50. Gross PA, Hermogenes AW, Sacks HS, Lau J, Levandowski RA: The efficacy of influenza vaccine in elderly persons. A meta-analysis and review of the literature. *Ann Intern Med* 123: 518–527, 1995
51. Centers for Disease Control and Prevention: How many health care workers got vaccinated last season? Available at: <http://www.cdc.gov/flu/healthcareworkers.htm>. Accessed April 2, 2014
52. Centers for Disease Control and Prevention (CDC): Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Morb Mortal Wkly Rep* 61: 816–819, 2012
53. Association for Professionals in Infection Control and Epidemiology (APIC): Guide to the elimination of infections in hemodialysis. 2010. Available at: [http://www.apic.org/Resource/\\_EliminationGuideForm/7966d850-0c5a-48ae-9090-a1da00bcf988/File/APIC-Hemodialysis.pdf](http://www.apic.org/Resource/_EliminationGuideForm/7966d850-0c5a-48ae-9090-a1da00bcf988/File/APIC-Hemodialysis.pdf). Accessed April 7, 2014.
54. Centers for Disease Control and Prevention: Infection prevention in dialysis settings. June 1, 2012. Available at: <http://www.cdc.gov/dialysis/clinician/CE/infection-prevent-outpatient-hemo.html>. Accessed July 23, 2014.
55. World Health Organization: Clean care is safer care. Save Lives: Clean Your Hands observation form. August 2009. Available at: [http://www.who.int/gpsc/5may/tools/training\\_education/en/](http://www.who.int/gpsc/5may/tools/training_education/en/). Accessed March 26, 2014.
56. Centers for Disease Control and Prevention: CDC Dialysis Collaborative. Audit tool: hemodialysis hand hygiene observations. Available at: <http://www.cdc.gov/dialysis/PDFs/collaborative/Hemodialysis-Hand-Hygiene-Observations.pdf>. Accessed March 26, 2014
57. Kowitz B, Jefferson J, Mermel LA: Factors associated with hand hygiene compliance at a tertiary care teaching hospital. *Infect Control Hosp Epidemiol* 34: 1146–1152, 2013
58. Szilágyi L, Haidegger T, Lehotsky A, Nagy M, Csonka EA, Sun X, Ooi KL, Fisher D: A large-scale assessment of hand hygiene quality and the effectiveness of the “WHO 6-steps.” *BMC Infect Dis* 13: 249, 2013
59. Centers for Disease Control and Prevention: Guide to infection prevention for outpatient settings: Minimum expectations for safe care. Available at: <http://www.cdc.gov/HAI/pdfs/guidelines/Outpatient-Care-Guide-withChecklist.pdf>. Accessed July 24, 2014

60. Cohen SH, Gerding DN, Johnson S, Kelly CP, Loo VG, McDonald LC, Pepin J, Wilcox MH; Society for Healthcare Epidemiology of America; Infectious Diseases Society of America: Clinical practice guidelines for *Clostridium difficile* infection in adults: 2010 update by the society for healthcare epidemiology of America (SHEA) and the infectious diseases society of America (IDSA). *Infect Control Hosp Epidemiol* 31: 431–455, 2010
61. Wullt M, Odenholt I, Walder M: Activity of three disinfectants and acidified nitrite against *Clostridium difficile* spores. *Infect Control Hosp Epidemiol* 24: 765–768, 2003
62. World Health Organization: Hand hygiene: Why, how & when? August 2009. Available at: [http://www.who.int/gpsc/5may/Hand\\_Hygiene\\_Why\\_How\\_and\\_When\\_Brochure.pdf](http://www.who.int/gpsc/5may/Hand_Hygiene_Why_How_and_When_Brochure.pdf). Accessed March 26, 2014.
63. Centers for Disease Control and Prevention: Sequence for donning and removing personal protective equipment (PPE). Available at: <http://www.cdc.gov/HAI/pdfs/ppe/ppeposter148.pdf>. Accessed April 4, 2014
64. Environmental Protection Agency: Selected EPA-registered disinfectants. Available at: <http://www.epa.gov/oppad001/chemregindex.htm>. Accessed July 24, 2014
65. Centers for Disease Control and Prevention: Environmental surface disinfection in dialysis facilities: notes for clinical managers. Available at: [http://www.cdc.gov/dialysis/PDFs/collaborative/Env\\_notes\\_Feb13.pdf](http://www.cdc.gov/dialysis/PDFs/collaborative/Env_notes_Feb13.pdf). (Accessed April 2, 2014).
66. Centers for Disease Control and Prevention: Checklist: Dialysis station routine disinfection. Available at: [http://www.cdc.gov/dialysis/PDFs/collaborative/Env\\_checklist-508.pdf](http://www.cdc.gov/dialysis/PDFs/collaborative/Env_checklist-508.pdf). Accessed April 4, 2014
67. Association for the Advancement of Medical Instrumentation (AAMI): Water for hemodialysis and related therapies. ANSI/AAMI/ISO 13959. 2009. Available at: [http://marketplace.aami.org/eseries/scriptcontent/docs/Preview%20Files/139591104\\_preview.pdf](http://marketplace.aami.org/eseries/scriptcontent/docs/Preview%20Files/139591104_preview.pdf). Accessed April 7, 2014
68. Association for the Advancement of Medical Instrumentation (AAMI): Water for hemodialysis and related therapies. ANSI/AAMI RD62. 2006. Available at: [http://marketplace.aami.org/eseries/scriptcontent/docs/Preview%20Files/rd620612\\_preview.pdf](http://marketplace.aami.org/eseries/scriptcontent/docs/Preview%20Files/rd620612_preview.pdf). Accessed April 7, 2014
69. U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Antibiotic resistance threats in the United States, 2013. Available at: <http://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf>. Accessed July 25, 2014
70. Chambers HF: The changing epidemiology of *Staphylococcus aureus*? *Emerg Infect Dis* 7: 178–182, 2001
71. Centers for Disease Control and Prevention (CDC): Invasive methicillin-resistant *Staphylococcus aureus* infections among dialysis patients—United States, 2005. *MMWR Morb Mortal Wkly Rep* 56: 197–199, 2007
72. Patel PR: Infection control: New challenges under the new conditions. Presented at Preparing for the New Medical Director Responsibilities meeting, Chicago, IL, October 21, 2008
73. Centers for Disease Control and Prevention: Recommendations for preventing transmission of infections among chronic hemodialysis patients. *MMWR* 50(RR05): 1–43, 2001
74. Centers for Medicare & Medicaid Services: ESRD interpretative guidance update. October 3, 2008. Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>. Accessed November 18, 2014
75. Agarwal SK, Dash SC, Gupta S, Pandev RM: Hepatitis C virus infection in haemodialysis: the “no-isolation” policy should not be generalized. *Nephron* 111: c133–140, 2009.
76. Harmankaya O, Cetin B, Obek A, Seber E: Low prevalence of hepatitis C virus infection in hemodialysis units: effect of isolation? *Ren Fail* 24: 639–644, 2002
77. Saxena AK, Panhotra BR, Sundaram DS, Naguib M, Venkateshappa CK, Uzzaman W, Mulhim KA: Impact of dedicated space, dialysis equipment, and nursing staff on the transmission of hepatitis C virus in a hemodialysis unit of the middle east. *Am J Infect Control* 31: 26–33, 2003
78. Centers for Disease Control and Prevention (CDC): Update: *Staphylococcus aureus* with reduced susceptibility to vancomycin—United States, 1997. *MMWR Morb Mortal Wkly Rep* 46: 813–815, 1997
79. Centers for Disease Control and Prevention (CDC): *Staphylococcus aureus* resistant to vancomycin—United States, 2002. *MMWR Morb Mortal Wkly Rep* 51: 565–567, 2002
80. Centers for Disease Control and Prevention: CDC Infection prevention checklist for outpatient settings: Minimum expectations for safe care. 2011 version 1.0. Available at: <http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf>. Accessed April 2, 2014
81. Centers for Medicare & Medicaid Services: Surveyor laminates. Available at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/surveyorlaminates.zip>. Accessed May 28, 2014
82. Centers for Medicare & Medicaid Services: Conditions for Coverage (CfCs) & Conditions of Participations (CoPs). November 6, 2013. Available at: [http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/cfcsandcops/16\\_asc.asp](http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/cfcsandcops/16_asc.asp). Accessed April 2, 2014

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

This article contains supplemental material online at <http://cjasn.asnjournals.org/lookup/suppl/doi:10.2215/CJN.06050614/-/DCSupplemental>.

## What Medical Directors Need to Know about Dialysis Facility Water Management

Ted Kasperek and Oscar E. Rodriguez

### Abstract

The medical directors of dialysis facilities have many operational clinic responsibilities, which on first glance, may seem outside the realm of excellence in patient care. However, a smoothly running clinic is integral to positive patient outcomes. Of the conditions for coverage outlined by the Centers for Medicare and Medicaid Services, one most critical to quality dialysis treatment is the provision of safe purified dialysis water, because there are many published instances where clinic failure in this regard has resulted in patient harm. As the clinical leader of the facility, the medical director is obliged to have knowledge of his/her facility's water treatment system to reliably ensure that the purified water used in dialysis will meet the standards for quality set by the Association for the Advancement of Medical Instrumentation and used by the Centers for Medicare and Medicaid Services for conditions for coverage. The methods used to both achieve and maintain these quality standards should be a part of quality assessment and performance improvement program meetings. The steps for water treatment, which include pretreatment, purification, and distribution, are largely the same, regardless of the system used. Each water treatment system component has a specific role in the process and requires individualized maintenance and monitoring. The medical director should provide leadership by being engaged with the process, knowing the facility's source water, and understanding water treatment system operation as well as the clinical significance of system failure. Successful provision of quality water will be achieved by those medical directors who learn, know, and embrace the requirements of dialysis water purification and system maintenance.

*Clin J Am Soc Nephrol* 10: 1061–1071, 2015. doi: 10.2215/CJN.11851214

DaVita HealthCare Partners, Denver, Colorado

**Correspondence:**  
Ted Kasperek, DaVita HealthCare Partners, 1551 Wewatta Street, Denver, CO 80202.  
Email: Theodore.Kasperek@davita.com

### Introduction

#### Be Engaged

It can be disconcerting to medical directors when they realize that, as a Centers for Medicare and Medicaid Services (CMS) condition for coverage (CFC), “the medical director is responsible for the safety and quality of the water used for dialysis treatments” (1). Although this reaction is understandable, with education and training, all medical directors can show the appropriate leadership necessary to keep their clinic's water treatment system running smoothly and provide a foundation for optimal patient care through the provision of purified water for dialysis. To this end, informed engagement from the medical director around water quality is critical. The medical director shapes the facility attitude toward water quality, and he/she has both the authority and responsibility to make the issue a high priority (2).

Verifying efficient operation of the water treatment system should be an integral component of each clinic's quality assessment and performance improvement program (QAPI). Achieving the necessary CMS CFC for dialysis water quality involves reaching thresholds for both chemical purity (Table 1) and microbiologic and endotoxin purity (Table 2), all of which require proficient operation of the water treatment system and vigilant monitoring. QAPI meetings are convened regularly and attended by the medical director and the clinic's interdisciplinary team, so that among

facility, personnel, and patient care topics, results of product water chemical analyses, dialysate and product water laboratory testing, and microbiologic testing of the water distribution system can be reviewed. In the context of continuous improvement and CFC compliance (Section 494.40 Condition: Water and Dialysate Quality [1]), the medical director and the facility biomedical technician should review the operation and testing records of the water treatment system recorded in the maintenance and monitoring log. Over and above remaining compliant in this regard, a monthly QAPI meeting would be the appropriate forum for risk analyses and assessment of water quality improvement initiatives. As necessary, the medical director should drive root-cause analyses to establish indicators of water quality problems, evaluate the associated risks, and determine mitigation in the context of existing QAPI processes.

#### Know Your Source Water

With assistance from the facility's biomedical technician or another person with operational understanding of the dialysis facility, the medical director should ascertain from where the clinic's water is derived. The quality and characteristics of the facility's source water could affect the operation of the facility's water treatment system and guide planning efforts, especially in cases where the source water may become compromised, which may be the case in a

Chemical	Water Safety Thresholds	
	Maximum Allowable Chemical Contaminant Levels (mg/L)	EPA Drinking Water Standard (mg/L)
Calcium	2 (0.1 mEq/L)	—
Magnesium	4 (0.3 mEq/L)	—
Potassium	8 (0.2 mEq/L)	—
Sodium	70 (3.0 mEq/L)	—
Antimony	0.006	0.006
Arsenic	0.005	0.01
Barium	0.10	2
Beryllium	0.0004	0.004
Cadmium	0.001	0.005
Chromium	0.014	0.1
Lead	0.005	0.015
Mercury	0.0002	0.002
Selenium	0.09	0.05
Silver	0.005	0.1
Aluminum	0.01	0.5–0.2
Chloramines	0.10	4.0 (Cl <sub>2</sub> )
Free chlorine	0.50	4.0 (Cl <sub>2</sub> )
Copper	0.10	1.0
Fluoride	0.20	2.0
Nitrate (as N)	2.0	1.0
Sulfate	100	250
Thallium	0.002	0.002
Zinc	0.10	5.0

Information from the Association for the Advancement of Medical Instrumentation RD52 (5) and the US Environmental Protection Agency (EPA) (4).

Guideline and Contaminant	Maximum Allowable Level	Typical Action Level
<b>ANSI/AAMI RD52:2004 and current CMS standard for United States dialysis facilities</b>		
Bacteria water and dialysate	<200 CFU/ml	50 CFU/ml
Endotoxin water and dialysate	<2 EU/ml	1 EU/ml
<b>ANSI/AAMI/ISO 13959:2009<sup>a</sup> and 23500:2011 and ANSI/AAMI RD 23500:2014</b>		
Bacteria water and dialysate	<100 CFU/ml	50 CFU/ml
Endotoxin water	<0.25 EU/ml	0.125 EU/ml

ANSI, American National Standards Institute; AAMI, Association for the Advancement of Medical Instrumentation; CMS, Centers for Medicare and Medicaid Services; EU, endotoxin unit; ISO, International Standards Organization.

<sup>a</sup>The 2014 ANSI/AAMI United States guideline cites the thresholds of the 2011 and 2009 documents but diverges from ISO with respect to recommended bacterial culture methodologies. Currently, these documents are not CMS conditions for coverage.

natural disaster. As a best practice, medical directors should verify that the clinical team communicates directly with the providers of source water no less frequently than annually to advise providers of the water's intended use and the need for advance notice when there may be a disruption in provision of source water. In addition, advance warning is needed in the case of urgent or scheduled source water disinfection by hyperchlorination or permanganate treatment. Similarly, any medical director of an acute-care facility located on the campus of a medical center must consider that the medical center could further

treat source water for use in the hospital setting. In such instances, maintaining close communication with hospital operations is critical to know when the plant manager may be treating the hospital water, so that the dialysis facility does not draw hospital water during times of disinfection or treatment (3).

The Environmental Protection Agency (EPA) has minimum standards for municipal drinking water (4); however, the EPA standards for acceptable levels of contaminants are many times greater than those permissible for water used in dialysis treatment (Table 1) (3,5). The 2004



Association for the Advancement of Medical Instrumentation (AAMI) RD52 thresholds for acceptable levels of inorganic chemical contaminants in purified dialysis water have been adopted by the CMS (Table 1) (1,5). Accordingly, chemical testing should be performed for facility-purified product water and source water annually or as required by local regulation. Additional testing should also be considered when system monitoring shows a decline in product water quality or after repairs to the water treatment system that could affect product water quality, such as when reverse osmosis membranes are replaced. Medical directors should know that, since the original publication of RD52, the AAMI has updated its recommendations for tolerable bacterial and endotoxin concentrations in product water and dialysate without modifying its threshold for inorganic contaminants (Table 2). Despite these changes, the CMS continues to use the AAMI RD52 guideline to define CFC compliance. However, it is possible that, in the future, the CMS may update its position, although currently there is no definitive timeline for any changes.

Understanding the characteristics of the facility’s source water will allow the medical director, biomedical technician, and clinical team to create a practical and effective quality assurance plan in the event that the source water is compromised because of natural or manmade disasters (Table 3) (6–8). Appropriately, any quality assurance plan should identify backup water sources for emergencies (9). Plans that include the use of tap water or dechlorinated tap water

are feasible only with “evidence the source water has been found safe for such use (*i.e.*, has levels below the AAMI accepted limits of aluminum, copper, chloramines, fluoride, nitrate, sulfate, zinc, and other contaminants known to be toxic to dialysis patients)” (2). The quality assurance preparations of every dialysis clinic should outline both a plan of action and a plan of correction for anticipated failures in source water availability as well as within the water treatment system itself.

**Understand the Water Treatment System**

Water treatment systems are designed to produce dialysis-quality water, but the types of components used can vary significantly according to the local water quality–defined pretreatment needs, the volume of product water needed by the facility, and the chosen water treatment technology. The water system components depicted here are typical but by no means represent the totality of those used. There is no one size fits all water treatment system, because water treatment steps are routinely tailored to the local water and the contaminants that must be removed.

The dialysis facility water treatment system is usually located in a dedicated, secured, and access-controlled water room that has been fitted appropriately to provide source water, drains, and electric power needed to support the system. The water room should be well organized, uncluttered, clean, and dry. There should be no water leaks or unpleasant odors. The system should have accurate

**Table 3. Expect the unexpected: Quality assurance planning**

Event	What Happened	Medical Director Takeaway
Charleston, West Virginia chemical spill	A chemical spill in the Elk River contaminated the municipal water source, poisoning water for 300,000 residents and a number of dialysis clinics in the area (6)	Plan ahead; quality assurance plans should identify the dialysis clinic water source in case the municipal water becomes nonpotable
Lake Erie algal bloom	Algae blooms involving cyanobacteria (blue-green algae) have been known to contaminate public water with the hepatotoxin microcystin at levels five times the acceptable level (8)	Be alert; changes in source water can occur, creating chemical contamination that is not easily testable; quality assurance plans should include contingencies for diverse contamination scenarios
Water treatment system bacterial contamination	Fouling of a reverse osmosis membrane caused an epidemic of illness in 44 patients on hemodialysis, of whom two patients died; a sulfur-smelling odor was detected during water sampling from the reverse osmosis device (19)	Ask questions; any water room variable (appearance or odor) out of the ordinary may indicate a problem
Carbon filter failure	Patients receiving dialysis were exposed to chloramine-contaminated water caused by inadequate carbon filter dechlorination (20,21)	Test frequently; chloramine should be tested multiple times every day to protect patients from hemolysis associated with chlorine contamination of dialysis water
Municipal pipe repair	A change in a source water pipe caused aluminum contamination, subsequent aluminum intoxication, and possibly, hard water syndrome; 10 patients died (22)	Stay current; source water quality can change at any time



**B**

## BLENDING VALVE

### PURPOSE:

The mixing valve blends hot and cold water to establish a preset water temperature at the valve outlet;

77° +/- 5° F for 23G RO systems

70° +/- 5° F for CWP RO systems

The performance of downstream components, in particular the carbon filters and the RO system will be affected if the water temperature varies outside of this range.

### HOW DOES IT WORK:

The mixing valve is equipped with a thermometer and an adjustment knob, which allows the operator to set the desired temperature. Water must be flowing through the mixing valve when making temperature adjustments. When the operator has set the desired temperature, temperature sensitive springs will automatically adjust to make minor changes and keep the temperature at or near the desired setting.

### QUALITY CHECKS:

Daily observation and recording of the blended water temperature.

**NOTIFY FA AND BMT IF WATER TEMPERATURE IS NOT BETWEEN \_\_\_\_ AND \_\_\_\_ DEGREES FAHRENHEIT.**

### FACTORS AFFECTING OPERATION:

Improper operation of the mixing valve is usually denoted by an inability to adjust the valve to a proper temperature, leaking or dripping from the valve, or a large pressure drop across the mixing valve. The inability to adjust the mixing valve to the desired temperature may be caused by a lack of hot water entering the valve, or an incoming cold water temperature, which exceeds the operators desired temperature setting.

Leaks or excessive pressure drop (delta pressure) across the valve may cause shutdown or improper operation of the downstream water treatment components.

**For detailed information on operating this component of the water system, refer to the system operator manual and/or clinic policies.**

**Figure 1.** | A well kept water room is orderly with labeled treatment system components. (A) A well kept water room. Shown is a photograph of a dialysis facility water room. The space is immaculate, and system components are properly labeled. (B) Appropriate labeling for a water treatment system component. This blending valve label describes the device and refers operators directly to clinic reference materials for maintenance and troubleshooting. BMT, biomedical technician facility; CWP, clean water products; FA, facility administrator; RO, reverse osmosis.

up-to-date signage and flow diagrams indicating the direction of water movement and on and off valve positions, as well as a log book listing system components with fields for recording device pressure readings, water flow readings, and purity measures made by the facility team (Figure 1). Each system component should be labeled (1,2), and component manufacturers should be identified on each label, including contact information and a source for the manufacturer’s recommendations for correct use (Figure 1).

Medical directors should fully acquaint themselves with the components of their water treatment system and recognize the appearance of a smoothly running water room. Additionally, he/she should inspect the water room whenever possible; if conditions are not as they should be, prompt follow-up with the facility’s clinical leaders and biomedical technician is imperative. To identify potentially dangerous conditions or failure of water treatment system components (Table 3), the medical director should never hesitate to question conditions that seem unusual.

**Pretreatment**

Water treatment system source water will need to be pretreated before it can be purified. Pretreatment consists of several steps, including temperature adjustment, backflow prevention, pressurization, filtration of grit and sediment, water softening, and carbon filtration for dechlorination (Figure 2).

Typically, the first step in pretreatment is temperature adjustment. This step occurs in the blending valve, where heated and unheated source water is mixed to a desired temperature, typically between 60°F and 85°F. It is important to have a properly sized water heater to provide adequate hot water that will accommodate the clinic’s demand. The facility team should monitor and record the output temperature at least daily, which should remain relatively constant within a 2–3°F range (Figure 2, Table 4).

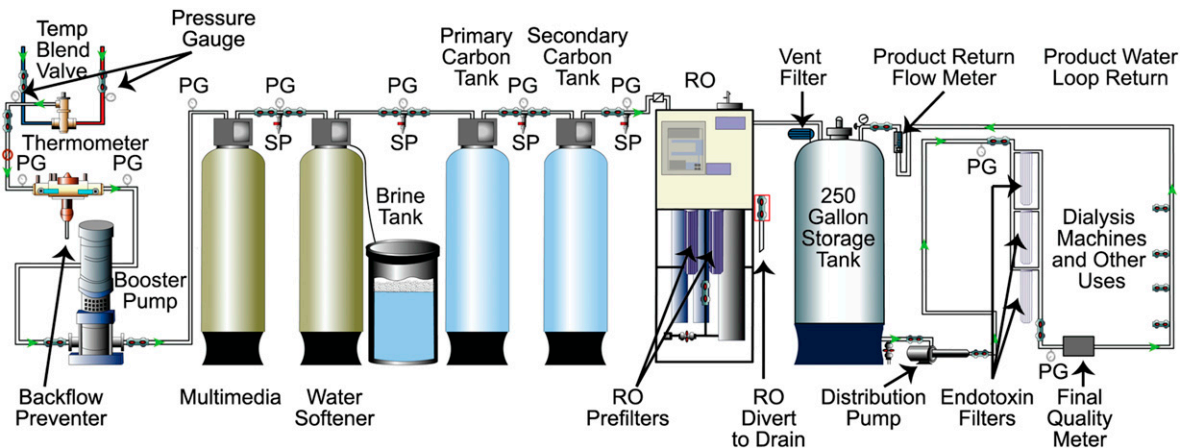
After the source water temperature has been adjusted by the blending valve, the system should be fitted with a backflow or reverse flow prevention device. This water treatment system component keeps the water flowing in the direction of the purification system and never backward

toward the water source. There is a pressure gauge on either side of it as well as a filter, which may become clogged. Pressure differences >30 psi across the device suggest an obstruction of the filter that requires maintenance (Figure 2, Table 4).

After the backflow prevention device is the booster pump, which pressurizes the system. As its name implies, the purpose of the booster pump is to keep water moving through the water treatment system, optimizing system performance and purification. A pressure switch turns the booster pump on and off as needed. When system pressure falls below the required threshold (the set point), the pump will automatically turn on; it will turn off again when the system pressure is adequately restored. Set points will vary according to the facility’s water need and are unique to the system. The biomedical technician should periodically check the booster pump to ensure that it is applying the appropriate pressure (Figure 2, Table 4).

The next step in pretreatment is filtration of grit and sediment from the feed water (Figure 2, Table 4). This is accomplished by the depth multimedia filter. This device removes large suspended particles from the water and prevents clogging of downstream water system components, including the reverse osmosis unit. At the start of each day, a facility team member should ensure there is a <15-psi difference across the filter. The depth multimedia device should be equipped with a backflush feature programmed to occur automatically outside the normal hours of facility operation.

After larger particulate matter has been reduced, the feed water is ready for water softening (Figure 2, Table 4). The resin media contained in the water softener have a high affinity for calcium and magnesium cations, which are known to make water hard. Feed water containing calcium and magnesium can form scale deposits downstream on the reverse osmosis membrane, fouling the membrane (Table 3) and reducing the quality of purified product water. The calcium- and magnesium-binding capacity of the water softener resin should be regenerated on a routine basis by washing with a concentrated sodium chloride solution or brine. Located adjacent to the water softener is a brine



**Figure 2. | The water treatment system.** This schematic delineates a water treatment system with indirect product water distribution (*i.e.*, a holding tank). PG, pressure gauge; RO, reverse osmosis; SP, sampling port.

Table 4. Monitoring tasks for a clinic water treatment system			
Component	Monitor	What to Look For	How Often
<b>Pretreatment</b>			
Blending valve	Water temperature	Appropriate temperature (65–85°F)	Start of each day of operation
Booster pump	Water pressure	Pump turns on and off at appropriate times or flow rates	Periodically
Depth/multimedia filter	Pressure drop across device; backflush timer	$\Delta \leq 15$ psi; set to backflush after facility operation hours	Start of each day of operation
Water softener	Pressure drop across device	$\Delta \leq 15$ psi; timer always visible	Start of each day of operation
Water softener	Media regeneration time	Set to regenerate media with brine wash after facility operation hours	
Brine tank	Salt level in tank	Adequate amount of salt pellets; no salt bridge in the tank	Start of each day of operation
Carbon tanks	Pressure drop across device; backflush timer	$\Delta \leq 15$ psi per tank; set to backflush after facility operation hours	Start of each day of operation
Carbon tanks	Chlorine and chloramine levels in the water between primary and secondary tanks	Total chlorine $\leq 0.1$ PPM	Before the first patient treatment of the day and every 4 h after the first patient until the end of day
Reverse osmosis prefilter	Pressure drop across device	$\Delta \leq 20$ psi	Start of each day of operation
<b>Purification</b>			
Reverse osmosis device	Percentage rejection level	$\geq 90\%$	Start of each day of operation
Reverse osmosis device	Product water purity	Device sensors for conductivity and TDS are set according to the manufacturer's recommendations	
<b>Distribution</b>			
Distribution loop	Flow of water at end of the loop	$>3$ ft/s (indirect) $>1.5$ ft/s (direct)	Periodically
<b>Bacterial cultures and LAL testing</b>			
Reverse osmosis device, holding tank, and distribution loop	Water cultures	$<50$ CFU/ml	No less than one time per month
Reverse osmosis device, holding tank, and distribution loop	LAL testing for endotoxin	$<1$ EU/ml	
<b>Chemical testing</b>			
Source water entering the water treatment system; product water from the reverse osmosis product line	AAMI inorganic chemical analysis; contamination analysis	Chemical compounds below the AAMI safety thresholds for purified dialysis water <sup>a</sup>	Annually and when a new water system is installed, the reverse osmosis membrane is replaced, rejection is $<90\%$ , or there are seasonal changes in source water

PPM, parts per million; TDS, total dissolved solids; LAL, limulus amoebocyte lysate; EU, endotoxin unit; AAMI, Association for the Advancement of Medical Instrumentation.

tank containing salt pellets and water, creating a supersaturated salt solution used for softener regeneration. After a media backwashing step, brine is drawn from the tank into the water softener. During the regeneration process, the calcium and magnesium are displaced from the softener resin media through competitive inhibition by sodium ions in the concentrated brine. Afterward, residual salt solution is rinsed out of the water softener. Automatically regenerating water softeners should be equipped with a lockout device to prevent the regeneration process from occurring during patient treatments. The clock and timer integral to the water softener should be read at the start of each treatment day, compared with real time, and adjusted as necessary (Figure 2, Table 4), because power failures might possibly reset media regeneration to occur during patient treatment hours. Pressure gauges on the inlet and outlet of the water softener should be fitted to monitor pressure drop ( $\Delta$ ), and softener water samples should be tested at the end of the use-day to verify that appropriate capacity is maintained. Immediate postsoftener water test results showing  $<1$  grain per gallon or 17 mg/L hardness indicate adequate water softening. The timer-setting verification,  $\Delta$ -pressure, and hardness test results should be documented daily in the maintenance log (Figure 2, Table 4).

The next step in water pretreatment is carbon filtration, which is used to remove the chlorine and/or chloramines added to municipal water systems. This process typically involves use of a pair of filter tanks placed in series that contain granular-activated carbon (GAC). The first carbon filter tank, called the primary or worker tank, must have adequate capacity to provide a sufficient volume of GAC media to dechlorinate the feed water given the water demands of the dialysis facility. Frequent testing of the feed water flowing from the primary tank outlet is necessary to verify that total chlorine levels remain  $\leq 0.1$  parts per million (PPM). Thus, the facility team should test total chlorine at the total chlorine sample test port between the two tanks several times a day during clinic operation: at the beginning of each use day, before the start of patient treatment, and no less than every 4 hours throughout each treatment day (Figure 2, Table 4).

The carbon filtration process is critical: chlorine and chloramine exposure can harm patients (Table 3). Moreover, chlorine compounds are reactive and can damage the reverse osmosis membrane, the water treatment system component most necessary for purification. Because this step is so essential, a secondary polisher GAC filter tank is placed immediately downstream from the primary worker tank and after the total chlorine sample test port. In the event that the worker filter has a chlorine breakthrough, this series design provides dechlorination redundancy. Like the primary worker filter, the secondary polisher filter is adequately sized to protect the patients from chlorine and chloramine exposure and also fitted with a sample test port. Should the worker filter have a chlorine breakthrough, the facility team must use the sample test port after the secondary polisher GAC filter to verify total chlorine levels. If total chlorine levels are  $\leq 0.1$  PPM threshold, patient dialysis treatments can continue. However, after any incidence of chlorine breakthrough from the primary tank, it is recommended that the facility team monitor the total chlorine level at the sample port after the secondary GAC filter tank every

30 minutes until patient treatment is completed, the primary GAC filter tank is replaced, or the primary filter GAC media are replaced (10).

The last component typically considered part of the pretreatment system is the water purification system prefilter (Figure 2, Table 4). This particulate filter (or filters) is positioned in the water treatment system after the secondary GAC filter tank and just before the feed water inlet to the water purification system. The prefilter will catch residual carbon fines (small carbon particles), resin beads, and other debris in the pretreated feed water that might otherwise foul or damage the downstream water purification system. Typically, the prefilter will have a pore size ranging from 1 to 5  $\mu\text{m}$ . Two gauges monitor the inlet and outlet pressures across the filter, and therefore, the operator can monitor filter pressure drop. The facility team must record all filter changes in the water treatment system maintenance log. The reverse osmosis prefilter is typically changed after the cleaning and/or disinfection procedures are completed or whenever pressure drop readings indicate that filter replacement is needed.

### Purification

With the pretreatment steps completed, the feed water is ready for purification. The most common method used to purify water for hemodialysis treatment is reverse osmosis. (Figure 2, Table 4). The reverse osmosis device is a self-contained unit that uses a high-pressure pump and a semi-permeable membrane to purify water (Figure 2, Table 4). In this purification process, pretreated water pressurized by the reverse osmosis high-pressure pump is forced to flow across and through the reverse osmosis membrane, which is specifically designed to reject or not allow passage of most dissolved inorganic elements, such as ions of metals, salts, and chemicals as well as organic materials, such as bacteria, viruses, and endotoxin. A properly functioning membrane will reject organics with  $>200$  D as well as 95%–99% of ion particles, which are concentrated and redirected to drain. Device performance is determined by percentage rejection ( $>90\%$ ) and the conductivity of final product water (measured in micro-Siemens per 1 cm or by the total dissolved solids in milligrams per liter or PPM), both of which are measured continuously by an integral monitor set according to the manufacturer's recommendations. The device should display these data and have working audible and visual alarms that, when quality thresholds are not met, can be heard at the reverse osmosis device and in the patient care area. The reverse osmosis device needs periodic maintenance administered by qualified service technicians strictly adhering to the manufacturer's instructions. All maintenance procedures should be accurately recorded.

A less common approach for water purification is deionization (DI). Using DI as a primary water purification method is strongly discouraged (2), but if used as an additional purification step (*i.e.*, for polishing) or in emergency circumstances, DI requires fail-safe systems to divert or block product water flow when product water resistivity drops to  $<1$  M $\Omega$  cm, precluding patient exposure to product water outside accepted quality limits. DI may be used to polish product water after reverse osmosis or as a standby method when a reverse osmosis system fails. DI water resistivity readings should be measured

continuously using an appropriate temperature-compensated monitor that will stop product water flow to the distribution system and provide both audible and visual alarms in the water treatment room and patient care area when product water quality drops below the acceptable range. Operator documentation of DI status and performance should be recorded in the water system log before starting patient treatment on a given use-day; additional checks should be documented at the end of a use-day (2).

### Distribution

The last step in dialysis water preparation is distribution of purified water to the points of use required to make dialysate solution for patient treatment (Figure 2, Table 4).

The two common types of distribution systems used in dialysis clinics are known as direct and indirect feed systems. With direct feed water distribution systems, pressurized by the reverse osmosis high-pressure pump, the purified water exits the reverse osmosis system and passes through an endotoxin filter before proceeding to the distribution loop designed to provide purified water to the various points of use on the dialysis floor. The unused purified water is returned through the loop to the pump inlet of the direct feed reverse osmosis system to be recycled through the reverse osmosis pump and membrane(s). With indirect water distribution systems, the purified water exiting the reverse osmosis system enters a specially designed holding tank equipped with water-level control devices. These devices interact with the reverse osmosis system, turning it off and on as needed and keeping the appropriate water level in the holding tank, so that the tank does not go dry or overflow. The purified water in the holding tank is repressurized by the distribution booster pump, which directs the purified water from the tank through an endotoxin filter before proceeding out to the distribution loop, providing purified water to the various points of use on the dialysis treatment floor. Indirect purified water distribution systems return unused purified water back to the holding tank. The distribution loop and holding tank should not be made of materials that could contribute chemicals to the purified water, including tubing and plumbing made of aluminum, copper, lead, or zinc.

Ultraviolet (UV) irradiation is sometimes used to help control bacterial proliferation in dialysis water distribution systems (both direct and indirect types). It is important that any UV device used for bacterial control be sized to allow appropriate irradiation contact time at the maximum expected water flow of the water distribution system and be followed by an endotoxin filter. UV devices must also be monitored and serviced as required by the manufacturer to prevent sublethal UV dose delivery. Failure to size and maintain a UV device can lead to proliferation of UV-resistant bacteria in the water distribution system.

### Microbial Surveillance

#### Bacteria and Endotoxin

The water treatment and distribution systems are designed to include sample ports to allow water collection. Collected samples should be sent to an accredited laboratory (preferentially one that specializes in dialysis water testing) for bacterial cultures and endotoxin-level examination (11); sample collection should always occur before

disinfection of the water treatment system, distribution loop, or dialysis machines (2). The facility team should draw water samples from the first and last outlets within the distribution loop and other outlets used to provide purified water for dilution of concentrate and other applications, such as dialyzer reprocessing, using the sampling and testing methodologies specified in the RD52 document (5). The CMS RD52 standards for action-level contamination within dialysate and purified water are 50 CFU/ml and 1 endotoxin unit/ml for bacterial and endotoxin contamination, respectively (Table 2) (5). Necessary "actions may be to repeat cultures, particularly when one in a set of cultures was above the action limit, or to disinfect the system and repeat cultures at several sites" (2). Tests showing bacteria and endotoxin concentrations in excess of the maximum allowable levels (<200 CFU/ml and <2.0 endotoxin unit/ml) can result in discontinuation of dialysis treatment and immediate remediation as deemed most appropriate by the medical director.

The RD52 document contains a map outlining the appropriate sample collection and culturing methods (5). All new dialysis water purification and distribution systems should be tested weekly for bacterial growth and endotoxin until a pattern of compliance with RD52 is shown. After some weeks consistently reaching the required CMC CFC quality standards, testing can be performed monthly; however, more frequent testing will be necessary when cultures from multiple sites are repeatedly positive (2). Using the test results to determine where the system contamination might be is essential; isolation and disinfection of the potential point of contamination are required accordingly. An analysis of bacterial contamination data over time is also recommended to deduce whether contamination by microorganisms, both above and below the action level, may have changed compared with prior testing. Additional testing would also be necessary on clinician request should patients experience illness or pyrogenic reaction during or after dialysis.

#### Disinfection

The pipes and storage tanks of water distribution systems are at risk for microbiologic contamination, and, therefore, need regular disinfection. All routine and urgent disinfection actions should be recorded in the water treatment system maintenance log and regularly reviewed as a CFC and best practice. The general strategy should be for the biomedical technician to keep a strict schedule designed to avoid the proliferation of organisms in purified water rather than disinfect for bacteria after an action-level contamination test result. There are guidelines for medical directors to consider in this regard: the RD52 document contains a map outlining the necessary steps according to the chosen disinfection method (5).

The methods used to provide the scheduled routine disinfection of the water purification equipment and distribution loops will depend, in part, on the type of system and material being disinfected. The appropriate disinfection process for a particular system should be recommended and/or approved by the manufacturer of the system. Peracetic acid-type chemicals are commonly used to disinfect most systems; in some cases, sodium hypochlorite (bleach) or ozone might be recommended for use. Hot water disinfection is becoming more commonly

used to provide disinfection in a number of systems. In the absence of unacceptable bacteria and endotoxin results, distribution equipment should be disinfected no less frequently than every 4 weeks.

Microorganisms and in particular, Gram-negative bacteria remaining in pipes outside the hours of dialysis operation will proliferate and adhere to wet surfaces, likely forming communities of microorganisms called biofilms (5). In fact, biofilm may be present in water storage and distribution systems even when bacteria and endotoxin test results are low. However, inconsistent and erratic bacteria testing results could suggest the presence of bacteria-shedding biofilm in the water storage or distribution system (2). Microorganisms detected through testing represent only those organisms suspended in water; it may take weeks to detect any biofilm problem. It is also important to recognize that cultures quantifying planktonic bacteria represent a small fraction of organisms released from accumulated biofilm within

the system. When bacterial contamination persists despite frequent and aggressive disinfection, it may be necessary to determine if biofilm is a cause. In such instances, use of alternative disinfection methods or even replacement of equipment may be required to remediate biofilm.

**Monitor System Functions**

All water systems are susceptible to failure without monitoring, even contemporary systems using the most advanced equipment. The medical director can trust that the water treatment system is running smoothly and that dialysis water is adequately pure only through collaboration and verification with his/her facility team. Water systems and their individual components should be maintained according to the manufacturer’s recommendations, and maintenance information should be accurately recorded (Table 3).

**Table 5. Contaminants toxic to patients on dialysis**

Contaminant	Source	Adverse Event	Notable
Aluminum	Municipal water treatment	Fatal encephalopathy syndrome, bone disease, anemia	Aluminum is usually included in the laboratory AAMI water quality panel of compliance tests
Calcium/magnesium	Municipal source water, municipal water treatment	Nausea, vomiting	Calcium and magnesium can scale and foul the reverse osmosis membrane, reducing membrane performance
Copper	Dialysis water treatment	Hemolysis, nausea, vomiting	Copper can leach from plumbing and fixtures in acidic conditions
Cyanotoxin	Municipal water treatment	Hepatic failure	Blue-green algal toxins should not be in the treated water; may create a pyrogenic reaction in exposed patients
Endotoxin	Dialysis water treatment	Pyrogenic reaction, chronic inflammation	Reverse osmosis and endotoxin filtering work to reduce endotoxin contamination in purified water; if endotoxin is present, however, it can pass through the dialyzer membrane into blood by backfiltration
Fluoride	Municipal water treatment	Nausea, abdominal pain, pruritus, arrhythmia	Fluoride may also be associated with uremic bone disease
Monochloramine	Municipal water treatment	Hemolysis	In addition to depleting carbon filters, chloramines can degrade some reverse osmosis membranes
Nitrates	Municipal water treatment	Anemia	Nitrates have no known effects on the function of the water treatment system
Zinc	Dialysis water treatment	Hemolysis, nausea, vomiting	Zinc oxide can interfere with carbon filter function and cation exchange in the water softener

AAMI, Association for the Advancement of Medical Instrumentation. Modified from ref. 11, with permission.

Typically, the water system maintenance log should be kept with the same standard that is expected of medical records. Monitoring functions are conducted by trained facility teammates, sometimes including a biomedical technician. However, all service repair, preventive maintenance, and troubleshooting should be performed by the facility's biomedical technician. The maintenance log should be used to record all monitoring and maintenance data, including the date and time of record as well as the personnel who completed the task. Such documentation will be an important part of the CMS surveyor evaluations.

### Know the Clinical Significance of Water System Failure

The wellness of patients on dialysis starts with meeting the minimum standards for dialysis water quality (Table 1). Chemical and metal contaminants that are safe in drinking water for ingestion by healthy patients are not safe in patients on hemodialysis who are exposed to approximately 400 L dialysis water per treatment three times per week (12).

The associations between illness and dialysis water contaminants are well described (Table 5), ranging from sometimes benign (pruritus) to deadly (encephalopathy) (13). Chloramine is widely known to cause hemolysis, anemia, and death in patients on dialysis (14). However, high concentrations of other minerals can also be fatal: eight patients had fatal encephalopathy shown to be associated with the addition of aluminum compounds to municipal water, resulting in a 3- to 16-mg load of aluminum with each dialysis treatment (15); the outbreak of illness was stopped with the addition of a DI step in the dialysis water purification process. More recently, dialysis water contaminants have been implicated in the lack of response to erythropoietin of patients on hemodialysis. Fluck *et al.* (16) published that, over time, chloramine levels in water were inversely associated with mean hemoglobin and directly associated with mean erythropoietin dosing in patients on hemodialysis. Rahmati *et al.* (17) published that, under stable erythropoietin dosing, patients' mean hemoglobin levels increased after the addition of a new reverse osmosis filter. Masuhashi and Yoshioka (18) showed a similar result. When additional endotoxin was removed from dialysis water, mean patient hematocrit was increased, whereas mean erythropoietin dosing was reduced in the 5 months after the removal. Cumulatively, these results suggest that endotoxin contaminants in dialysis water at concentrations below those causing clinical symptoms, such as fever, may reduce patients' response to erythropoietin therapy, possibly through chronic inflammatory stimulus. These studies call into question whether the minimum purity standards currently used by the CMS for dialysis water could be raised to potentially improve clinical outcomes in patients. Data such as these should inspire medical directors to think beyond the minimal requirements used by the CMS.

### Consider Continuing Improvements

When the processes to provide product water of appropriate quality and quantity for the facility are adequately routinized, the medical director might consider goals for continuing improvements in water quality, such as adoption of higher quality thresholds. In 2014, the AAMI

released a revised guideline for dialysis water quality, providing new recommendations for acceptable bacterial testing methods, although the inorganic contaminants, viable bacteria, and endotoxin thresholds remain at the AAMI 2009/2011 guideline levels (11). Despite these AAMI updates over the past decade, the CMS compliance is still defined by the 2004 AAMI RD52, and many dialysis clinics have voluntarily chosen to use the more stringent newer guidelines.

As a part of QAPI discussions at every dialysis facility, the medical director and clinic staff should decide what level of water quality they wish to attain (Tables 1 and 2) to meet the CMS CFC and promote patient wellness. For some dialysis facilities, voluntarily providing higher-quality water than outlined in RD52 might involve upgrades in water treatment system components or even replacement of older systems. Decisions to do so will keep facilities ahead of the curve in terms of compliance and continuing improvement but must not be made in a clinical vacuum. Having a sound understanding of the needs and requirements of water treatment allows the medical director to help the facility find the best system for the facility, both clinically and financially.

### Conclusions

Medical directors should be equipped to tackle water quality standards in their dialysis facilities and understand the level of accountability that the CMS expects. Those medical directors who learn, know, and embrace the requirements for providing high-quality dialysis water will be most successful in this task.

### Acknowledgments

The authors thank Donna Jensen of DaVita Clinical Research (DCR) for medical writing assistance and editorial support. DCR is committed to advancing the knowledge and practice of kidney care.

### Disclosures

T.K. and O.E.R. work at DaVita HealthCare Partners.

### References

- Centers for Medicare & Medicaid Services, HHS: Medicare and Medicaid programs: Conditions for coverage for end-stage renal disease facilities. Final rule. *Fed Regist* 73: 20369–20484, 2008
- Centers for Medicare and Medicaid Services: *ESRD Basic Technical Surveyor Training Interpretive Guidance. Interim Final Version 1.1*. Bethesda, MD, Centers for Medicare and Medicaid Services, 2008
- Layman-Amato R, Curtis J, Payne GM: Water treatment for hemodialysis: An update. *Nephrol Nurs J* 40: 383–404, 2013
- US Environmental Protection Agency: *National Secondary Drinking Water Regulations EPA 816-f-09-004*, Washington, DC, US Environmental Protection Agency, 2009
- ANSI/AAMI RD52: *Hemodialysis Systems*, Arlington, VA, Association for the Advancement of Medical Instrumentation, 2004
- Manuel J: Crisis and emergency risk communication lessons from the Elk River spill. *Environ Health Perspect* 122: A214–A219, 2014
- Dialysis clinics scramble after West Virginia chemical spill shuts off water source. *Nephrol News Issues* 2014, Available at: <http://www.nephrologynews.com/articles/109983-dialysis-clinics-scramble-after-west-virginia-chemical-spill-shuts-off-water-source>. Accessed January 1, 2014
- Davis TW, Watson SB, Rozmarynowycz MJ, Ciborowski JJ, McKay RM, Bullerjahn GS: Phylogenies of microcystin-producing cyanobacteria in the lower Laurentian Great Lakes suggest extensive genetic connectivity. *PLoS ONE* 9: e106093, 2014
- Kopp JB, Ball LK, Cohen A, Kenney RJ, Lempert KD, Miller PE, Muntner P, Qureshi N, Yelton SA: Kidney patient care in disasters: Emergency planning for patients and dialysis facilities. *Clin J Am Soc Nephrol* 2: 825–838, 2007



10. AAMI: *ISO 26722: Water Treatment Equipment for Hemodialysis Applications and Related Therapies*, Arlington, VA, Association for the Advancement of Medical Instrumentation, 2009
11. AAMI TIR58: *Water Testing Methodologies*, Arlington, VA, Association for the Advancement of Medical Instrumentation, 2014
12. Pontoriero G, Pozzoni P, Andrulli S, Locatelli F: The quality of dialysis water. *Nephrol Dial Transplant* 18[Suppl 7]: vii21–vii25, 2003
13. AAMI: *ISO 23500: Guidance for the Preparation and Quality Management of Fluids for Haemodialysis and Related Therapies*, Arlington, VA, Association for the Advancement of Medical Instrumentation, 2011
14. Eaton JW, Kolpin CF, Swofford HS, Kjellstrand CM, Jacob HS: Chlorinated urban water: A cause of dialysis-induced hemolytic anemia. *Science* 181: 463–464, 1973
15. Rozas VV, Port FK, Rutt WM: Progressive dialysis encephalopathy from dialysate aluminum. *Arch Intern Med* 138: 1375–1377, 1978
16. Fluck S, McKane W, Cairns T, Fairchild V, Lawrence A, Lee J, Murray D, Polpitiye M, Palmer A, Taube D: Chloramine-induced haemolysis presenting as erythropoietin resistance. *Nephrol Dial Transplant* 14: 1687–1691, 1999
17. Rahmati MA, Homel P, Hoenich NA, Levin R, Kaysen GA, Levin NW: The role of improved water quality on inflammatory markers in patients undergoing regular dialysis. *Int J Artif Organs* 27: 723–727, 2004
18. Matsuhashi N, Yoshioka T: Endotoxin-free dialysate improves response to erythropoietin in hemodialysis patients. *Nephron* 92: 601–604, 2002
19. Selenic D, Alvarado-Ramy F, Arduino M, Holt S, Cardinali F, Blount B, Jarrett J, Smith F, Altman N, Stahl C, Panlilio A, Pearson M, Tokars J: Epidemic parenteral exposure to volatile sulfur-containing compounds at a hemodialysis center. *Infect Control Hosp Epidemiol* 25: 256–261, 2004
20. Tipple MA, Shusterman N, Bland LA, McCarthy MA, Favero MS, Arduino MJ, Reid MH, Jarvis WR: Illness in hemodialysis patients after exposure to chloramine contaminated dialysate. *ASAIO Trans* 37: 588–591, 1991
21. de Torres JP, Strom JA, Jaber BL, Hendra KP: Hemodialysis-associated methemoglobinemia in acute renal failure. *Am J Kidney Dis* 39: 1307–1309, 2002
22. Berend K, van der Voet G, Boer WH: Acute aluminum encephalopathy in a dialysis center caused by a cement mortar water distribution pipe. *Kidney Int* 59: 746–753, 2001

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

## The Medical Director in Integrated Clinical Care Models

Thomas F. Parker III\*<sup>†</sup> and George R. Aronoff<sup>‡</sup>

### Abstract

**Integrated clinical care models, like Accountable Care Organizations and ESRD Seamless Care Organizations, present new opportunities for dialysis facility medical directors to affect changes in care that result in improved patient outcomes. Currently, there is little scholarly information on what role the medical director should play. In this opinion-based review, it is predicted that dialysis providers, the hospitals in which the medical director and staff physicians practice, and the payers with which they contract are going to insist that, as care becomes more integrated, dialysis facility medical directors participate in new ways to improve quality and decrease the costs of care. Six broad areas are proposed where dialysis unit medical directors can have the greatest effect on shifting the quality-care paradigm where integrated care models are used. The medical director will need to develop an awareness of the regional medical care delivery system, collect and analyze actionable data, determine patient outcomes to be targeted that are mutually agreed on by participating physicians and institutions, develop processes of care that result in improved patient outcomes, and lead and inform the medical staff. Three practical examples of patient-centered, quality-focused programs developed and implemented by dialysis unit medical directors and their practice partners that targeted dialysis access, modality choice, and fluid volume management are presented. Medical directors are encouraged to move beyond traditional roles and embrace responsibilities associated with integrated care.**

*Clin J Am Soc Nephrol* 10: 1282–1286, 2015. doi: 10.2215/CJN.05120514

### Introduction

The penetration of integrated clinical care models into nephrology practice presents new opportunities to affect changes in care for individual patients undergoing dialysis: changes that result in improved patient outcomes. Unfortunately, there is sparse literature concerning dialysis facility medical directors and the application of associated responsibilities to integrated care models. What follows is an opinion-based commentary on the potential for them to expand their current role.

Two definitions are required before building a proposition for medical director involvement. One is to establish the perceived and real responsibilities of the medical director. Additionally, we need a common understanding of what is meant by integrated care. The first definition is easy: the regulatory responsibilities specified in the conditions for coverage for the medical director are precise (1). Especially noteworthy among the wide array of responsibilities articulated in this regulatory document is the absence of coordination of care within an integrated or any other coordinated care model. This is not a criticism but merely a statement of fact.

The second definition relates to what is meant by integrated care. There are numerous acronyms, but there are certain similarities: Accountable Care Organizations (ACOs) and Medicare Shared Savings Programs resulting from the Affordable Care Act, other shared savings models, integrated care systems, ESRD Seamless Care Organizations, Medicaid programs merged into managed care programs, and global capitated care processes. Likely, there are many more. However, the common

features are an attempt at seamless care between physicians and providers of services, including dialysis facilities, hospitals, and payers, to achieve better outcomes at lower cost. Central to this approach is a coordination of care to achieve this savings while maintaining or achieving a high quality of care. Some models offer sharing in the savings, and others do not. All expect more value: enhanced quality at optimal costs.

The growth in the number of these programs is going to place pressure on providers of services to respond. This paper will use the term integrated care to indicate any of the aforementioned models.

### Background

Integrated care models can initiate from the Centers for Medicaid and Medicare Services (CMS), payers, hospitals, or regional health systems. Each will have unique aspects, and this document will not address the variances. Likely, the models will require that the amalgamation of services, by whatever name, is responsible for a capitated, fully loaded life, a cost-plus, or a base payment with exceptional carve-outs. In addition, there may be outlier insurance. Regardless, for the most part, the entity and its constituents will manage every aspect of health care for that individual and that population.

In the United States, ACOs represent a well developed and widely distributed option for integrated care. According to a recent report from the accounting firm Oliver Wyman, on the basis of the announcement of CMS's approvals for Medicare ACOs, more than two

\*Department of Medicine, Baylor University Medical Center, Dallas, Texas; <sup>†</sup>Renal Ventures Management, LLC, Lakewood, Colorado; and <sup>‡</sup>Department of Medicine, University of Louisville School of Medicine, Louisville, Kentucky

### Correspondence:

Dr. Thomas F. Parker III, 100 Highland Park Village, Suite 200, Dallas, TX 75205. Email: tfparker3rd@yahoo.com

thirds of the United States population live in localities served by at least one of an estimated 520 ACOs (2). The number of ACOs has doubled in 2013. They also estimated that about 5.3 million people or nearly 10% of all Medicare beneficiaries participate in ACOs (2).

To further put this issue into context, currently, a Medicare patient with ESRD has a fully loaded cost when receiving hemodialysis costing >\$87,000 or peritoneal dialysis costing >\$71,000 (3). Are these costs actionable? Can they be changed? Clearly, payers believe so. To meet this demand for change, the responsibilities, roles, and accountability of the medical director, in our opinion, must also change.

### The Dialysis Facility Medical Director

Historically, medical directors took an active role in designing, maintaining, and managing their dialysis facilities. Previously, when most facilities were owned by the medical director and his/her practice partners, every aspect of the dialysis operation was the responsibility of the medical director. In parallel, the primary care of the patient on dialysis fell to the nephrologist. With the shift of dialysis facility ownership toward large, medium, and small dialysis organizations, many of the previous tasks of the medical director are now perceived to be corporate responsibilities. As an employee of the dialysis company, through the medical director contract or agreement, the job description of the medical director is now mostly perceived as limited to assuring compliance with the CMS Conditions for Coverage for ESRD Facilities.

Furthermore, coordination of care has become vastly more complex. Presently, the primary care of patients on dialysis occurs outside the dialysis unit and is largely provided by non-nephrologists. There are many more venues for care other than the dialysis facility and a nearby hospital. Transportation to more remote tertiary care centers is common, procedures are often performed in independent outpatient specialty facilities, short stays at extended care or rehabilitation facilities occur regularly, and nursing home placement frequently follows hospitalization. Complicating care coordination further is the proliferation of multiple electronic health records that do not communicate among facilities. Clearly, there are many opportunities for the dialysis facility medical director to improve patient outcomes by supervising care processes that improve outcomes.

We know, as nephrologists, that there are certain comorbid conditions and factors that lead to the high costs of care for these patients: patients who would have been best managed with conservative care, patients with catheters or volume overload, patients returning from the hospital, care within the first 120 days to name the ones most responsible. Rather than managing myriad extrinsic issues, the medical director, in its simplest approach, can merely offer programs that change outcomes for the involved parties.

### New Responsibilities

The dialysis provider, the hospitals in which the medical director and staff physicians practice, and the payers with which they contract are going to insist that, as care becomes more integrated, dialysis facility medical directors take on new responsibilities. These responsibilities, at the very least, will include the following tasks:

Awareness of high-cost patients who require extraordinary services. This information will become available from the payer or entity responsible for the capitated life (likely a hospital consortium).

Analysis of those patients with ESRD within the context of comorbid conditions who have frequent hospitalizations and overall higher costs.

A lessening from an average of 1.8 hospitalizations per year per patient (4).

A lessening from an average of 11.7 days in the hospital per year per patient (4).

A significant reduction in the 33% of patients returning to the hospital within 30 days (4).

The most extensive review of traditional responsibilities of medical directors has been outlined by Maddux and Nissenson (5) in this series on medical directors. Although Maddux and Nissenson (5) do not specifically address the medical director's responsibility in integrated care, they do make the following comment:

An effective Medical Director is asked to be more capable of influencing effective operations, culture, staff development, education, and sustainability of the facility. Medical Directors should seek and obtain background in basic business principles so that they can understand how to influence good decisions about equipment, standardized processes and hiring. This knowledge supports the need for developing a sustainable, healthy dialysis facility. Although specifics regarding business competency are not a regulatory requirement of the CFC, such expertise enhances effectiveness of the Medical Director. When a Medical Director does not participate in the business and operational decisions regarding the promotion of safe, effective and efficient care the facility will suffer sustainability risk (5).

Clearly, involvement in developing ongoing care models is associated. Furthermore, the Renal Physicians Association has provided a compendium on meeting the requirements of the medical director (6).

### Elements of Integrated Care for the Medical Director

However, it is noteworthy that none of these sources addresses the medical director's role in the setting of integrated care. Integrated care was simply not part of a vocabulary at the time. The following represents our view of this new responsibility, which extends beyond the usual activities previously noted. We present this vision in a stepwise manner as a sort of template for adaptation.

### Awareness of Regional Medical Care Delivery Systems

No one is in a better position than the medical director to understand what the regional hospitals and their respective payers are doing to develop integrated care models. Whether they are in a stage of purchasing practices, are developing unique payment plans with payers, are evaluating data to establish cost and care issues, or have moved beyond all of this must be known. The medical director should be in contact with the chief medical officer, the chief financial officer, or other appropriate decision makers within the care

system to understand the immediate and long-range plans within the region. If the dialysis provider that the medical director represents is going to be integrated into the process and a preferred provider, then the conversations cannot begin early enough. Likely, attention will have been given to cardiovascular disease, oncology, orthopedics, and others, but the emphasis on patients with ESRD will not be at the forefront. However, there will be an awareness of the complicated care required, the cost of that care, and the need to be responsive. Our experience is that hospital administrators are overwhelmed with the complexity of taking care of patients with ESRD and their comorbidities. This is an opportunity for the medical director to simplify the understanding and process.

Then, communicating these conversations to the dialysis facility physician staff, where appropriate, and the dialysis provider would be a next logical step. Facilitating communication between the hospital and the dialysis provider becomes the domain of the medical director. Unless the provider has an acute dialysis contract, it is unlikely that the entities have even met. Determining how to proceed to the next step is essential. Call it facilitating, brokering, being a catalyst, or being a leader. Communication at this point is the dominant element.

It must be fully understood that some patients may be undergoing dialysis in a specific facility and may not be part of an integrated hospital system (may not go to those hospitals and providers). There is no official integrated care responsibility for the medical director in that setting. However, the medical director may, indeed, find himself/herself negotiating and involved with several integrated systems. This is all very new, and sensitivity to this will be hugely complicated. Thus, there is a need for a leader who understands the full process.

### Developing Actionable Data

Hospitals generally have an overabundance of data about patients and physician providers. Assisting in gaining an understanding of what data are significant is an area where in the medical director can be of enormous assistance. What is the cost of an incident or prevalent patient with ESRD within that system? What can be done to change those costs? It is known that almost 50% of hospitalizations and the associated costs for patients on dialysis are caused by three entities: cardiovascular disease, infection, and access (the latter two are codependent on catheter rates). What can be done to change the aforementioned rehospitalization rate?

Accurate and timely data are essential. Information by patient, physician, location of care, and provider will be required. Who are the high-cost patients and why? What are the quality of care issues and why? Are there differences in caretakers? Where does the care take place? Who is responsible?

### Determine Mutual Outcomes

For the first time, perhaps, the alliance between patients, hospitals, and other providers, including the dialysis providers, can align outcomes. Clearly, there is agreement that all want high quality. However, there likely have not been significant conversations related to concurrence of just what is entailed in high quality. Is this just hitting the numbers of

regulatory agencies? Is it patient satisfaction and quality of life? Is it patient safety? Is it measured by hospitalizations, durations of stay, and rehospitalization rates? Is it achieving goals that have never been set by any of the represented parties (goals that extend quality beyond what has been discussed separately or collectively)? This is an opportunity for the medical director to inform the various providers as to what really determines outcomes in patients undergoing dialysis.

### Developing a Process

There is no one better to take the lead in developing a process for managing patients with ESRD than the nephrologist, and there is no one better to coordinate care among the various providers of care than the medical director of the dialysis facility. Systems for the major comorbid conditions that affect outcomes must be developed. Foremost are those conditions that cause the greatest numbers of hospitalizations and rehospitalizations (*i.e.*, fluid volume-related hospitalizations, catheter-related infections, wounds, pneumonia, and the results of missed treatments). What is the dialysis provider doing to avoid hospitalizations associated with these factors? How can the provider assure the integrated care system that these conditions are being optimally managed?

Developing effective methods for transitions of care is essential. The smooth movement of patients and records from one care location and provider to another is critical. The handoff of records and plans of care, discharge planning, appointments, and points of contact are elements that must be rigorously maintained.

Optimizing the care of patients while in the hospital, maintaining anemia control and volume control, medication reconciliation, and awareness of the prevalence of depression in patients with ESRD are just a few needs that are vital. How are these ongoing needs communicated to the caring medical team, especially if care is led by a hospitalist rather than a nephrologist? The dialysis unit medical director should be empowered to develop processes that reflect understanding of the acuity of the issue for patients returning from the hospital, especially during the vulnerable 30 days after discharge.

This approach requires systems of care. The medical director needs to lead the team to assure that these systems are in place and being audited and enforced. A typical dialysis provider thinks about how to provide dialytic care. The paradigm must shift to caring for the patient who happens to need dialysis in addition to many other essential elements of care.

If we start with the notion that improved quality of care results in lower costs, then the dialysis facility medical director has an enormous opportunity to increase value for the managing care organization by simultaneously improving quality and decreasing costs. To accomplish this goal, however, the medical director must develop and enforce systems of care that improve meaningful outcomes. Participation in an integrated care model makes such efforts both possible and mandatory. Nissenson (7) recently proposed that the traditional focus on biochemical quality surrogates be replaced by patient-centered care, which results in improved longevity, decreased hospitalizations, better experience of care, and improved quality of life for patients on dialysis. To illustrate the concept, Nissenson (7)

proposed a patient-focused quality hierarchy, now widely referred to as the quality pyramid. With a nearly 20% annual mortality rate, an almost 40% mortality rate for patients starting dialysis, an average of about two hospitalizations each year, and a very high rehospitalization rate, even a modest improvement in quality outcomes would enhance thousands of lives and decrease costs. Also, according to Nissenson (7), this is not likely to occur if we continue to simply use biochemical measures. We must move up the pyramid.

Renal Ventures Management, LLC (RVM), a small dialysis organization with 36 facilities (T.F.P. is the Chief Medical Officer of RVM, and G.R.A. is the Assistant Chief Medical Officer of RVM), implemented a system-wide, quality-focused program for patients with stages 4 and 5 CKD. Dialysis unit medical directors and their practice partners developed and implemented protocols that decreased emergent dialysis starts, maintained better volume control, and improved nutritional status, while focusing on hemodialysis access placement and dialysis options decisions (T.F. Parker, G.R. Aronoff, unpublished data). Although these results have not appeared in reviewed journals, the results of this initiative were clear. Almost 90% of the patients enrolled in the program started dialysis with a noncatheter permanent dialysis access; >30% chose a home dialysis modality. We, too, were startled at the outcomes.

RVM also implemented an initiative to identify our most vulnerable patients on dialysis (patients in the first 120 days after initiation of dialysis). Within 120 days, <5% of patients were dialyzing with a catheter only. Peritoneal dialysis prevalence rates increased from 7% to 15% within 2 years. This program, by giving extraordinary attention to the sickest of patients, changes those outcomes that are of interest to integrated care administrators (8).

In an effort to improve volume management and decrease hospitalizations and rehospitalizations for fluid volume overload, we are also testing the universal monitoring of intravascular volume. In a previous quality collaboration on intradialytic volume management with large dialysis organizations, we showed a dramatic decrease in volume-related hospitalizations. Our additional internal studies have confirmed this finding (T.F. Parker, G.R. Aronoff, unpublished data).

These initiatives and others show at the facility level that, while concentrating on the usual markers to which we are held accountable, if we are truly going to make a difference in quality for emerging models of care, we must move up the pyramid.

### Leading and Informing Medical Staff

Within each dialysis facility, attending physicians from single or varied practices may have patients for whom they care. They must be on board with an understanding of the importance of the integrated care model, the data, the systems, and the auditing process. The medical director's responsibility is to instruct them, gain their understanding, and then, hold them accountable. This task is easy to describe, but difficult to accomplish. However, these tasks are necessary. It is not the responsibility of the medical director to oversee the care of each individual patient or coordinate that care with each provider. Rather, it is the

responsibility of the medical director to fully inform the attending physicians of the issues, processes, and systems in place and oversee their compliance. Future credentialing by payers and health systems will likely include such participation.

### Discussion and Summary

The medical director is in a complicated and diverse situation. On the one hand, she or he is a nephrologist practitioner and must represent the clinical practice entity, whether it is owned privately, corporately, or by a hospital consortium. On the other hand, she or he is expected to represent the entity paying the privately negotiated but federally regulated medical director agreement fee. For the dialysis provider (the company managing the dialysis facilities), this commitment takes priority over the other possibly conflicting relationships.

Of course, there is the issue of compensation for these aforementioned activities. The relationship between the medical director and the dialysis provider is a contractual one, usually a robust legal relationship. The activities described in this paper are clearly in addition to those that have traditionally been performed. The CMS suggests that a medical director should be spending 25% of their time performing medical director responsibilities. If these activities go beyond that time, then the medical director will need to change the contractual relationship for compensation. It clearly translates to an advantage to the provider to have the medical director involved in these activities. The benefits of fewer hospitalizations and rehospitalizations and therefore, fewer missed treatments and the possibility that better integrated care leads to lessened morbidity and even mortality accrue benefit to the dialysis provider. Additionally, the CMS is considering the inclusion of standardized rehospitalization rates, a measure that integrated care should minimize, as a component of the Quality Improvement Program, which has direct financial implications. Because both the dialysis provider and the integrated health care system stand to benefit financially through medical directors' additional activities, additional payment will need to come from either or both to compensate for the medical directors' added duties.

Dialysis unit medical directors may have been comfortable managing those responsibilities associated with the CMS conditions for coverage. Now, we are encouraging them to move beyond the traditional and the comfort to the frontier of medical care by taking a leadership role in the development of systems and processes of care that result in improved patient outcomes.

### Disclosures

T.F.P. is a salaried employee of Renal Ventures Management, LLC. G.R.A. is a salaried employee of Renal Ventures Management, LLC, and the University of Louisville School of Medicine.

### References

- Centers for Medicare & Medicaid Services (CMS), HHS: Medicare and Medicaid programs; conditions for coverage for end-stage renal disease facilities. Final rule. *Fed Regist* 73: 20369–20484, 2008
- Oliver Wyman: ACO Update: Accountable Care at a Tipping Point, 2014. Available at: <http://www.oliverwyman.com/insights/publications/2014/apr/aco-update-accountable-care-organizations-now->

- serve-17-of-amer.html#.U2pF\_53D-01. Accessed May 7, 2014
3. US Renal Data System: USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2013. Available at: [http://www.usrds.org/2013/pdf/v2\\_ch11\\_13.pdf](http://www.usrds.org/2013/pdf/v2_ch11_13.pdf). Accessed May 7, 2014
  4. US Renal Data System: USRDS 2013 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2013. Available at: [http://www.usrds.org/2013/pdf/v2\\_ch3\\_13.pdf](http://www.usrds.org/2013/pdf/v2_ch3_13.pdf). Accessed May 7, 2014
  5. Maddux FW, Nissenson A: The evolving role of the medical director of the dialysis facility. *Clin J Am Soc Nephrol* 2: 326–330, 2015
  6. Renal Physicians Association: *RPA Position Paper on Dialysis Facility Medical Director Responsibilities under Revised CMS Conditions for ESRD Facilities*, Rockville, MD, Renal Physicians Association, 2009
  7. Nissenson AR: Improving outcomes for ESRD patients: Shifting the quality paradigm. *Clin J Am Soc Nephrol* 9: 430–434, 2014
  8. Reddy N, Brooks K, Schmidt L, Parker TF 3rd: A crucial lifeline: Reducing mortality in the first 120 days. *Nephrol News Issues* 26: 22–27, 2012
- Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

## Managing Disruptive Behavior by Patients and Physicians: A Responsibility of the Dialysis Facility Medical Director

Edward R. Jones\* and Richard S. Goldman†

### Abstract

The Centers for Medicare & Medicaid Services' Conditions for Coverage make the medical director of an ESRD facility responsible for all aspects of care, including high-quality health care delivery (e.g., safe, effective, timely, efficient, and patient centered). Because of the high-pressure environment of the dialysis facility, conflicts are common. Conflict frequently occurs when aberrant behaviors disrupt the dialysis facility. Patients, family members, friends, and, less commonly appreciated, nephrology clinicians (*i.e.*, nephrologists and advanced care practitioners) may manifest disruptive behavior. Disruptive behavior in the dialysis facility impairs the ability to deliver high-quality care. Furthermore, disruptive behavior is the leading cause for involuntary discharge (IVD) or involuntary transfer (IVT) of a patient from a facility. IVD usually results in loss of continuity of care, increased emergency department visits, and increased unscheduled, acute dialysis treatments. A sufficient number of IVDs and IVTs also trigger an extensive review of the facility by the regional ESRD Networks, exposing the facility to possible Medicare-imposed sanctions. Medical directors must be equipped to recognize and correct disruptive behavior. Nephrology-based literature and tools exist to help dialysis facility medical directors successfully address and resolve disruptive behavior before medical directors must involuntarily discharge a patient or terminate an attending clinician.

*Clin J Am Soc Nephrol* 10: 1470–1475, 2015. doi: 10.2215/CJN.05220514

\*Nephrology Section, Chestnut Hill Hospital, Delaware Valley Nephrology and Hypertension, Philadelphia, Pennsylvania, and †Renal Medicine Associates, Albuquerque, New Mexico

### Correspondence:

Dr. Edward R. Jones, Delaware Valley Nephrology and Hypertension, Suite 100, 10 E Moreland Avenue, Philadelphia, PA 19002. Email: dredj@comcast.net

### Introduction

The Centers for Medicare and Medicaid Services (CMS) 2008 Conditions for Coverage (CfC) (1) expanded the role of the dialysis facility medical director. The Renal Physicians Association (RPA) (2) and the Forum of ESRD Networks (3) elucidated these changes in white papers. Before the CfC, many nephrologists were unclear about their precise responsibilities in the dialysis facility. The revised CfC specified and mandated medical director leadership and oversight responsibilities for everything that occurs in the facility (1,4). The medical director's role includes establishing, maintaining, and implementing all procedures and policies, including daily staff conduct and educating all new staff. CMS, *via* the ESRD Networks and state agencies, monitors facilities to ensure that directors are adequately fulfilling their responsibilities. In addition, owners of dialysis facilities compensate the medical director to fulfill these responsibilities. Consequently, dialysis facility owners have the same expectations of medical directors as does CMS.

Conflict is inevitable within a dialysis facility because of the stressful environment. Dealing with patients with acute and chronic problems, within the same four walls, three times per week, 52 weeks per year can be very demanding. Within the practice of medicine, heavy workloads, increasing responsibilities, and financial insecurity add to the stress level. Disruptive behavior is a frequent cause of dialysis-related conflict. Disruptive behavior creates an environment that impedes the

safe and effective delivery of the highest quality of care or disrupts the flow of operations within the facility (5). To meet their regulatory requirements, medical directors must learn to manage disruptive behavior. The authors recommend focusing on the aberrant behavior, not the individual manifesting the behavior. This focus minimizes defensive posturing and personality conflicts, while enhancing understanding and appropriate intervention (6).

The nephrology community is well aware of disruptive behavior manifested by patients (7). However, stakeholders are generally less aware of disruptive behavior manifested by nephrology clinicians. The general medical literature (5,8) addresses the disruptive physician. Nephrology can extrapolate from the general medical experience. The general medical literature associates disruptive behavior with medical errors, poor patient satisfaction, staff turnover, adverse outcomes, and excessive costs (5,9,10). Disruptive behavior, whether by a patient or nephrology clinician, creates an unsafe patient environment and impedes the delivery of high-quality care (11,12). Excellent resources are available to the nephrology clinician to help them resolve disruptive behavior (12–16).

### Disruptive Behavior by Patients

The Decreasing Dialysis Patient-Provider Conflict project (DPC), a coalition of stakeholders and behavioral

experts, addressed disruptive behavior in 2005 (12). The coalition selected several issues fundamental to understanding conflict and disruptive behavior in dialysis centers (Table 1). The group released a white paper analyzing the ethical, legal, and regulatory underpinnings of “entitlement,” involuntary discharge (IVD), medical abandonment, and nonadherence to medical advice (12). Patients and providers (7,12) often misunderstand the legal and regulatory meaning of “entitlement.” Many incorrectly assume the term means “entitled to dialysis treatment.” Instead, “dialysis-related entitlement,” defined by statute and regulation, actually means providers are “entitled” to receive payment from the federal government for dialysis services provided to qualified beneficiaries. However, it is axiomatic that patients have the right to expect high-quality, safe, and ethical care from their dialysis providers, as codified in the CfC by CMS.

The concepts for understanding nonadherence to medical advice are as follows: (1) The patient has the right to refuse treatment (ethical principle of autonomy), and (2) the provider has no statutory authority to deny treatment to nonadherent patients. Nonadherence to medical advice is not a justifiable reason for IVD or involuntary transfer (IVT). For example, missed or shortened treatments are not necessarily cause for IVD or IVT. Rather, the DPC recommends that the interdisciplinary care team seek specific causes for this behavior, such as painful treatments, family illness, child or adult care schedule conflicts, work schedule conflict, travel problems, inadequate understanding of consequences, or inadequate understanding of the cultural context for the behavior. Specific causes should be addressed and resolved to everyone’s satisfaction. Other creative solutions exist for solving the problem of frequently missed dialysis treatments (17). Medical abandonment and IVD/IVT are discussed later in this paper.

The DPC developed categories of disruptive behaviors based on whom the behavior placed at risk: (1) risk to others, (2) risk to the facility, or (3) risk to self. These categories allow stratification by lowest to highest risk and provide a framework for determining the appropriate intervention, such that the “penalty fits the crime.” Using this taxonomy, DPC defined disruptive behavior: Written, verbal, or physical abuse (risk to others) were stratified as high risk, property damage or theft (risk to the facility) as intermediate risk, and nonadherence to medical advice (risk to self) as lowest risk. This approach led to the development of a DPC tool kit algorithm (Figure 1) (14). The Forums’ Medical Director Toolkit exemplifies the stratification (3).

### Interventions for Dealing with Disruptive Behavior Exhibited by Patients

Medical directors and dialysis administrators should be trained to analyze and diffuse disruptive behavior. They should also learn how to train other dialysis professionals to diffuse disruptive behavior and codify the training in written policies and written procedures for implementing those policies. An important first step in dealing with patient-generated disruptive behavior to exclude medical reasons for abnormal behavior, including drug and alcohol abuse, psychologic disorders (particularly depression [18]), adverse drug reactions, inadequate dialysis, metabolic abnormalities

(such as hypercalcemia), subdural hematomas, or occult sepsis (7). Once medical or metabolic causes are excluded, the issue may be framed in a behavioral context.

Resolving behavioral conflicts requires a systematic approach. Each facility should have its own grievance process. The grievance process should be readily available, effective, and easy to use and should respect confidentiality. Having a sincere, effective “in-house” grievance process is one of the best ways to address conflict without requiring an ESRD Network formal grievance intervention. The DPC (Figure 1, Table 2) and RPA (13) have described additional systematic approaches to conflict resolution, including disruptive behavior or strong negative emotions. Sufficient time and a quiet environment must be allotted to elucidate the perceptions of those involved in a nonjudgmental way called active or effective listening. Active listening demonstrates the listener’s empathy and an honest desire to understand the behavior through the eyes of the patient. The method excludes agreeing or disagreeing with the behavior and is not a debate. Focus is kept on the behavior, avoiding “personality conflicts.” Once the dialysis professional has demonstrated empathy toward and understanding of the patient’s perspective, good-faith negotiation toward a settlement can begin. As suggested in RPA’s guideline (“Shared Decision Making in the Initiation and Withdrawal from Dialysis”), if an agreement cannot be reached, then a “timed trial” can be negotiated (13). The trial is conducted for an agreed-upon time. Agreed-upon measures of the desired goals and outcomes of the trial are collected from both sides before and after the trial. Then the parties reassess whether the trial achieved their desired goals. If the trial did not achieve the goals or outcomes, most people will be willing to consider the other side’s proposals. Wertheim *et al.* (19) have developed an approach to conflict resolution that may also be helpful in the dialysis facility setting but is beyond the scope of this discussion.

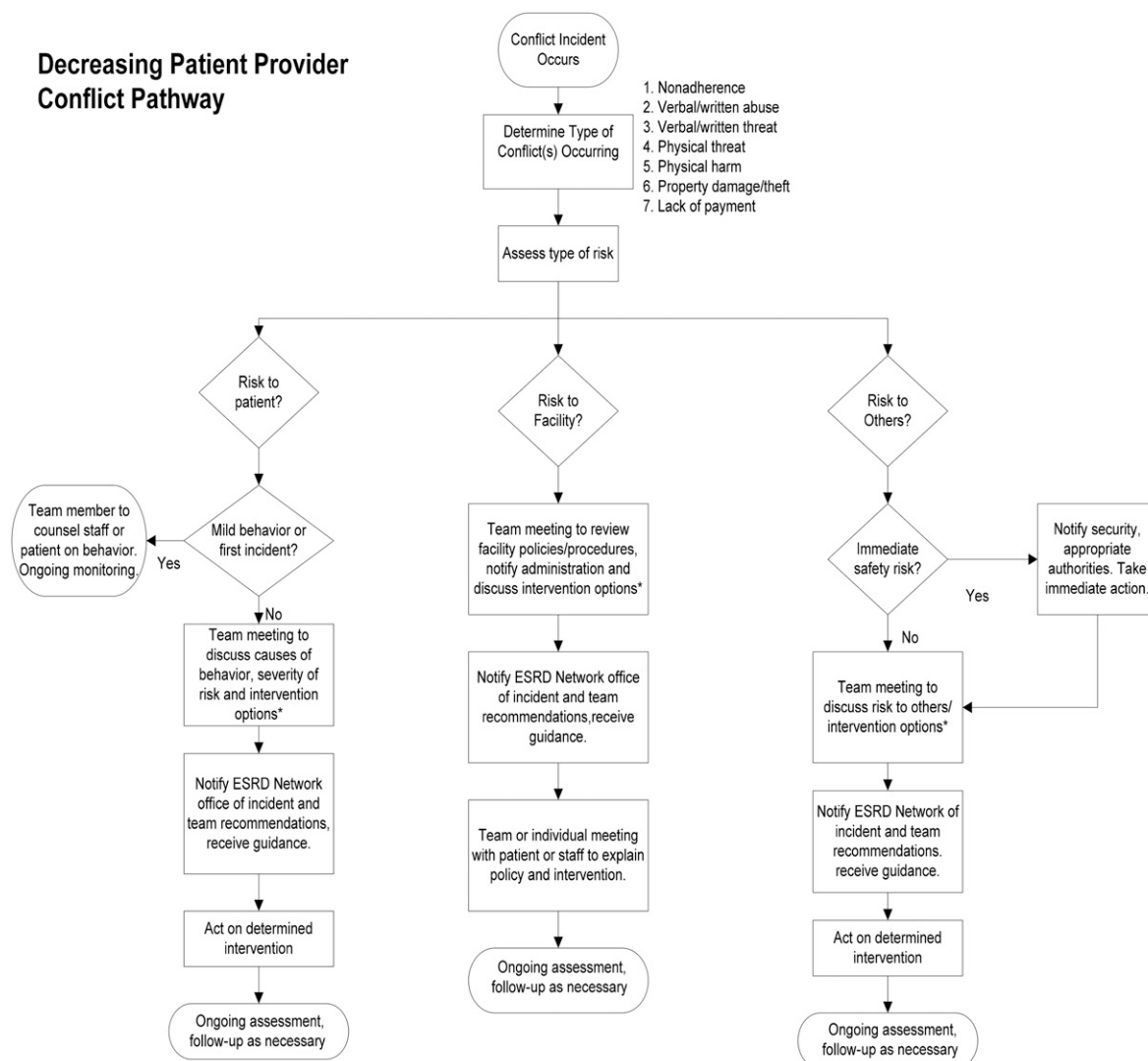
In the past, dialysis facilities used behavioral contracts to enforce solutions to disruptive behavior. If this tool is a sincere effort to formalize an agreement beneficial to both sides and with consequences to both sides in the event of failure, then the tool may be helpful, at least providing a written record of a mutually agreed-upon solution. If, however, it is merely a prelude to an IVD or IVT, CMS and the ESRD Networks promptly discount the value of the contract, seeing it for what it really is: an attempt to protect the facility from any negative legal or regulatory consequences.

IVDs and IVTs increased by 13% from 2010 to 2011 (20), with an estimated increase of 11% from 2011 to 2012 (Dialysis Annual Report 2014, currently in draft form). Six of 18 ESRD Networks reported  $\leq 20$  IVDs from 2010 to 2011 (20). IVDs and IVTs are the least satisfactory resolutions for patient-manifested disruptive behavior because they compromise continuity of care and frequently increase morbidity and mortality. CMS and ESRD Networks carefully review the process that leads to every IVD or IVT. If any CfC requirements are omitted, the facility can expect more Network involvement and even financial sanctions.

The CfC regulations allow for only four reasons for IVD or IVT: (1) A patient fails to pay (*e.g.*, keeping insurance payments intended for the facility); (2) the facility ceases to operate; (3) a transfer is necessary for the patient’s welfare



## Decreasing Patient Provider Conflict Pathway



\* Intervention options: Rule out any metabolic causes for behavior, then consider patient/staff counseling, patient/staff education patient/family meetings including review of care plan, review of policies/procedures, ethics committee review, patient psychiatric evaluation referral and treatment, patient behavior contract, patient dismissal/discharge or staff suspension or termination only if other interventions have failed or there is an immediate safety risk or harmful environment (no patient dismissal if the risk of the behavior does not affect others and is only a risk to the patient).

**Figure 1. | Algorithm for resolving disruptive behavior.**

because the facility can no longer meet the patient's medical needs; and (4) the facility has reassessed the patient and determined that the patient's behavior is so disruptive that the delivery of high-quality and safe care to the individual or the ability of the facility to operate effectively is seriously impaired. The important terms for the fourth reason are "reassessed" and "seriously impaired." The facility must have documented repeated attempts to solve the problem before IVD or IVT. The threat to the facility must be significant and imminent, not merely hypothetical. IVD must be in complete accordance with CfC §494.180 (1). The regulations require the following: (1) notification of the ESRD Network, (2) completion of a comprehensive reassessment and revision of the plan of care intended to resolve the problem before IVD or IVT, (3) documentation that includes

the ongoing problems, and the effect of the behavior on others and the facility, (4) documentation of the steps taken to resolve the conflict, and (5) documentation of the patient's response to steps taken.

The facility must obtain written orders for IVD or IVT of the patient, signed by the attending physician *and* the medical director. The patient must be given at least 30 days' notice of the impending IVD or IVT. A termination letter can be sent by certified mail to the patient. The facility (preferably the medical director) must contact other facilities to try to place the patient without trying to "blacklist" the patient. Although the facility should give the patient a list of facilities to contact, many believe the medical directors should contact other medical directors, requesting transfer of the patient. In this way, the "transferring" medical director can assure that

Table 1. Examples of disruptive behavior in patients
Arriving late for scheduled appointments and signing off early Failing to keep scheduled dialysis appointments Nonadherence to treatment prescription particularly if it significantly effects others Making false allegations against staff Threatening language or actions Refusing needle placement Presenting for treatment with firearms

Table 2. Decreasing CONFLICT
Create a calm environment Open yourself to understanding others Need a nonjudgmental approach Focus on the issue Look for solutions Implement agreement Continue to communicate Take another look

reciprocation will be carefully and sincerely considered in the future. The facility should also transfer the patient’s medical records within 72 hours. The facility must notify the regional ESRD Network and the state agency.

There are two circumstances in which the dialysis facility *must* involuntarily discharge or transfer a patient. First, if the attending nephrology clinician refuses to provide care to the patient and the facility cannot find an adequate replacement, the facility must discharge or transfer the patient. A facility may not provide care to a patient without an attending clinician. If an attending clinician refuses to provide care, the clinician must avoid “medical abandonment” (as codified in tort law) by informing the patient he or she will no longer be providing care after a “reasonable” period and making a “reasonable” attempt to place the patient into another clinician’s care. The Court defines “reasonable” as what a “reasonable person” would do given the same set of circumstances. The second reason for expedited IVD is when the disruptive behavior results in a clear, serious, and imminent threat to the physical safety of others. In this case, the DPC and ESRD

Networks recommend that the facility immediately notify law-enforcement authorities, who are equipped to safely remove the threatening patient from the facility.

**Disruptive Behavior by Physicians**

As previously noted, discussions regarding physician disruptive behavior seem lacking in the nephrology literature. However, the general medical literature examines this source of aberrant behavior (5,6,8,9,11) and associates it with medical errors, poor patient satisfaction, preventable negative patient outcomes, increased staff turnover, higher costs, and malpractice claims (10,21). Consequently, The Joint Commission (JC) and the American Medical Association (AMA) have developed several recommendations and interventions concerning physicians exhibiting disruptive behavior (15,16,22). The JC has created physician leadership standards, including a code of conduct defining disruptive behavior and a process for managing such behavior (22,23). The AMA has published “The Actions and Activities Reflective of Disruptive Behavior,” provided in Table 3 (15,16). These actions and activities apply to nephrologists as well (see Table 4). The JC published a Sentinel Event Alert (21) recognizing disruptive behavior as a threat to the performance of the health care team and maintenance of a culture of safety (11,12).

Published survey results from nondialysis health care employees note varying incidence and prevalence rates of professional disruptive behavior (24,25). An informal email survey of dialysis facility clinical managers in one author’s area suggests that physician disruptive behaviors, as listed in Table 3, are not rare. There are no data on dialysis practitioners. In the general medical community, one Midwestern hospital of 400 beds noted that they incurred a \$1 million dollar loss due to physician disruptive behavior (*i.e.*, medication errors and staffing turnover) (9,10,21). In another hospital, a poll of 840 physicians executives noted that 18.2% of the types of physician disruptive behavior described in Table 4 occur at least monthly (6). Although some survey participants opined that the behavior was a product of the work environment (*e.g.*, fatigue, stress, and being overworked), none of these factors justifies physician disruptive behavior or mitigates the consequences.

Table 3 lists some examples of disruptive behaviors exhibited by nephrologists. Several behaviors can be

Table 3. Examples of disruptive behaviors in nephrologists	
Condescending and abusive language Not returning phone calls in a timely fashion Not responding to medical director inquiries Constantly refusing to follow established protocols The medical director is late for QAPI meetings Physical abuse Fraudulent billing Solicitation of patients Repetitively not fulfilling attestation issues ( <i>e.g.</i> , signing of CMS 2728 attestation form ) Placing financial needs ahead of patients needs	Lack of participation in interdisciplinary rounds Noncompliance with patient visits Not fulfilling roles and responsibilities Refusing to participate in facility programs Cherry-picking patients Substance abuse and impairment Initiating dialysis inappropriately Bad-mouthing employees and facility Insulting, intimidating, or demeaning patients, family members, staff, colleagues or facility Throwing objects/anger management
QAPI, Quality Assurance and Performance Improvement; CMS, Centers for Medicare & Medicaid Services.	

**Table 4. Actions and activities reflective of disruptive behavior****Overt actions**

Verbal outbursts and physical threats

**Passive activities**

Refusing to perform assigned tasks or following by laws

Quietly exhibiting uncooperative attitudes during routine activities

Refuses to fulfill roles and responsibilities or achieving efforts to maximize outcomes

Reluctance or refusal to answer questions or return phone calls or pages

Condescending language or voice intonation

Impatience with questions

Refusing to follow policies

Adapted from American Medical Association Code of Ethics, December 2000 (16).

\*Drawn from author's experience and publications (4,5)

combined under the heading of demeaning staff, colleagues, patients, or family members. Physicians who demean, ignore, or intimidate staff or patients implicitly discourage repeat contact from those patients and staff, probably resulting in decreased safety surveillance, fewer notifications of acute or chronic changes in health status, fewer opportunities for collaborative problem-solving, and increased nonadherence to medical advice. Some behaviors noted in Table 3 (e.g., not signing the CMS 2728 attestation form or refusing to participate in facility quality of care programs) place the facility at risk for charges of "fraud" or noncompliance with government regulations, either of which disrupts the facility's ability to provide a safe and high-quality of care environment. Other behaviors, such as physical abuse, impairment, and solicitations of patients, are more easily identified as disruptive.

Consequent to the untoward, *sub rosa* consequences of disruptive physician behavior, and the mandates of the CFC, medical directors must intervene when they encounter this behavior (11,12). A facility's written policies, procedures, and credentialing by-laws should provide explicit directions for dealing with physician disruptive behavior by the medical director and the governing body. Unfortunately, physician disruptive behavior frequently goes unreported because of tolerance and indifference (23). In the

authors' experience, when dialysis staff or patients are subjected to abusive physician behavior, the staff and patients under-report the occurrences as a result of retaliation. At the facility level, the fear of retaliation often takes the form of threats that offending nephrologists will take "their patients" elsewhere. Although this has not been studied, we believe that physicians who habitually manifest disruptive behavior ultimately cause diminished patient quality outcomes, patient safety, and patient and staff satisfaction. Medical directors and dialysis providers must not yield to such threats, and, if they do, will share responsibility for the negative consequences.

**Interventions for Disruptive Behavior in Physicians**

The medical director is responsible for leading conflict resolution, particularly when it involves physician disruptive behavior. The governing body of the facility assures effective and timely implementation of facility policies and procedures. If a physician feels he or she has been unjustly accused of disruptive behavior, the physician should have easy access to the credentialing by-laws and a clear grievance and remediation process. If the medical director exhibits disruptive behavior (Table 3), the facility manager or nurse manager must engage supervisors and the governing body to resolve the issues. Many of the same interventions used to resolve disruptive behavior by patients can also be applied to disruptive behavior by physicians. Principles of resolving conflict noted above and in Table 2 and Figure 1 can be implemented, where applicable. Table 5 lists additional interventions for physicians who exhibit disruptive behavior.

**A New, "Old" Intervention for Correcting Aberrant Behavior in a Medical Context**

The Information, Motivation, and Behavioral Skills model, a relatively old intervention for changing behavior, is receiving increased attention in the medical literature. The model has proven effective at improving behavior in various countries and various diseases (26–28). Physicians, nurses, and social workers trained in the use of the model can apply it one-on-one, in peer groups, by telephone, or by video conference. Research demonstrates that the model is substantially more successful at changing aberrant health-related behavior (e.g., HIV risk reduction) and improving physiologic variables (e.g., BP, weight, glucose control, cholesterol) than is merely providing knowledge

**Table 5. Suggested interventions for physicians exhibiting disruptive behavior**

1. Engage the physician one-on-one with data and examples of the behavior; keep the discussion focused on the behavior and try to avoid personality conflicts (7)
2. Refer to and make available the credentialing by-laws of the facility, including issues of due process
3. Consider and exclude potential medical reasons, including depression and drug dependence
4. If necessary, engage all who may oversee the functioning of the medical director, such as the governing body, company medical advisory board, chief medical officer and dialysis organization's legal department
5. Suspend or terminate recalcitrant physicians. Dialysis providers must be vigilant and firm in this regard, even if it means the transfer of patients. The facilities' quality of care must take precedence.
6. If necessary, report the disruptive behavior to the state medical society. This allows the medical society to adjudicate the appropriateness of the complaints and to recommend or mandate actions.

and motivation about changing behavior (29). To information concerning what has to change and motivation for why it has to change, the model adds instruction concerning the behavioral skills necessary to actually change the aberrant behavior. To our knowledge, this program has never been applied to dialysis-related disruptive behavior, but it is reasonable to expect it would be as effective in this venue as in any other aspect of health care.

## Conclusion

Disruptive behavior by any member of the renal care team impedes providing high-quality care. The medical literature describes disruptive behavior exhibited by patients, and many resources are available to deal with these occurrences. However, physician-exhibited disruptive behavior in the dialysis facility has been under-appreciated despite the likelihood that the behavior compromises the delivery of safe and effective quality care. Medical directors are responsible for all care delivered in the dialysis facility, in particular for the delivery of high-quality care. Thus, dealing with disruptive behavior regardless of the source is the responsibility of the medical director.

## Disclosures

E.R.J. provides consulting services to Fresenius Medical Care, Physician Choice Management and Reliant Renal Care. He is a board member of Cytosorbent. He is a counselor to the Renal Physician Services.

## References

1. Conditions for Coverage for End-Stage Renal Disease Facilities: Final Rule Available at: <http://www.cms.hhs.gov/CFCSSsAndCoPs/downloads/ESRDfinalrule0415.pdf> Accessed April 15, 2008
2. Renal Physicians Association. Available at: <http://www.renalmd.org>. Accessed May 14, 2014
3. National Forum of ESRD Networks: Download the resource toolkits. Available at: <http://esrdnetworks.org/mac-toolkits>. Accessed May 5, 2014
4. Gutman RA: Medial direction of dialysis—a critical leadership role. *Semin Dial* 20: 258, 2000
5. Physicians with Disruptive Behavior: CEJA Report 2-A-2000. Available at: <http://www.ama-assn.org/ama/pub-physician-resources/medical-ethics.page>. Accessed May 24, 2014
6. Weber DO: Poll results: Doctors' disruptive behavior disturbs physician leaders. *Physician Exec* 30: 6–14, 2004
7. Goldman RS: Medical director responsibilities regarding disruptive behavior in the dialysis center—leading effective conflict resolution. *Semin Dial* 21: 245–249, 2008
8. Manthous CA, Ivy M: Commentary: Disruptive physicians. *Am J Med Qual* 27: 258–260, 2012
9. Rosenstein AH, O'Daniel M: Disruptive behavior and clinical outcomes: perceptions of nurses and physicians. *Am J Nurs* 105: 54–64, quiz 64–65, 2005
10. Rawson JV, Thompson N, Sostre G, Deitte L: The cost of disruptive and unprofessional behaviors in health care. *Acad Radiol* 20: 1074–1076, 2013
11. Gluck PA: Physician leadership: Essential in creating a culture of safety. *Clin Obstet Gynecol* 53: 473–481, 2010
12. Morales M: Building a strong culture of safety in dialysis. *Renal Business Today* November: 28–30, 2013
13. Renal Physicians Association: Shared decision making in the appropriate initiation of and withdrawal from dialysis, 2nd Edition. Available at: <http://www.renalmd.org/catalogue-item.aspx?id=682&terms=shared+decision>. Accessed September 12, 2014
14. ESRD Networks: Decreasing Dialysis Patient-Provider Conflict (DPC). Available at: [http://www.esrdnetworks.org/special-projects/copy\\_of\\_DPPCProviderManual.pdf](http://www.esrdnetworks.org/special-projects/copy_of_DPPCProviderManual.pdf). Accessed May 10, 2014
15. American Medical Association: Opinion 9.045: Physicians with disruptive behavior. December 2000. Available at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9045.page>. Accessed May 3, 2014
16. American Medical Association: Principles of Medical Ethics. Revised June 2001. Available at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.page>. Accessed May 10, 2014
17. The Renal Network: Dialysis by available slot: Recommended guidelines. Available at: [http://www.therenalnetwork.org/services/resources/AdherenceToolkit/Dialysis\\_by\\_slot.pdf](http://www.therenalnetwork.org/services/resources/AdherenceToolkit/Dialysis_by_slot.pdf). Accessed May 10, 2014
18. Kimmel PL, Peterson RA, Weihs KL, Simmens SJ, Boyle DH, Verme D, Umana WO, Veis JH, Alleyne S, Cruz I: Behavioral compliance with dialysis prescription in hemodialysis patients. *J Am Soc Nephrol* 5: 1826–1834, 1995
19. Wertheim E, Love A, Peck C, Littlefield L: Skills for Resolving Conflicts, Eruditions Press, Melbourne, 2006
20. Donato-Moore S: Self cannulation for home hemodialysis: strategies for success. *Nephrol Nurs J* 40: 37–40, quiz 41, 2013
21. Institute for Safe Medical Practices: Results from ISMP Survey on Workplace Intimidation. Available at: <https://ismp.org/Survey/surveyresults/Survey0311.asp> Accessed May 10, 2014
22. Gray RW: Disruptive behavior now a sentinel event: pt. II. *Tenn Med* 102: 30, 2009
23. Keogh T, Martin W: Managing unmanageable physicians: Leadership, stewardship and disruptive behavior. *Physician Exec* 30: 18–22, 2004
24. Rosenstein AH, Naylor B: Incidence and impact of physician and nurse disruptive behaviors in the emergency department. *J Emerg Med* 43: 139–148, 2012
25. Rosenstein AH, O'Daniel M: Disruptive behavior and clinical outcomes: Perceptions of nurses and physicians. *Am J Nurs* 105: 54–64, quiz 64–65, 2005
26. Mayberry LS, Osborn CY: Empirical validation of the information-motivation-behavioral skills model of diabetes medication adherence: A framework for intervention. *Diabetes Care* 37: 1246–1253, 2014
27. Starace F, Massa A, Amico KR, Fisher JD: Adherence to anti-retroviral therapy: An empirical test of the information-motivation-behavioral skills model. *Health Psychol* 25: 153–162, 2006
28. Gao J, Wang J, Zhu Y, Yu J: Validation of an information-motivation-behavioral skills model of self-care among Chinese adults with type 2 diabetes. *BMC Public Health* 13: 100, 2013
29. Mazzuca SA: Does patient education in chronic disease have therapeutic value? *J Chronic Dis* 35: 521–529, 1982

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

## Legal Issues for the Medical Director

William G. Trulove

### Abstract

The nephrologist serving as medical director of a dialysis clinic must understand that the role of director is not simply an extension of being a good nephrologist. The two roles—nephrology practice and the leadership of a dialysis clinic—may be filled by a single person. However, each role contains unique tasks, requiring specific skill sets, and each role comes with inherent, associated legal risks. The medical director assumes a new level of responsibility and accountability defined by contractual obligations to the dialysis provider and by state and federal regulations. Hence, a medical director is accountable not only for providing standard-of-care treatment to his or her private practice patients dialyzed at the clinic but also for maintaining the safety of the dialysis clinic patient population and staff. Accordingly, a nephrologist serving in the role of medical director faces distinct legal risks beyond typical professional liability concerns. The medical director must also be mindful of regulatory compliance, unique avenues to licensure board complaints, and implications of careless communication habits. A thoughtful and prepared medical director can mitigate these risk exposures by understanding the sources of these challenges: contractual obligations, pertinent regulatory responsibilities, and the modern electronic communications environment.

*Clin J Am Soc Nephrol* 10: 1651–1655, 2015. doi: 10.2215/CJN.06440614

DaVita HealthCare Partners Inc.,  
Kingwood, Texas

**Correspondence:**  
William G. Trulove,  
DaVita HealthCare Partners Inc., 600  
Rockmead Drive,  
Suite 211, Kingwood,  
TX 77339. Email:  
william.trulove@  
davita.com

### Introduction

For the nephrologist serving as medical director of an outpatient long-term dialysis clinic, the additional director responsibilities are of a different scale and scope than those of an attending physician. While the attending nephrologist role and the medical director role share a focus on clinical excellence, the medical director role confronts often underappreciated legal risks as one person effectively undertakes these two distinct and specific roles. The medical director faces novel legal risks for professional liability, regulatory compliance, licensure board complaints, and careless communication habits. However, a more thoughtful understanding of the distinct obligations and potential legal risks, as presented here in brief, may help the medical director avoid unnecessary stress and minimize the chances of legal entanglements.

The practice of nephrology rightly requires focus on clinical excellence. Practicing nephrologists are accustomed to frontline care for their patients, both providing appropriate, standard-of-care treatment and reviewing health outcomes. Keeping apprised of peer-reviewed literature and medical research in the field is also familiar to the working nephrologist, who often becomes a medical information resource for staff members and colleagues in other specialties. When serving patients with chronic kidney failure, nephrologists often find themselves in the practical circumstance of coordinating care among multiple comorbidities. For most patients with ESRD, loss of kidney function is not the primary disease process. The practicing nephrologist understands, as do physician specialists, that professional liability risk exposures are best mitigated by providing appropriate standard-of-care treatments and

properly maintaining local, state, and federal credentialing or licensure.

Some nephrologists are presented with the opportunity to serve as a medical director at some point in their career. This most often takes the form of a leadership role in the outpatient, long-term dialysis clinic environment. All medical directors are credentialed nephrologists who, practically speaking, treat at least some of their dialysis patients at the clinic where he or she is the director. The “attending” role, as care coordinator and primary prescriber for patients with CKD and ESRD in private practice, is familiar from experience, but many nephrologists are less familiar with the new responsibilities imposed by their medical director role.

The medical director role encompasses specific, clinical oversight functions that are neither identical nor coequal to the role of attending nephrologist. In short, the medical director assumes additional oversight accountability for the entire patient population of the dialysis facility, a distinction sometimes opaque even to those with long, successful private practices.

This additional accountability is most prescriptively defined by the Centers for Medicare & Medicaid Services (CMS) Conditions for Coverage because every patient with ESRD is or will be a Medicare beneficiary and therefore within the purview of the Conditions for Coverage. Further, medical directors also undertake defined duties under the contract, or medical director agreement, with the dialysis provider (1). In day-to-day terms, these obligations are personified by the facility governing body. A medical director is in the unique position of serving as clinical head of the dialysis facility governing body (including facility administrator, clinical nurse manager, dietitian, social worker, and other

staff members who are responsible for dialysis facility quality and safety) and also accountable to it. Finally, the medical director is accountable by regulation to federal and state agencies (e.g., state surveyors) that enforce the CMS Conditions for Coverage and, in some locales, state-specific regulations. Accordingly, the medical director's professional purview extends to safety of the facility as a whole, including patient outcomes, staff training, documentation, and quality of care. This includes oversight of other attending nephrologists seeing patients in the clinic, who may be unaffiliated with the medical director's private nephrology practice. With these more expansive obligations in mind, let's examine the areas of legal navigation for the medical director.

### Professional Liability

"Professional liability" is another way of saying "medical malpractice." Professional liability is a function of state law, and most physicians have a basic familiarity with this legal risk in their professional lives. While substantive law and procedural rules vary from state to state (2), the general framework for professional liability is a civil lawsuit or claim in which the plaintiff alleges that the medical practitioner was negligent. For purposes of this discussion, "negligence" is defined loosely as "failure to exercise ordinary care" or failing to act within the "standard of ordinary care." Ordinary care in turn can be roughly expressed as "doing that which a reasonable and prudent nephrologist (or other specialty) would do under the same or similar circumstances." Professional or medical malpractice lawsuits are usually conducted in state courts and the core anatomy of a professional liability claim is fairly standard: a plaintiff will seek to establish three elements—negligence, proximate cause, and damages (economic or noneconomic)—in order to recover compensation. Many states' laws require the first two elements be established by expert testimony; the plaintiff's attorney will retain an expert (e.g., another nephrologist) to opine on those issues.

Generally speaking, nephrologists are not sued as commonly as physicians in other specialties, such as obstetrics. From the point of view of a plaintiff's attorney, who essentially pursues a given claim with the hope of a future return in the form of a monetary damages award or settlement, nephrology malpractice claims represent comparatively complex legal cases because they often involve patients with multiple comorbidities. Therefore, even if successful, these claims may have a low or capped damages value. To illustrate, economic damages (e.g., lost income) are rarely pursued because patients with ESRD are older and either disabled or retired from the work force.

One way to overcome the "low damages potential" reality for a lawyer in the business of pursuing malpractice litigation is to consider alternative theories of recovery beyond the usual malpractice question (i.e., "Did the physician fail to comply with the standard of care in treating a particular patient?"). In this regard, a medical director role offers opportunity to the legal opponent. Our hypothetical plaintiff's attorney can consider other avenues of liability in order to "take two bites at the apple" (sue the same physician on multiple theories of recovery) or to add defendants (sue the medical director, attending physician, or dialysis provider). Allegations against a medical director might include

those based on any deficiencies in clinic-wide quality (e.g., outcomes), safety (e.g., infection control), compliance with policies and procedures, training or education, or patients' rights. The argument will be that the medical director was negligent in his or her distinct role, separate and apart from any direct care issues. In states where state survey Statements of Deficiency are public record, for example, regulatory survey history can be used as an evidentiary source to argue negligence in the form of departure from the minimum requirements imposed by the CMS Conditions for Coverage.

Most practicing physicians, naturally including nephrologists, carry professional liability insurance, which will respond to and defend against medical negligence claims and also pay any indemnity payment up to the limits of the policy. Medical directors will want clarity, with both their professional malpractice carrier and the dialysis provider (through the terms of the medical director agreement), as to what coverage (theirs and/or the dialysis provider's) would respond to alleged acts or omissions sounding specifically in the medical director role.

In this landscape of legal liability, it may appear that the medical director and the dialysis provider are in competition for protecting themselves individually. In reality, accountability is shared between the medical director and dialysis provider in order to mitigate liability exposure and meet the standard of care for patient treatment. For example, in the typical arrangement, the provider underwrites liability by carrying insurance for the dialysis facility staff and by contracting or self-insuring for the administrative duties of the medical director, while the medical director as nephrologist maintains his or her personal malpractice insurance for the practice of medicine. In this example, the providers and physicians collaboratively discharge shared accountability as the provider hires and insures qualified staff and the medical director regularly reviews and approves staff competencies, skills, and professionalism. The medical director can build goodwill and rapport by fulfilling all points of the director contract and fully engaging the work of the governing body (i.e., patient safety and quality of care) where the provider is broadly represented by the facility administrator, clinical nurse manager, dietitian, and social worker. Fundamentally, for the medical director and the dialysis provider, professional engagement should not be driven by crisis management but rather should be a longstanding working relationship with both parties fully invested. Then, when legal risk exposures are incident, shared accountability is best managed.

### Regulatory Liability—Conditions for Coverage

In assuming the medical director role, a nephrologist agrees to abide by two basic commitments: to the dialysis provider organization contract (through the medical director agreement) and to federal (and in some geographic locations, state) regulations. The medical director role typically is initiated as a contractual agreement between the nephrologist and a dialysis provider organization. The contract language defines the roles and responsibilities of the medical director vis-à-vis the contracting provider. Typical provisions speak to compliance with the dialysis provider's policies and procedures, quality assurance processes, peer review processes, clinical oversight for the facility, and compliance with laws and regulations.

A medical director is accountable for compliance with federal regulation, most immediately expressed by the CMS Conditions for Coverage. As a practical matter, all patients with ESRD receiving dialysis are or will become Medicare beneficiaries (3), and kidney disease represents a disproportionately large section of the Medicare budget (4). Therefore, the federal government highly regulates the dialysis industry. The CMS Conditions for Coverage define regulatory standards that health care organizations must meet to participate in the Medicare and Medicaid programs. These regulations define regulatory policy for general provisions, patient safety, patient care, and clinic administration. In the realm of ESRD, the Conditions for Coverage extensively define the medical director's roles and responsibilities, giving global responsibility to the medical director for the dialysis patient population safety, the facility staff safety and training, and clinical oversight for all patients in the facility, including those attended by other nephrologists credentialed in the facility. The primary enforcement process for evaluation of compliance is the state/CMS survey, which is an audit of the dialysis clinic. Through this method, state or CMS surveyors evaluate and document a clinic's degree of compliance with federal regulations. A section of these surveys specifically evaluates the medical director's defined roles and responsibilities, and the physician in that role can be held accountable (as part of his or her oversight function) for any general clinic noncompliance and any personal noncompliance (5).

### Regulatory Liability—Privacy

While the Conditions for Coverage most directly affect the medical director's day-to-day responsibilities, there is another regulatory source worthy of mention in this context. "Covered entities" are obligated to safeguard patients' protected health information (PHI). Before 2009, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 was the primary federal regulation for protecting the privacy of individually identifiable health information (6). In 2009, HIPAA was amended and expanded by the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was part of the American Recovery and Reinvestment Act signed into law that year (7). As a result of HITECH, the Office of Civil Rights inside the US Department of Health and Human Services was authorized to enforce the privacy and security rule, and penalties for noncompliance were increased (8,9). While many dialysis providers take the laboring oar to implement sophisticated technical, policy, training, and audit solutions to comply with HIPAA/HITECH, it is prudent for the medical director to understand the obligations imposed upon him or her as a "covered entity" (10). Many continuing medical education courses are available to physicians on patient privacy regulations, and this is an extensive, constantly evolving area of the law. Full treatment of this topic is beyond the scope of this article, and readers are encouraged to avail themselves of continuing medical education resources. However, as discussed below regarding communication habits, today's technology platforms provide ample opportunity to run afoul of HIPAA/HITECH.

### Licensure Boards

Complaints against licensure are another consideration of which the prudent medical director should be mindful (11). Like professional malpractice, this is a risk area originating at the state, rather than federal, level. Although each state medical licensure board's regulatory scheme is unique, all have a similar, basic function: to control entry into and police the medical profession in the given state. As a matter of public policy, most state medical boards have patient complaint mechanisms in place. Furthermore, these mechanisms are designed so that it is relatively easy for a patient, or any other member of the public, to register a complaint against a physician. Complaints can be anonymous. Even when complaints are not anonymous, the medical board may not reveal the identity of the person(s) making the complaint to the target physician, depending on the board's rules of procedure.

It can prove expensive and time consuming for the target physician to satisfactorily resolve a board complaint, even if it lacks merit. It is typical for a board inquiry to come to the physician's attention first with a letter from the medical board. It is unwise to ignore or procrastinate in reacting to an inquiry letter. There are deadlines for the practitioner to respond to board requests (*e.g.*, requests for records or narrative response to the complaint), and noncompliance can put the physician in a position of facing sanction for failing to cooperate or to respond to the inquiry itself, regardless of the underlying merits. It is wise to seek legal counsel immediately and avoid "going it alone." Fortunately, professional liability insurance policies will often include provisions for retaining counsel and responding to board inquiries. The prudent practitioner will have a good understanding of their coverage on this point ahead of such a contingency, however unlikely it may seem.

Complaints regarding the role of the nephrologist may come from any patient receiving treatment under the physician's license, and complaints regarding the role of the medical director may come from any patient treated at the dialysis clinic, even if a different nephrologist coordinated the patient's care. Furthermore, complaints against the medical director could encompass dialysis clinic-related issues, such as treatment, safety, or facility conditions. Patient grievances inside the facility can result in a complaint to the board. Good familiarity with grievance policies (most dialysis providers promulgate policy around grievance), active engagement with the renal networks, and aggressive resolution of patient grievances within the facility will help mitigate this risk substantially. The medical director is unwise to disengage from any patient grievance process, even if it does not involve the director's personal care (*e.g.*, a grievance related to an attending physician).

### Communications

A final area in which the unwary medical director may encounter traps is in electronic or online communication. Physicians can unintentionally use modern communication methods such as email, text messaging, instant messaging, and social media in ways that violate HIPAA/HITECH, contractual agreements, or confidentiality agreements or that stray past the boundaries of professionalism. While

this area of the law is extensive and evolving, the prudent medical director should observe some basic rules, particularly in the online and social media arenas:

- Assume and believe there is no anonymity online.
- Remember that personal opinions, carelessly expressed, can have professional consequences.
- Know that once the “post” or “send” button is clicked, the author has lost control of the content.
- Note that there is no predicting how a message or post can be repackaged or forwarded.
- Draft all online communication as though it will be public.
- Never betray a confidence or share PHI online.
- Do not “overshare” with patients or family members in an unprofessional manner. (If it isn’t appropriate in the clinical setting, it likely isn’t appropriate online.)
- Remember that most electronic communications platforms are not secure.
- Remember that social media platforms have extensive data-mining capabilities.
- Assume electronic communications, no matter how informal, will exist forever.

In 2010, the “Email Statistics Report” noted that roughly 25% of all email accounts belonged to corporate users who exchanged approximately 110 email messages daily (12). In this fast-paced environment of quickly exchanged information, physicians must understand that email communications are generally not secure and routinely are subject to discovery in litigation. For example, during the trial involving the diet drug Phen-Fen, several million corporate emails were produced as evidence. When emailing patients, physicians should consider the content of the email. Although emailing for administrative purposes (*e.g.*, appointment scheduling and notifications) presents relatively little risk, if PHI is included in the email content, then legal liability increases (9). For example, PHI breaches easily occur upon emailing a patient at a corporate email address or a personal email address that is accessible by another person (*e.g.*, unauthorized spouse or family members). Because of the uncertainty of the end viewer, it is advisable to exclude PHI from physician-patient electronic correspondence. Sophisticated providers design online portals and secure email communication systems in order to facilitate convenient patient communication in a secure environment. The same protections do not exist with the typical physician’s email account. The takeaway is that electronic communications are not an area in which to experiment or “take chances” if secure portal systems are not in place and administered by competent information technology professionals.

Social media use has exploded in recent years, with the creation of numerous social and professional platforms such as Facebook, YouTube, LinkedIn, Twitter, and Pinterest. Many physicians feel the desire or need to access these platforms as a branding or marketing exercise. In 2011, the American Medical Association adopted guidance titled “Professionalism in the Use of Social Media” (13). In this guidance, the American Medical Association encourages physicians to be mindful of patient privacy, monitor their own Internet presence, maintain appropriate patient-physician boundaries, encourage good Internet behavior from colleagues, and

recognize that online content can negatively affect individual careers or the medical profession.

The legal community has taken notice of this trend and is increasingly surveying social media for informal discovery (14–18). How can Internet use be exploited in a professional liability case? Each of the social media platforms builds a profile about the user with parameters such as location, behavior, and “likes” (19–23). Tweets and Facebook posts create timelines of activities and (incomplete) portraits of personal character. Thoughtless and unprofessional social or “party” Tweets or Facebook status updates can call into question the professional competence of the physician at that point in time. Embarrassing or incriminating photos, even if not posted by the physician, can bring unwelcome legal risk. Even physicians who are mindful of their own social media presence may find their image or words posted, without their knowledge, by another user. Accordingly, in this environment of instant sharing, even small gatherings should be treated as public spaces.

Social media use is not immune from litigation. Libel or defamation may be charged based on online comments that rate other sites or organizations or assert information as a fact (24,25). To illustrate, calling someone a “jerk” and a “buffoon” may be safe from a lawsuit because it states an opinion. However, saying someone wrongly “pocketed” money could lead to a defamation claim because it asserts something as a fact. Under federal law, websites generally are not liable for comments posted by outsiders. Websites can, however, be forced to reveal the poster’s identity if the post includes false information presented as fact.

In addition, physicians and medical directors must guard against creating online physician-patient or treatment relationships. Not only is this type of relationship inappropriate and unethical, but it also easily allows for PHI breaches and imposition of professional liability. Finally, a medical director, as a dialysis clinic leader, must consider the implications of “friending” or otherwise signifying online relationships with patients, family members, employees, or clinic staff. This can lead to appearances of favoritism or unprofessional demeanor, affecting safety or quality in the facility.

## Conclusions

Assuming the role of medical director involves widening the professional gaze from providing care for a particular patient to overseeing the overall safety of the patient population and staff in the dialysis facility. It is critical for medical directors to understand that their role is not simply an extension of their nephrology practice. Rather, the medical director assumes a new level of responsibility and accountability principally defined by CMS Conditions for Coverage and contractual obligations to the dialysis provider. As such, the medical director uniquely faces legal risks in both roles—nephrologist and medical director. Understanding the expectations of the government regulators and the contracted provider are cornerstones of serving competently, leading the clinical team, and minimizing risk exposure to professional malpractice claims or patient complaints to the licensing board. Common sense habits with electronic communications will similarly minimize exposure to attacks on professional credibility and keep clear boundaries between personal and professional life.



### Acknowledgments

The author is solely responsible for the concept, analysis, synthesis, and interpretation of the topic, and he contributed intellectual content and writing during manuscript drafting and revision. The author has full knowledge to provide final approval and accountability for all aspect of the work. For this publication, Christopher A. Graybill, of DaVita Clinical Research, provided medical writing assistance, including outlining and drafting some sections based on the author's notes, proofreading and copyediting some sections written by the author, and facilitating online manuscript submission. This manuscript is based on the oral presentation "Legal Issues for the Medical Director" delivered at the American Society of Nephrology Kidney Week 2013 (November 5–10, 2013, Atlanta, Georgia).

### Disclosures

W.G.T. is employed by DaVita HealthCare Partners, Inc.

### References

- Centers for Medicare & Medicaid Services: US Department of Health and Human Services: Medicare and Medicaid Programs; conditions for coverage for end-stage renal disease facilities. Final rule. *Fed Regist* 73: 20370–20484, 2008
- National Conference of State Legislatures: State Medical Malpractice Tort Laws. Available at: <http://www.ncsl.org/research/financial-services-and-commerce/medical-liability-medical-malpracticelaws.aspx>. Accessed June 27, 2014
- Centers for Medicare & Medicaid Services: US Department of Health and Human Services: Medicare program; end-stage renal disease prospective payment system, quality incentive program, and durable medical equipment, prosthetics, orthotics, and supplies. Final rule. *Fed Regist* 78: 72156–72253, 2013
- U.S. Renal Data System: *USRDS 2010 Annual Data Report: Atlas Of Chronic Kidney Disease and End-Stage Renal Disease in the United States*. Bethesda, MD, National Institute of Diabetes and Digestive and Kidney Diseases, 2010
- Centers for Medicare & Medicaid Services, *US Department of Health and Human Services: ESRD Core Survey Field Manual, version 1.6*
- Health Insurance Portability and Accountability Act of 1996. Pub L No 104-19. 1996
- Health Information Technology for Economic and Clinical Health Act. Title XIII or Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 Pub L No 111-5. 2009
- Murphy DF: HIPAA—a paper tiger no more? *AHLA Connections* March: 36–38, 2011
- Kobus TJ III, Sessions L: The anatomy of a healthcare data breach. *AHLA Connections* June: 38–41, 2012
- Esperne E: Risk management and HIPAA compliance for corporate counsel. *ACC Docket* June: 41–50, 2011
- Schillaci A: Physician discipline and licensure issues. *For the Defense* October 2011
- The Radicati Group: Email Statistics Report, 2010. Available at: <http://www.radicati.com/wp/wp-content/uploads/2010/04/Email-Statistics-Report-2010-2014-Executive-Summary2.pdf>. Accessed June 27, 2014
- American Medical Association: *Professionalism in the use of social media*. 2011. Available at: <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9124.page?>. Accessed June 27, 2014
- Laitinen SP, Loynes HJ: Social media: a new "must use" tool in litigation. *For the Defense* August: 16–21, 2010
- McNamee EJ, Magyar KS: Are you building a house of cards? Social networking in the office. *ACC Docket* September: 29–38, 2010
- Newman M, Isenath FC: Social networking in the workplace. *For the Defense* March: 57–60, 2010
- Henderson WC, McVay GC: Twittering the day away and potential legal pitfalls for employers. *ACC Docket* July/August: 88–97, 2010
- Information Risk Executive Council: IT Practice Survey. 2010. Available at: <https://www.irec.executiveboard.com/Public/Default.aspx>. Accessed June 15, 2014
- Angwin J, Stecklow S: 'Scrapers' dig deep for data on web. *The Wall Street Journal* October 12, 2010. Available at: <http://online.wsj.com/articles/SB10001424052748703358504575544381288117888>. Accessed October 13, 2010
- Boorman C: *Why data mining is the next frontier for social media marketing Mashable* February 25, 2011. Available at: <http://mashable.com/2011/02/25/data-mining-social-marketing/>. Accessed February 25, 2011
- Bosker B: *Facebook to share users' home addresses, phone numbers with external sites. Huffington Post* February 28, 2011. Available at: [http://www.huffingtonpost.com/2011/02/28/facebook-home-addresses-phone-numbers\\_n\\_829459.html](http://www.huffingtonpost.com/2011/02/28/facebook-home-addresses-phone-numbers_n_829459.html). Accessed March 4, 2011
- Mlot S: Facebook wants to add profile pics to facial-recognition tool. *PCMag* August 29, 2013. Available at: <http://www.pcmag.com/article2/0,2817,2423801,00.asp>. Accessed August 30, 2013
- Coffield RL, Joiner JE: Risky business: Tweeting the symptoms of social media. *AHLA Connections* March: 10–14, 2010
- Savage DG: Blogger beware: Postings can lead to lawsuits. *Los Angeles Times* August 23, 2010. Available at: <http://articles.latimes.com/2010/aug/23/nation/la-na-blogger-suits-20100823>. Accessed August 23, 2010
- Silverman RE: Facebook and Twitter postings cost CFO his job. *The Wall Street Journal* May 24, 2012. Available at: <http://online.wsj.com/articles/SB10001424052702303505504577404542168061590>. Accessed May 13, 2014

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).

## Medical Director Responsibilities to the ESRD Network

Peter B. DeOreo\* and Jay B. Wish†

### Abstract

The 18 regional ESRD Networks are established in legislation and contract with the Centers for Medicare and Medicaid Services to improve the quality and safety of dialysis, maximize patient rehabilitation, encourage collaboration among and between providers toward common quality goals, and improve the reliability and the use of data in pursuit of quality improvement. The Networks are funded by a \$0.50 per treatment fee deducted from the reimbursement to dialysis providers, and their deliverables are determined by a statement of work, which is updated in a new contract every 3 years. The Conditions for Coverage require dialysis providers to participate in Network activities, and failure to do so can be the basis for sanctions against the provider. However, the Networks attempt to foster a collegial relationship with dialysis facilities by offering tools, educational activities, and other resources to assist the facilities in meeting the evolving requirements by the Centers for Medicare and Medicaid Services on the basis of national aims and domains for quality improvement in health care that transcend the ESRD program. Because of his/her responsibility for implementing the quality assessment and performance improvement activities in the facility, the medical director has much to gain by actively participating in Network activities, especially those focused on quality, safety, patient grievance, patient engagement, and coordination of care. Membership on Network committees can also foster the professional growth of the medical director through participation in quality improvement activity development and implementation, authorship of articles in peer-reviewed journals, creation of educational tools and presentations, and application of Network-sponsored materials to improve patient outcomes, engagement, and satisfaction in the medical director's facility. The improvement of care of patients on dialysis will be beneficial to the facility in achieving its goals of quality, safety, and financial viability.

*Clin J Am Soc Nephrol* 10: 1852–1858, 2015. doi: 10.2215/CJN.05350514

\*Chief Medical Officer, Centers for Dialysis Care, Cleveland, Ohio; and †Department of Medicine, Division of Nephrology, Indiana University Health, Indianapolis, Indiana

**Correspondence:** Dr. Jay B. Wish, Division of Nephrology, Indiana University Health, 550 North University Boulevard, Suite 6100, Indianapolis, IN 46202. Email: jaywish@earthlink.net

### Introduction

The ESRD Networks were established in the original Medicare Conditions for Coverage (CfC) in 1972 (Part 405, subpart U section 405.2110). Although the Centers for Medicare and Medicaid Services (CMS; then the Health Care Financing Administration) reduced the number of Networks from 32 to 18 in 1987, their essential task has not changed. The Networks are independent contractors to CMS. Their deliverables are detailed in their statement of work (SOW); their contracts and SOW are updated every 3 years. The Networks are tasked to improve the quality and safety of dialysis, maximize patient rehabilitation, encourage collaboration among and between providers toward common quality goals, and improve the reliability and the use of data in pursuit of quality improvement (1,2). The dialysis facility's responsibilities to the Network are described in the interpretive guidance of the CfC (V772) as follows:

*Standard: Relationship with the ESRD Network.* The governing body receives and acts upon recommendations from the ESRD Network. The dialysis facility must cooperate with the ESRD Network designated for its geographic area in fulfilling the terms of the Network's current statement of work. Each facility must participate in ESRD Network activities and pursue Network goals (3).

Networks have the same task irrespective of their organizational structure. Some Network contracts are held by Quality Improvement Organizations (QIOs), and some are held by companies that have only ESRD Network contracts. QIOs and ESRD Networks-only companies may hold one or more of 18 CMS ESRD Networks contracts. CMS funds Networks' activity from a \$0.50 per treatment fee deducted from the monthly payment to dialysis providers. The current SOW of the ESRD Networks expects the Networks to "...serve as partners in quality improvement with beneficiaries, practitioners, health care providers, other healthcare organizations and other stakeholders" (1). Networks have three standing committees: patient advisory, medical review board (MRB), and patient grievance. They may have one or more subcommittees to manage the quality improvement activities (QIAs) of the MRB.

### Networks and Medical Directors as Partners in Improvement

Quality of care is defined as the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (4). Since the Institute of Medicine formulated that definition in 1990, current professional knowledge now encompasses specific aims, strategies, and principles pertinent

to health care in general and ESRD in particular. The Patient Protection and Affordable Care Act (PPACA; P.L. 111–148) (5) directed the Secretary of Health and Human Services to develop a “national strategy for quality improvement in healthcare” and establish priorities for accomplishing the triple aim of better care for patients, better care for populations, and cost reduction through quality improvement (6).

Table 1 matches the triple aim pertinent to ESRD and the domains of the quality improvement tasks of the

Networks as defined in the current SOW. Table 2 shows the priorities from the national quality strategy that support the Networks’ domains of quality. The national quality strategy has a set of core principles for actions and priorities. The fourth principle of the national quality strategy (not shown in Table 2, which lists the priorities) is to align “the efforts of public and private sectors” (7). The Networks, as contractors to CMS, are the agent of alignment in ESRD. Table 3 outlines the authority granted the

**Table 1. Aims and domains of the ESRD Network statement of work**

Aims/Domains	Subdomains
<p><b>Aim 1: Better care for the individual through beneficiary and family-centered care</b>                      Patient and family engagement</p> <p>Patient experience of care</p> <p>Patient-appropriate access to in-center dialysis care</p> <p>Vascular access management</p> <p>Patient safety: HAIs</p>	<p>Foster patient and family engagement at the facility level</p> <p>Involve patients/families in CMS meetings</p> <p>Convene patient engagement in LAN</p> <p>Evaluate and resolve grievances</p> <p>Promote use of ICH CAHPS and/or any similar survey identified by CMS</p> <p>Address issues identified through data analysis</p> <p>Decrease IVDs and IVTs</p> <p>Address patients at risk for IVD/IVT and failure to place</p> <p>Generate monthly access to dialysis care reports</p> <p>Improve arteriovenous fistula rates for prevalent patients</p> <p>Reduce catheter rates for prevalent patients</p> <p>Support facility vascular access reporting</p> <p>Spread best practices</p> <p>Provide technical support in the area of vascular access</p> <p>Recommend sanctions</p> <p>Support the NHSN</p> <p>Establish HAI LAN</p> <p>Reduce rates of dialysis facility events</p>
<p><b>Aim 2: Better health for the ESRD population</b>                      Population health innovation pilot project</p>	<p>Reduce identified disparity through projects</p> <p>Project A: Increase hepatitis B, influenza, and pneumococcal vaccination rates</p> <p>Project B: Improve dialysis care coordination with a focus on reducing hospital use</p> <p>Project C: Improve transplant coordination</p> <p>Project D: Promote appropriate home dialysis in qualified beneficiaries</p> <p>Project E: Support improvement in quality of life</p>
<p><b>Aim 3: Reduce costs of ESRD care by improving care</b>                      Support for ESRD QIP and performance improvement on QIP measures</p> <p>Support for facility data submission to CROWNWeb, NHSN, and/or other CMS-designated data collection system(s)</p>	<p>Assist facilities in understanding and complying with QIP processes and requirements</p> <p>Assist facilities in improving their performance on QIP measures</p> <p>Assist CMS in monitoring the quality of and access to dialysis care</p> <p>Assist beneficiaries and caregivers in understanding the QIP</p>

HAI, health care–acquired infection; QIP, Quality Incentive Program; CMS, the Centers for Medicare and Medicaid Services; LAN, Learning and Action Network; ICH CAHPS, in-center hemodialysis consumer assessment of healthcare providers and systems; IVD, involuntary discharge; IVT, involuntary transfer; NHSN, National Healthcare Safety Network.

**Table 2. National strategy for quality improvement in health care**

- (1) Making care safer by reducing harm caused in the delivery of care
- (2) Ensuring that every person and family are engaged as partners in their care
- (3) Promoting effective communication and coordination of care
- (4) Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease
- (5) Working with communities to promote wide use of best practices to enable healthy living
- (6) Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models

Networks by the federal regulations. The primary focus of Networks' activity is to represent, protect, and support the beneficiary (patient and family). The federal regulations make it possible for CMS to apply alternative sanctions (suspension of payment for services) to facilities that fail to participate in Networks' activities and cooperate with Networks' goals. The challenge for dialysis facilities is to comply with and participate in the Networks' quality and safety initiatives. The opportunity is to leverage the expertise and technical assistance available from the Networks to advance the facility quality and safety initiatives.

The federal regulations make the medical director the accountable person for the quality of service, safety, and care provided by the other members of the interdisciplinary team (IDT) and the medical staff (§494.150 [8], V710 [3]). In effect, the medical director has the same responsibilities for his or her dialysis facility that the Network has for the facilities under its supervision (9). That makes the Network a natural partner for the medical director. All 18 ESRD Networks' websites can be accessed through the National Forum of ESRD Networks' website ([www.esrdnetworks.org](http://www.esrdnetworks.org)). All Networks develop tools that can be used by medical directors to further their facility's culture of safety and quality. The medical director can bring the best professional knowledge to the IDT to inform the discussion and decision making. The medical director is able to develop medical staff consensus about care paths, medication choices, and goals for important clinical outcomes. He or she is able to bring members of the medical staff into the quality assessment and performance improvement (QAPI) process (10). The medical director is usually a member of the medical staffs of one or more of the hospitals where the facility's patients receive inpatient and outpatient services. His or her position on the hospital staffs allows participation in discussions relating to, for example, continuity of care, transfer of information, medication reconciliation, access placement, vein sparing, and elimination of peripherally inserted central catheter lines.

The language of the federal regulations focuses on the obligation of the governing body to the Network. The relationship of the medical director to the governing body clearly delegates that obligation to the medical director. Although the language is prescriptive with the threat of sanctions, the practical reality is that the relationship between the Network and the medical director (and IDT) can and should be collaborative and collegial. The medical director can and should participate in the activities of his or her ESRD Network and quality improvement committees of the MRB. The medical director likely spends much of his or her time working with and directing the facility QAPI team. CMS Quality Incentive Program (QIP) for the

performance/payment cycle of 2014/2016 includes measures of anemia, dialysis adequacy, mineral metabolism, vascular access, infection (National Health Safety Network [NHSN] reporting), and patient experience of care (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems). Although the industry is moving away from emphasis on laboratory measures to issues more centered on patient health-related quality of life, facilities have to be proficient in controlling these fundamental metrics before they move up the quality pyramid to more complex issues driving health-related quality of life (11).

The Networks are contractors for CMS. They are obligated to the aims and timelines in the SOW. The priorities established by CMS in the SOW and, consequently, levied on the facilities may not always be congruent with local, regional, or corporate priorities. Network QIAs may compete for staff time budgeted to other equally worthy projects. Some of these projects may require burdensome paper-based data collection, reporting, and other mandated facility actions. Ultimately, the Networks have little choice but to expect compliance from facilities, because the Networks' evaluations and contract renewals are performance based. Accordingly, each Network's response to the SOW goes through multiple revisions in the MRB. There is ample opportunity to modify, mitigate, and bring alignment between Networks' SOW and facility goals and objectives. The Medical Advisory Committee of the National Forum of ESRD Networks is comprised of all of the MRB chairpersons from the 18 Networks. It is another setting where such conflicts can be addressed.

It is a goal of value-based purchasing principles that there be more transparency and reporting of outcomes. The Dialysis Facility Compare website (<http://www.medicare.gov/Dialysis-FacilityCompare/search.html>) will soon include a five-star rating for dialysis facilities comparable with the one in place for nursing homes (<http://www.cms.gov/site-search/search-results.html?q=fives%20star>). Physicians are listed on the Physician Compare website (<http://www.medicare.gov/physiciancompare/search.html>). Some (but not all) of a facility's score by its Network for participation in QIAs is on the basis of the facility's performance in relation to a designated threshold. As such, QIAs can be seen as punitive. The goal of the QIA is to improve performance. Although this might be distressing to a facility and its medical director, it does provide a focused opportunity to improve the outcome and the report card.

Facilities are expected to bring their processes and outcomes in line with the triple aim and the national quality priorities. The Network is an obvious resource for the dialysis facility and medical director. Consider five categories of

**Table 3. Conditions and VTags (3) concerning Networks and dialysis providers**

42 CFR Section/Tag	Summary
§488.604(b)	Termination of Medicare coverage on the basis of the supplier’s failure to participate in Networks’ activities and pursue Networks’ goals (cf. §494.180); alternative sanctions
§494.60	
V416	Collaboration with ESRD Networks for disaster preparedness
§494.70	
V466	Patient informed of option to call ESRD Networks for grievances
V467	Patient free of fear of reprisal if grievance is filed
V470	Duty to post patient rights, including contact information for ESRD Networks
§494.100	
V585	Home patients provided with contact information and information about ESRD Networks
§494.110	
V628	QAPI team to consider data from external sources, including ESRD Networks
§494.170	
V728	Networks have the right to review medical records and take offsite if necessary
§494.180	
V750	Requires the governing body to have a signed agreement with and respond to requests from the ESRD Networks
V755	Summary of Networks’ SOW and the duty of the facility to cooperate and comply with Network requests within the SOW
V767	Give a 30-d notice to Network for planned involuntary discharge or immediate notice of abbreviated involuntary discharge procedure
V772	Defines governing body’s obligation to cooperate with Networks’ SOW

CFR, code of federal regulations; QAPI, quality assessment and performance improvement; SOW, statement of work.

activities in the domain of the QAPI team: quality, safety, patient grievance, patient engagement, and coordination of care.

**Domains for Improvement**

**Quality**

To assist in the fundamental QAPI process, a Network can provide consultation and assistance in problem solving in general or for specific problems. It can assist with formats, best practices, and references and provide onsite assistance (12). The QAPI program is to be data driven and use comparative national, Network, and state data to compare outcomes and establish benchmarks (§494.150 [8], V710 ff [3]). Performance feedback drives improvement in care (13). The Network is a source for comparative data through the Network Coordinating Center, its distribution of CROWNWeb data reports, and the results of Networks’ QIAs.

The role of CROWNWeb is evolving. The Networks are resources to assist the non-Large Dialysis Organizations (nonbatch-reporting facilities) in completing their data input. As the QIP moves from claims-based reporting to CROWNWeb data, the assistance of the Networks to the facilities will be increasingly important.

Since the initiation of the Fistula First Breakthrough Initiative (FFBI), the Networks gathered and disseminated data and best practices on catheter reduction and increasing arteriovenous fistula prevalence. The FFBI is an excellent example of the dramatic improvement in outcomes (increased arteriovenous fistula and decreased central venous catheter prevalence rates) that can occur when stakeholders, including CMS, the Networks, dialysis providers, professional organizations, and patients, collaborate to achieve a goal

that, several years ago, was thought to be unattainable (14). The FFBI website ([www.fistulafirst.org](http://www.fistulafirst.org)) and many individual Network websites provide tools for implementing the change concepts, tracking progress, and providing education to all stakeholders. Their current SOW gives Networks the responsibility for helping facilities understand and comply with the QIP and be successful in CROWNWeb data reporting. As the QIP evolves each year to decrease the weighting of laboratory-based indicators and increase the weighting of outcome-based indicators, such as infections, satisfaction, and hospitalization/rehospitalization, the Networks will have an important role in preparing providers for this transition.

The input of medical directors is critical to the development of the Networks’ quality agenda. Unlike individual nephrologists who may view quality on a patient-by-patient basis, their QAPI experience gives medical directors a population-based view of barriers and opportunities for improvement that may be generalizable to the geographic region. Using FFBI as an example, medical directors may offer the Networks insight into issues, such as predialysis care/education, referral patterns, and reimbursement, that transcend individual practices and offer high yield for intervention.

**Safety**

In the current Networks’ SOW, reducing health care-acquired infections is the safety topic. The QIP requires monthly reporting to the NHSN. The Networks can assist facilities in registering, organizing, and reporting events and using the resources on the NHSN website (15). At a more basic level of promoting safety and a facility culture of safety, the Networks developed and promulgated the 5 Diamond Patient Safety Program (5DPSP) (16). The 5DPSP is a modular curriculum that allows a facility to

implement an effective program to develop a culture of safety in small steps. Each of the modules advances an important concept of safety, such as infection control, immunization, hand hygiene, etc. The 5DPSP has been endorsed by the Renal Physicians Association (RPA), the American Nephrology Nurses Association, and the American Association of Kidney Patients, and the RPA encourages its members who are medical directors to participate. 5DPSP certification assists dialysis facilities in meeting patient safety requirements of state surveyors.

Every medical director must be the champion for patient safety at his/her facility and work with the Network to establish a safety culture. This includes advocating for participation in the 5DPSP certification program, putting safety issues high on the QAPI priority list, and participating in educational activities (offered by many Networks and professional organizations) to become an effective safety officer for the facility.

### Patient Grievances

Assisting patients in understanding their right to file a grievance, assuring that facilities make the process visible and credible, and demanding that patients are protected from reprisal are core functions of the Networks as defined in both the current SOW and CfC. The Network's standing patient grievance committee evaluates and investigates grievances to substantiate (or not) the patient's complaint. In either outcome, the Network will work with the patient and facility to suggest ways to ameliorate the situation. From the facility's perspective, the Network can be a resource to reduce patient-provider conflict before a patient feels inclined to file a grievance (17). The Decreasing Dialysis Patient-Provider Conflict (DPC) toolbox contains a DPC Provider Manual with an orientation and suggestions for staff training along with several training modules and quality improvement tools related to tracking and reducing conflict. Despite best efforts and intentions, conflict may culminate in the decision by a facility to discharge or transfer a patient from its care. There are only a few justifications (failure to pay, posing an immediate threat to the safety of staff or patients, or irremediable behavior that poses a threat to the health and safety or the orderly conduct of care for patients and staff) for involuntary discharge (IVD) or involuntary transfer (IVT). The facility is obligated to notify the Network and state health agency of the intention to give a patient a 30-day notice of discharge or transfer or immediate discharge or transfer. The discharging facility has the obligation to assist in placing the patient and guaranteeing continuity of care.

The Network will advocate for the patient in circumstances of threatened IVD/IVT. The Network will hold the facility to a high standard. The Network will look for sincere efforts to mitigate and resolve the conflict. It will assist in that mitigation. If the Network supports the facility's decision, it will assist in placing the patient in an alternative facility, and it will assure that both the medical director and the patient's nephrologist have signed the discharge order. It is obviously preferable that facilities avoid the conflict that leads to threat of IVD/IVT. In individual cases where there may be consideration of IVD/IVT, consulting the Network before the decision is made may lead to mediation or interventions that obviate the IVD/IVT.

The grievance process is a regulatory and not a judicial process. It does not have to be adversarial. In the event that a patient grievance is substantiated, the obligation of the facility is to create a corrective action plan consistent with the findings. The Network will assist the facility and patient in correcting and improving the environment of care leading to the grievance. A substantiated grievance does not have the same significance as a survey finding of a condition out of compliance. In the former case, the Network is required to seek alternative sanctions on the facility from CMS. That process would have its own investigation and finding timeline.

It is a regulatory requirement that the medical director signs off on every IVD/IVT in the facility. Ideally, these will be few and far between, because the medical director will be familiar with conflict resolution tools and advocate for solutions that best serve the interests of all stakeholders. Ultimately, the safety of the facility staff and other patients must be paramount. A proactive approach by the medical director to address patient dissatisfaction issues may prevent their evolution into complaints or grievances. Medical directors can offer objectivity, staying above the fray. Experience in effective conflict resolution can inform QAPI activities in the facility and should be shared with Network.

### Patient Engagement

The Network can assist the medical director in developing a culture of professionalism and communication in the facility that leads to patient comfort in raising concerns, suggesting changes, and trusting in the internal grievance practices in the facility. The greater goal is to increase patient engagement and involvement in their care. The Networks have expertise in helping facilities move toward a more professional patient care staff and more engaged patient group. The Patient Whisperer Program is a recorded webinar housed on The Renal Network's website (18). It provides information about effective communication techniques and professionalism. It is designed to assist staff in developing skills to better interact and build rapport with patients. Network staff can also present this program live to facility staff on request. The medical director has a key role in assuring that the facility promotes a culture in which a patient can voice a complaint/grievance internally or externally without fear of reprisal. There are additional domains of patient engagement in which Networks and medical directors can collaborate to ensure that patients are given the appropriate opportunities to provide feedback regarding their care and provide informed input regarding their plan of care (Table 4).

The medical director can and should be perceived by staff and patients as the ultimate educational resource in the facility regarding medical issues. The medical director is required by regulation to have an active role in the ongoing education of facility staff. Well educated staff provide better guidance to patients to inform decision making and generate trust. The Networks offer regional educational activities for dialysis staff at annual conferences and focused intervention activities. Faculty for these activities is always in demand, and medical directors should strongly consider sharing their educational successes in such venues.

**Table 4. Dimensions of patient engagement**

<p><b>Patient feedback regarding experience of care</b>  Use of ICH-CAHPS aggregate data at the facility level to improve processes and patient-reported outcomes  Use of patient advocacy group(s) as advisory bodies at the facility level  Patient representation on the governing body</p> <p><b>Patient participation in plan of care</b>  Actively encouraging live participation by each patient in a multidisciplinary plan of care  Recruitment of patient champions for modality education (<i>e.g.</i>, peritoneal dialysis, home hemodialysis, or transplant)  Use of plan of care to set goals for the patient and the provider team with timelines and deliverables</p> <p><b>Patient empowerment</b>  Development of a website or another medium that patients can securely visit to review  <i>Plan of care with monthly updates to show progress</i>  <i>Recent laboratory data</i>  <i>Medications and enter updates</i>  <i>Transplant evaluation status (if applicable)</i>  <i>Vascular access plan (if applicable)</i>  Encourage patients to provide anonymous or identifiable feedback through a website or other medium</p>
--

ICH-CAHPS, in-center hemodialysis consumer assessment of healthcare providers and systems.

### Coordination of Care

The PPACA of 2010, through the Centers for Medicare and Medicaid Innovation, seeks to foster better care coordination and care integration. The most obvious way to reduce the cost of care of the patient with ESRD is to reduce hospitalization and rehospitalization. To that end, CMS is asking dialysis providers to apply for participation in an End Stage Renal Disease Continuous Care Organization (ESCO) (19). The proposed models allow for shared saving with or without downside risk. To be successful, the ESCO applicant must be able to manage the transitions of care between various settings (nursing home, hospital, emergency department, outpatient services, etc.). Success also depends on an engaged medical staff that works to maximize communication and follow-up from one venue of care to another. Regardless of whether a dialysis facility is planning to be part of an ESCO, it is in the best interests of patients and providers that the facility improves transitions of care. The medical director and the medical staff need to step up and invest the time and energy to develop systems and procedures in the hospital, office, and dialysis unit that enable smooth transitions. Some Networks have developed Care Transitions Change Concepts to establish a successful system of communication between health care settings. The Change Concepts provide the most effective and efficient processes identified as well as resource material. Every facility has different circumstances, faces different barriers, and will have different processes. No process is right or wrong, and processes may change over time. Communication is the key to care transitions that minimize the risk for hospitalization/rehospitalization (20–22).

The medical director, as the leader of the medical staff, is the point person for care coordination in the facility. Whether the facility becomes part of an ESCO or some other globally capitated payment model, the medical director will be expected to interface with his/her counterparts at other health care providers (hospitals, extended care facilities, and outpatient services) to develop and implement care coordination models and engage dialysis facility medical staff. Although much of the strategic planning for care coordination models

will occur at the corporate level in dialysis organizations, each facility and its medical director will have to address tactical implementation issues that may require knowledge, experience, and understanding of the unique political and/or economic landscape of the geographic area that the dialysis facility serves. Successes in care coordination will benefit patients by decreasing morbidity and costs associated with hospitalization and rehospitalization, and the Networks will be eager to disseminate these best practices to fulfill the aims of CMS.

### Professional Growth for the Medical Director

The Networks are peer-review organizations, meaning that they depend on stakeholders from the ESRD community to establish the quality agenda, adjudicate patient complaints/grievances, and provide oversight to the staff to assure that the SOW deliverables are met. Although the SOW establishes the strategic domains and subdomains for the triple aim, it is up to each Network, led by its local professional and patient committee members, to determine the most effective tactical approach to achieve the goals for each of these domains and subdomains, taking into account the unique challenges and opportunities for that geographic region. That includes developing the QIA that will have the highest yield and choosing the sampling methods, numerators, denominators, targets, and tools to achieve the desired outcomes. It includes developing the improvement tools and deciding how to disseminate them. It includes analyzing the data and determining whether the project was successful and then, changing the intervention as appropriate. These are the same skills required of a medical director to implement a QAPI project; however, the unit of interest is facilities rather than patients. Some of the more successful QIAs will be publishable in peer-reviewed journals, and the medical director may have the opportunity to participate as a coauthor. A medical director who participates on a Network's committees will be exposed to seasoned medical directors who can provide advice and resources that may assist the less experienced medical director in becoming more efficient and

improving patient outcomes in his/her own facility. The National Forum of ESRD Networks offers a Medical Director Toolkit free of charge that can be downloaded from their website ([www.esrdnetworks.org](http://www.esrdnetworks.org)) by following the appropriate links. Thus, active participation by the medical director in a Network's activities can be expected to improve the medical director's skills and professional growth. If part of the medical director's compensation is on the basis of patient metrics, the medical director's success in directing QAPI programs at his/her facility may also bring a financial reward.

## Conclusions

The medical director is obligated to cooperate and participate in the ESRD Networks' programs and goals. Although imposed by legislation and regulation, it is not an onerous burden. The Network is committed to the same aims, goals, and patient-centeredness that characterize a high-quality dialysis facility. The synergy available from collaboration toward the improvement of care of patients on dialysis will be beneficial to the facility in achieving its goals of quality, safety, and financial viability; to the medical director in increasing professional knowledge and skills; and to the patient in improving outcomes, engagement, and satisfaction.

## Disclosures

P.B.D. is chief medical officer at Centers for Dialysis Care, Inc. He is chairman of the medical review board of ESRD Network 9 and a member of the board of directors which has oversight for ESRD Networks 9, 10, and 12. J.B.W. is medical director of the outpatient dialysis facility at Indiana University Hospital and a consultant to DaVita, Inc. on quality of care issues. His spouse is executive director of ESRD Networks 9 and 10.

## References

- Centers for Medicare and Medicaid Services: ESRD Network Organizations. Available at: <http://cms.hhs.gov/Medicare/End-Stage-Renal-Disease/ESRDNetworkOrganizations/index.html>. Accessed May 26, 2014
- Wish JB, Meyer KB: ESRD Networks: Past, present, and challenges for the future. *Clin J Am Soc Nephrol* 7: 1907–1914, 2012
- Department of Health and Human Services: Centers for Medicare & Medicaid Services, Center for Medicaid and State Operations/Survey and Certification Group, End-Stage Renal Disease Program Interpretive Guidance, October 3, 2008. Available at: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf>. Accessed May 26, 2014
- Institute of Medicine; Lohr KN, editor: *Medicare: A Strategy for Quality Assurance*, Vols. I and II, Washington, DC, National Academy Press, 1990
- US Department of Health and Human Services: The Affordable Care Act, Section by Section (May 1, 2010). Available at: <http://www.hhs.gov/healthcare/rights/law/>. Accessed May 26, 2014
- US Department of Health and Human Services: 2011 Report to Congress: National Strategy for Quality Improvement in Healthcare. Available at: <http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm>. Accessed May 26, 2014
- US Department of Health and Human Services: Principles for the National Quality Strategy. Available at: <http://www.ahrq.gov/workingforquality/nqs/principles.htm>. Accessed May 26, 2014
- Department of Health and Human Services; Centers for Medicare & Medicaid Services: 42 CFR Parts 405, 410, 413 et al. Medicare and Medicaid Programs; Conditions for Coverage for End-Stage Renal Disease Facilities; Final Rule, April 15, 2008. Available at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/downloads/esrdfinalrule0415.pdf>. Accessed May 26, 2014
- Wish JB: What is expected of a medical director in the Centers for Medicare and Medicaid Services Conditions of Coverage? *Blood Purif* 31: 61–65, 2011
- Gutman RA: Medical direction of dialysis—a critical leadership role. *Semin Dial* 20: 257–260, 2007
- Nissenson AR: Improving outcomes for ESRD patients: Shifting the quality paradigm. *Clin J Am Soc Nephrol* 9: 430–434, 2014
- ESRD Network 9-10: Resources Available to Assist in a Broad Range of Quality and Safety Projects. Available at: <http://www.therenalnetwork.org>. Accessed May 26, 2014
- DeOreo PB, Wilson R, Wish JB: Can better understanding and use of treatment center performance feedback improve hemodialysis care? A role for the medical director. *Semin Dial* 25: 290–293, 2012
- Wish JB: Vascular access for dialysis in the United States: Progress, hurdles, controversies, and the future. *Semin Dial* 23: 614–618, 2010
- Centers for Disease Control and Prevention: Dialysis Safety. Available at: <http://www.cdc.gov/dialysis/index.html>. Accessed May 26, 2014
- 5-Diamond Patient Safety: The 5-Diamond Patient Safety Program. Available at: <http://5diamondpatientsafety.org/Home.aspx>. Accessed May 26, 2014
- ESRD Networks: Decreasing Dialysis Patient-Provider Conflict (DPC). Available at: [http://www.esrdnetworks.org/special-projects/copy\\_of\\_DPPCProviderManual.pdf](http://www.esrdnetworks.org/special-projects/copy_of_DPPCProviderManual.pdf). Accessed May 26, 2014
- The Renal Network, Professionalism and Communication: Patient Whisperer: Compassionate Care for Challenging Situations. Available at: [http://www.therenalnetwork.org/services/PSDtraining\\_PtWhisperer.php](http://www.therenalnetwork.org/services/PSDtraining_PtWhisperer.php). Accessed May 26, 2014
- Centers for Medicare and Medicaid Services: Comprehensive ESRD Care Initiative. Available at: <http://innovation.cms.gov/initiatives/comprehensive-esrd-care/>. Accessed May 26, 2014
- The Renal Network: Change Concepts for Improving Care Transitions. Available at: <http://www.therenalnetwork.org/qi/caretransitions.php>. Accessed May 26, 2014
- Chan KE, Lazarus JM, Wingard RL, Hakim RM: Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge. *Kidney Int* 76: 331–341, 2009
- Erickson KF, Winkelmayr WC, Chertow GM, Bhattacharya J: Physician visits and 30-day hospital readmissions in patients receiving hemodialysis. *J Am Soc Nephrol* 25: 2079–2087, 2014

Published online ahead of print. Publication date available at [www.cjasn.org](http://www.cjasn.org).