What is Expected of a Medical Director in the Centers for Medicare and Medicaid Services Conditions of Coverage?

Jay B. Wish, MD
USA

The Medicare Conditions for Coverage for dialysis facilities, effective since 2008, make the medical director responsible for all levels of quality patient care in the facility. This includes issues such as water quality, infection control, staff education, policy/procedure development and implementation, dialyzer reuse, involuntary discharges, and patient safety. Most importantly, the medical director is the leader of the team responsible for quality assessment and performance improvement, which is central to the process of continuous quality improvement in the dialysis facility and the basis for much of Medicare’s evaluation of facility performance. Through the measures assessment tool, continued on page 2
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the Conditions for Coverage specify the required domains for quality improvement activities in the dialysis facility, including dialysis adequacy, nutrition, bone disease, anemia management, vascular access, medical errors, patient satisfaction, and infection control. Under the leadership of the medical director, the quality assessment and performance improvement team identifies opportunities for improvement, tests and implements interventions, collects data, interprets results, and links system change with improved outcomes. These activities are rigorously documented and provide evidence to Medicare that the facility is acting responsibly to provide the best possible services to which it is being paid. The medical director is fairly compensated for his/her services by the facility, but must always act in the patients’ best interest when evaluating policy changes directed at cost containment. The success of a medical director in shepherding positive change in a dialysis facility can be immensely satisfying as it impacts on patients other than his/her own.

Potential Effects of the New Medicare Prospective Payment System on Drug Prescription in End-Stage Renal Disease Care

Wolfgang Winkelmaier, MD USA

The Centers for Medicaid and Medicare Services have announced a new Prospective Payment System to reimburse the care furnished by dialysis centers to patients with end-stage renal disease (ESRD). As of January 2011, most aspects of the outpatient treatment of patients with ESRD will be included in a single payment. In addition to the items previously included in the Composite Rate, injectable drugs and their oral equivalents will be included in this new capitation payment, as will the laboratory tests required for monitoring maintenance dialysis. As of January 2014, oral-only medications will also be included. Physician payments and payments for inpatient care, as well as for care not directly related to ESRD care will continue to be reimbursed separately. Patterns of medication treatment of ESRD patients will likely be revisited, and one can expect pronounced adjustments. Treatment of anemia will likely shift towards less use of erythropoiesis-stimulating agents and somewhat towards higher use of intravenous iron supplements. Average hemoglobin concentrations will decline. Use of intravenous vitamin D analogues will likely be reduced and substituted with their oral equivalents in many patients. One can also expect a temporary trend towards higher use of calcimetics, since their inclusion in the payment bundle is deferred until 2014. Treatment of problems with vascular access patency and of access infections will likely shift to the inpatient setting, and there may be reluctance to quickly accept recovering patients back to the outpatient setting after vascular access intervention. On aggregate, these changes have the potential to alter patient outcomes, but it is currently unclear how these will be and can be monitored.

Intestinal-Renal Syndrome: Mirage or Reality?

Eberhard Ritz, MD Germany

The recent interest in the role of the intestine in the cardiovascular stability of uremic patients, specifically on dialysis, but potentially also in chronic kidney disease, must be seen against the background of the recent great interest in the role of the gut in chronic heart failure [Curr Opin Clin Nutr Metab Care 2008;11:632-639]. There has been a long-standing interest in the role of the intestine in renal failure, mainly concerning the role of metabolites of bacterial metabolism in the gut as potential uremic toxins. This area has recently been given a new twist by the finding that increased endotoxin concentrations in the blood of dialyzed patients are associated with hypertensive episodes and myocardial ‘stunning’. Recent studies suggest that intradialytic underperfusion of myocar- dial areas, the so-called stunning, may be related to the entry of bacterial endotoxin and/or cytokines across the mucosal barrier into the circulation, where they have a negative impact on myocardial function (and presumably beyond the negative cardiac side effect also contribute to cachexia and malnutri- tion). Entry of bacterial endotoxin during dialysis sessions is presumably the result of intermittent underperfusion of the intestine if the effective blood vol- ume is rapidly reduced causing break- down of the mucosal barrier. Apart from the impact on myocardial perfusion, the entry of bacterial endotoxin and/or cytokines across the mucosal barrier may also contribute to malnutrition, wasting and reduced life expectancy in hemodia-lyzed patients. Such a causal relationship is absolutely plausible in view of an extensive literature on congestive heart failure where clinical and experimental evidence indicates that bacterial endo- toxin and/or cytokines may escape from a hypoperfused edematous gut, entering the circulation, triggering an inflamma- tory response, upregulating circulating cytokines and interfering with the func- tion of the heart through several patho- genic mechanisms.

Motivational Interviewing to Engage Patients in Chronic Kidney Disease Management

Steve Martino, PhD USA

Patients with chronic kidney disease (CKD) must manage numerous medical treatments and lifestyle changes that strain their treatment adherence. An important strategy to improve adherence is to activate the patients’ motivation to manage their CKD. This article describes an approach for enhancing patients’ motivation for change, called motivational interviewing (MI), a treatment that is increasingly being used in health care settings to counsel patients with chronic diseases. Its base principles, techniques, empirical support, published applications for improving CKD patients’ self-management, and how to learn MI are presented. Research is needed to determine the efficacy and mechanisms of MI for CKD treatment as well as the development of innovative ways to deliver it to patients and train busy health care practitioners in the approach.

Sodium: A Wolf in Sheep’s Clothing

Hans Obereitner Germany

High blood pressure is the main cause of disease-related morbidity and mortality worldwide. It is virtually absent in populations that consume natural foods low in sodium. In other countries, however, where the individual intake of sodium is at least 10 times greater, the prevalence of arterial hypertension is about 40%. Vascular endothelium plays a central role in blood pressure regulation. In addition to the kidney, the vasculature is a major target for aldosterone where it controls nonexcretable sodium channels in the endothelium. High sodium channel expression/activity downregulates the release of nitric oxide (NO), and thus determines endothelial function. Mechanical cell stiffness is therefore the means whereby high sodium channel activity reduces NO release. We have found that small changes of plasma sodium concentrations...
DIALYSIS TIMES

Sodium Gradient: A Tool to Individualize Dialysate Sodium Prescription in Chronic Hemodialysis Patients?

Lars Penne, MD, PhD
The Netherlands

Low dialysate sodium concentrations have been associated with intradialytic symptoms such as muscle cramps and hypotensive episodes. High dialysate sodium concentrations lead to sodium loading, thirst and subsequent increase in interdialytic weight gain and hypertension. The optimal dialysate sodium concentration for an individual depends on the serum sodium concentration. The difference between the dialysate sodium concentration and the predialysis serum sodium concentration has been defined as the sodium gradient. In this article, the role of the sodium gradient in fluid overload, hypertension, intradialytic symptoms and clinical outcome is discussed. Absolute serum sodium levels should always be taken into account when interpreting the relation between sodium gradient and clinical outcomes. Alignment of the dialysate sodium with the serum sodium concentration may be beneficial in many patients.

The Path to Wearable Ultrafiltration and Dialysis Devices

Stanley Cortell, MD
USA

Wearable blood processing devices offer an attractive solution to problems inherent in clinic-based, intermittent end-stage renal disease therapies. What is involved in transitioning even a part of the current clinic-based population to ambulatory therapy has not been clearly enumerated. This paper addresses what a first-generation wearable device might accomplish, how issues of safety will need to be addressed, and what will make the device attractive to, and manageable by, the patient. Medical, technological, and economic issues are identified.

Current State of Combined Kidney and Pancreas Transplantation

Bernd Schrippel, MD
USA

Glycemic control via the use of exogenous insulin injections in diabetic patients is incomplete, resulting in multiple long-term complications, such as retinopathy, neuropathy, vasculopathy, and nephropathy. The goal of whole-pancreas and kidney transplantation is to achieve long-term insulin independence and correct uremia. The proposed benefits of pancreas and kidney transplantation are improved quality of life, prevention of recurrent diabetic nephropathy, freedom from exogenous insulin, stabilization or improvement in secondary complications, and improved mortality. No other regimen of insulin delivery or renal replacement besides pancreas and kidney transplantation can achieve this level of physiologic regulation.

Hydrogen Sulfide, a Toxic Gas with Cardiovascular Properties in Uremia: How Harmful Is It?

Alessandra Perna, MD, PhD
Italy

Hydrogen sulfide (H(2)S) is a poisonous gas which can be lethal. However, it is also produced endogenously, thus belonging to the family of gasotransmitters along with nitric oxide and carbon monoxide. H(2)S is considered a neurotoxin and can cause central nervous system damage, reduce cerebrovascular perfusion, and modulate cerebral blood flow. The role of H(2)S in the pathogenesis of cardiovascular disease is still under investigation.

Arteriovenous Fistula Toxicity

Richard Ameling, MD
USA

The arteriovenous fistula (AVF) has been a mainstay of hemodialysis treatments and the preferred access route since its inception in the 1960s, due to its longevity and resistance to infection. However, the AVF is not benign. There is significant primary failure, as well as cardiac, vascular, and other, less well recognized, complications. Together, they represent toxicity, to which considerable morbidity and mortality can be attached. Officially, based on guidelines where AVF toxicity is given short shrift, drives an increase in use of these devices, and may have undesired consequences.

Central Artery Pulse Pressure in End-Stage Renal Disease: The Roles of Aortic Diameter, Aortic Stiffness and Wave Reflection

Gerard London, MD
France

In elderly subjects and patients with end-stage renal disease (ESRD), carotid pulse pressure (PP) is an independent and significant predictor of cardiovascular (CV) risk. Whereas in the elderly carotid diameter, but not carotid stiffness, is an associated CV risk factor, an opposite CV risk pattern was observed in ESRD patients that was associated with stiffness. Whether in ESRD patients' arterial diameter, stiffness or both are involved in the mechanism(s) of increased carotid PP has never been investigated. Nondiabetic ESRD patients (n = 144) were compared with 57 control subjects matched for age, sex and mean blood pressure, but with higher brachial and carotid PP. Noninvasive echo-Doppler techniques and pulse wave velocity (PWV) and pulse wave analysis were used to evaluate cardiac and carotid arterial structures and functions using multiple stepwise regressions. In controls, carotid PP was associated only with stroke volume, arterial wave reflections and aortic PWV, but not aortic diameter. In ESRD patients, it was associated with wave reflections, aortic PWV, stroke volume and higher aortic diameter.
In ESRD patients and controls, elevated carotid PP mainly reflected increased aortic PWV and earlier wave reflections. Aortic diameter had an impact only on ESRD patients, where it compensated for enhanced aortic stiffness and the more pronounced effect of reflected waves. This hemodynamic profile differs consistently from that in elderly subjects of the general population and selectively influences CV risk and drug treatment.

### Development of a Peritoneal Dialysis Program

**Frederic Finkelstein, MD**
**USA**

The development of a successful peritoneal dialysis program requires that the organization and structure of the program be carefully planned. Key ingredients include developing a robust chronic kidney disease education program, adequate training for physicians and nurses, full complement of support staff (including nurses, dietician, and social worker), appropriate continuous quality improvement programs, and a reasonable program size.

### Chronic Kidney Disease Stages Are Appropriate At All Ages

**Frederick Kaskel, MD, PhD**
**USA**

Chronic kidney disease (CKD) is associated with multiple detrimental consequences to the cardiovascular and musculoskeletal systems. The effects of CKD are even more significant when they begin in childhood as they affect growth and (neuro-) development as well. The division into stages of CKD serves as a guideline for the physician to better anticipate and treat early and later manifestations of CKD. For that matter, in adults, the National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative has published clinical practice guidelines, which are based on estimated glomerular filtration rate (eGFR). There are no such explicit guidelines published for the pediatric CKD population, mostly (and thankfully) due to its small number. However, given the excellent guidelines published in the adult literature and ongoing clinical work done by dedicated pediatric nephrologists, similar guidelines for children could be extrapolated and determined. As a matter of fact, the pediatric nephrology community is anxiously anticipating the results of the ongoing Chronic Kidney Disease in Children study, which is the first multicenter, prospective, observational pediatric study of such kind. This article summarizes the adequacy of CKD stages at all ages based not only on opinions of experienced clinicians, but also on evidence provided by cross-sectional data analyses of the Chronic Kidney Disease in Children study.

**Cardiovascular Imaging in Patients with Chronic Kidney Disease**

**Paolo Raggi, MD**
**USA**

Cardiovascular disease is highly prevalent in chronic kidney disease and has been associated with increased morbidity and mortality. Several morphological and functional tests are available to assess the cardiovascular system. Since structural and functional cardiovascular abnormalities have prognostic implications, their identification may become crucial for the implementation of effective preventive and therapeutic strategies. We review the most frequently used imaging methods to investigate structural and functional cardiovascular changes in patients with chronic kidney disease.

**A Quantitative Approach to Drug Dosing in Chronic Kidney Disease**

**Ali J Olyaei, PharmD**
**USA**

Chronic kidney disease (CKD) is increasing at an alarming rate. Medication prescribing in this growing population is especially difficult. Many pharmacological agents or their metabolites are eliminated unchanged through the kidney. Drug dosing in CKD is challenging as most patients have a number of comorbid conditions. Patients with CKD take pharmacological agents with potential for drug interactions. Most patients also have alterations to the normal functioning of a number of different organs or systems (e.g. heart, liver, gastrointestinal system) which affect pharmacokinetics of commonly used drugs in CKD. Pharmacokinetic behaviors of most drugs are highly variable in patients with CKD. In addition, pharmacological management of patients with CKD is imprecise and requires estimating renal function, applying clinical judgment and, if available, therapeutic drug monitoring to provide adequate pharmacotherapeutic concentrations to optimize pharmacodynamic response while minimizing toxicities. For drugs that are removed through the renal system unchanged, a dosing modification should be considered according to patient- and drug-specific factors. Renal replacement therapy and dialysis remove pharmacologic agents extensively, and thus a replacement dose is needed to avoid therapeutic failure. By applying a quantitative approach, health care providers can improve pharmacotherapeutic outcomes while reducing adverse drug reactions.

**Sleep Disorders Over the Full Range of Chronic Kidney Disease**

**Andreas Pieratos, MD**
**Canada**

Sleep disorders are common and under recognized in patients at all stages of chronic kidney disease. They include sleep apnea, insomnia, excessive sleepiness, restless legs syndrome and periodic limb movement disorder. They can be related to underlying uremia or comorbidities. Sleep disorders can affect the quality of life, and some are associated with increased morbidity and mortality. Clinical assessment, polysomnography and other standardized assessments are required for diagnosis. Therapeutic approaches include improvement in uremia management, treatment of comorbidities or specific interventions directed at individual sleep disorders. Diagnosis and treatment of sleep disorders in this population may improve quality of life and patient survival.

**Design and Rationale of Health-Related Quality of Life and Patient-Reported Outcomes Assessment in the Frequent Hemodialysis Network Trials**

**Mark Unruh**
**For the Frequent Hemodialysis Network Trial Group**

**Background**

End-stage renal disease patients experience significant impairments in health-related quality of life (HRQOL). Testing various strategies to improve patient HRQOL in multicenter clinical trials, such as the Frequent Hemodialysis Network (FHN) trials is vitally important.

**Aims**

The aim of this paper is to describe the design and conduct of HRQOL and patient-reported outcomes (PRO) assessment in the FHN trials.

**Methods**

In the FHN trials, HRQOL was examined as a multidimensional concept, and the SF-36 RAND Physical Health Composite score was one of the co-primary outcomes. The instruments continued on next page
Results

A number of small to medium-size interventional trials have shown that magnesium-based compounds can serve as effective phosphate binders. Observational studies suggest that higher serum magnesium concentrations in dialysis patients may improve survival and may slow the progression of vascular calcification. While a few small prospective trials support these findings, no large or long-term studies are available.

Conclusions

Magnesium balance remains poorly understood in patients with end-stage kidney disease. While observational and small randomized trials suggest that exogenous administration of magnesium may be useful as a phosphate binder and may have protective cardiovascular effects in terms of both arrhythmias and vascular calcification, large randomized trials are needed to test these hypotheses.

RIFLE-based Data Collection/Management System Applied to a Prospective Cohort

Multicenter Italian Study on the Epidemiology of Acute Kidney Injury in the Intensive Care Unit

Claudio Ronco, MD
Italy

The epidemiology of acute kidney injury (AKI) has been difficult to explore in the past, due to different definitions across various studies. Nevertheless, this is a very important topic today in light of the high morbidity and mortality of critically ill patients presenting renal dysfunction during their stay in the intensive care unit (ICU). The case mix has changed over the years, and AKI is a common problem in critically ill patients often requiring renal replacement therapy (RRT). The RIFLE and AKIN initiatives have provided a unifying definition for AKI, making possible large retrospective studies in different countries. The present study aims at validating a unified web-based data collection and data management tool based on the most recent AKI definition/classification system. The interactive database is designed to elucidate the epidemiology of AKI in a critically ill population. As a test, we performed a prospective observational multicenter study designed to prospectively evaluate all incident admissions in ten ICUs in Italy and the relevant epidemiology of AKI. Thus, a simple user-friendly web-based data collection tool was created with the scope to serve for this study and to facilitate future multicenter collaborative efforts. We enrolled 61 consecutive incident patients into the study; 25 patients with end-stage renal disease were excluded, leaving 576 patients for analysis. The median age was 66 (IQR 53–76) years; 59.4% were male, while median Simplified Acute Physiology Score II and Acute Physiology and Chronic Health Evaluation II scores were 35 (IQR 27–48) and 18 (IQR 13–24), respectively. The most common diagnostic categories for ICU admission were: respiratory (27.4%), followed by neurologic (17%), trauma (14.4%), and cardiovascular (12.1%). Crude ICU and hospital mortality were 21.7% and median ICU length of stay was 5 (IQR 3–14) days. Of 576 patients, 246 patients (42.7%) had AKI within 24 h of ICU admission, while 133 developed new AKI later during their ICU stay. RIFLE-initial class was Risk in 205 patients (54.1%), Injury in 99 (26.1%) and Failure in 75 (19.8%). Progression of AKI to a worse RIFLE class was seen in 114 patients (30.8% of AKI patients). AKI patients were older, with higher frequency of common risk factors. 116 AKI patients (30.6%) fulfilled criteria for sepsis during their ICU stay, compared to 33 (16.7%) of non-AKI patients (p < 0.001). 48 patients (9.3%) were treated with RRT in the ICU. Patients were started on RRT a median of 2 (IQR 0–6) days after ICU admission. AKI patients were started on RRT on median of 0–4 days after fulfilling criteria for AKI. Median duration of RRT was 5 (IQR 2–10) days. AKI patients had a higher crude ICU mortality (28.8 vs. 8.1%; non-AKI; p < 0.001) and longer ICU length of stay (median 7 vs. 3 days, non-AKI; p < 0.001). Crude ICU mortality and ICU length of stay increased with greater severity of AKI. 225 (59.4% of AKI patients) had complete recovery of renal function, with a serum creatinine at time of ICU discharge which was ≤120% of baseline; an additional 51 AKI patients (13.5%) had partial renal recovery, while 103 (27.2%) had not recovered renal function at the time of death or ICU discharge. The study supports the use of RIFLE as an optimal classification system to stage AKI severity. AKI is indeed a deadly complication for ICU patients, where the level of severity is correlated with mortality and length of stay. The tool developed for data collection was user-friendly and easy to implement. Some of its features, including a RIFLE class alert system, may help the treating physician to systematically collect AKI data in the ICU and possibly may guide specific decisions on the institution of RRT.

Micronutrients and Cardiovascular Disease: Insights into Novel Assessments and Treatment

Peter A. McCullough, MD, MPH
USA

Chronic kidney disease (CKD) is a recognized risk multiplier for develop...
Lipid Disorders and Their Relevance to Outcomes in Chronic Kidney Disease

Nasratola D. Vaziri, MD
USA

Cardiovascular disease is the major cause of death in patients with chronic kidney disease (CKD). Cardiovascular disease and many other complications of CKD are mediated by oxidative stress, inflammation, and dyslipidemia. This review provides a concise overview of the nature and mechanisms of CKD-induced lipid disorders and their adverse consequences. Lipid abnormalities in end-stage renal disease are characterized by: (a) reduced serum apoA-1 and high-density lipoprotein (HDL) concentrations, impaired HDL maturation and defective HDL antioxidant, anti-inflammatory and reverse cholesterol transport properties; (b) impaired clearance of very low-density lipoprotein and chylomicrons by the muscle and adipose tissue and of their remnants by the liver leading to hypertriacylglyceridemia, accumulation of intermediate-density lipoprotein and chylomicrons remnants, and (c) oxidative modification of LDL and lipoprotein remnants favored by their structural abnormalities, oxidative stress, and impaired HDL antioxidant activity. Together these abnormalities result in: (a) uptake of oxidized LDL and remnant particles by macrophages and resident cells in the artery wall which along with impaired HDL-mediated reverse cholesterol transport causes foam cell formation and atherosclerosis, (b) production of inflammatory mediators and reactive oxygen species by leukocytes and macrophages in response to stimulation by oxidized LDL and phospholipids leading to intensification of oxidative stress and inflammation, (c) dissemination of oxidative stress by circulating oxidized lipids and lipoproteins via lipid peroxidation chain reaction, (d) heightened injurious effects of oxidative stress and inflammation due to diminished antioxidant, anti-inflammatory and antiatherosclerotic activities of HDL, and finally (e) impaired ability of very low-density lipoprotein and chylomicron to deliver lipid fuel to muscle and adipose tissue contributing to muscle weakness and cachexia, which commonly occur in end-stage renal disease patients.
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