Implementing a Disease Management Program For Chronic Kidney Disease

Based on a conference held in Philadelphia on April 22, 2003

HIGHLIGHTS

• Managing Chronic Kidney Disease Stages 3 and 4
• Utilizing the K/DOQI Clinical Practice Guidelines
• Practical Applications in Chronic Kidney Disease Management
• Disease Management Opportunities for Chronic Kidney Disease
• Roundtable Discussion: CKD Management — Meeting the Challenges
Implementing Effective Chronic Kidney Disease Management Techniques

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This MANAGED CARE supplement derives from a gathering of health care and business experts who recently convened in Philadelphia to discuss how to improve the care of patients with chronic kidney disease (CKD). The second in a series of meetings supported by Ortho Biotech Products, L.P. on this subject, “Implementing a Disease Management Program for Chronic Kidney Disease” was preceded by the extremely successful program “Managed Care Guidelines for Management of Chronic Kidney Disease,” on which the April 2003 MANAGED CARE supplement was based.

The articles within this supplement offer a timely focus by providing insights into the implementation of practical approaches to CKD management — despite today’s economic climate of shrinking resources. Chronic kidney disease, which affects 20 million Americans, progresses to end-stage renal disease (ESRD) if left untreated, resulting in the need for dialysis or kidney transplant — both of which are high-cost procedures. To assist managed care decision makers, the authors point to the recently released Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines that are promoted by the National Kidney Foundation (NKF). These guidelines help to define the disease state and identify the coexisting conditions that need to be managed through all stages of CKD. Additionally, K/DOQI serves as a guide for provider and member education and addresses the timing of appropriate interventions.

Also in this supplement, the authors evaluate the common barriers that can deter implementation of innovative medical management techniques for CKD and ESRD. Specific challenges exist relative to identifying the population at risk for CKD and measuring the success of CKD disease management (DM) programs. The positive DM experience of Aetna and Optimal Renal Care relative to CKD stages 3 and 4 is described within these pages; the program exemplifies how heightened understanding of the typical challenges faced by MCOs can promote program success.

While MCOs recognize that successfully managing chronic illnesses is a proven methodology with long-term benefits, other priorities — such as meeting requirements for the Health Plan Employer Data and Information Set (HEDIS) — vie for attention. In the years ahead, however, DM programs for chronic kidney disease will demonstrate that improved outcomes and cost savings can be realized through well-timed and coordinated interventions.
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Twenty million Americans have chronic kidney disease (CKD), and large populations are at increased risk of developing CKD. Left untreated, CKD can progress to kidney failure, which necessitates renal replacement therapy (dialysis or kidney transplantation) to prevent death. The costs of maintaining a patient on dialysis are substantial — upwards of $70,000 annually. Further, the incidence and prevalence of individuals on renal replacement therapy (subsumed under the Medicare term end-stage renal disease [ESRD]) are projected to double between 2000 and 2010 (Figure 1, page 4). Medicare has established a program to reimburse expenditure for dialysis and transplantation. Medicare, however, is a second payer during a 30-month coordination period in patients with employer-based group health coverage. This highlights the importance of identifying patients with CKD at an earlier stage to prevent or delay progression to kidney failure.

Initiation of kidney disease often is heralded by proteinuria as a sign of kidney damage. As the disease progresses, a decrease in the glomerular filtration rate (GFR) signals the diminishing capacity of the kidney to filter waste products, until kidney failure finally ensues. Hypertension, diabetes, and older age are risk factors shared by CKD and cardiovascular disease (CVD), so that CKD frequently is accompanied by concomitant CVD. The stages of CVD often progress in parallel with the stages of CKD, culminating in clinically evident atherosclerosis or heart failure. In fact, it is likely that the high morbidity and mortality of individuals with CKD is related to their high burden of concomitant CVD, and many individuals with CKD die from CVD before they progress to kidney failure (Figure 2, page 4). Although CKD is a silent disease, with characteristic symptoms and signs often absent, early stages can be detected through laboratory tests that estimate kidney function or indicate kidney damage. Treatment during these stages is effective in preventing or delaying the progression of CKD and the development of complications. Likewise, early treatment of cardiovascular risk factors should be effective in reducing cardiovascular events before and after the onset of kidney failure.

K/DOQI initiative

To improve quality of care and outcomes for individuals with kidney failure, the National Kidney Foundation (NKF) launched the Dialysis Outcomes Quality Initiative (DOQI) in 1995. The clinical practice guidelines developed for DOQI in 1997 have had significant and measurable effect on the care and outcomes of dialysis patients. Nevertheless, it was recognized that underdiagnosis and undertreatment of the earlier stages of CKD result in lost opportunities for prevention of kidney failure, treatment of complications of kidney disease, and amelioration of comorbid conditions. Thus, in 1999, the DOQI clinical practice guideline initiative was expanded to encompass the entire spectrum of kidney disease and address the importance of early identification and treatment of patients with all stages of CKD. To reflect these expanded goals, the reference to dialysis in DOQI was changed to disease, and the new initiative was termed Kidney Disease Outcomes Quality Initiative (K/DOQI). Development of K/DOQI guidelines is guided by principles that call for scientific rigor (i.e., an evidence-based approach), interdisciplinary collaboration, independence...
Definition and staging of CKD

The centerpiece CKD guidelines define CKD as structural or functional abnormalities of the kidneys persisting for at least 3 months, as manifested by one or both of the following criteria: kidney damage or GFR less than 60 mL/min/1.73m² (Table 1). Kidney damage is defined by the presence of markers of kidney damage, for example proteinuria or other abnormalities (Table 2).

The staging system is based on disease severity because worse kidney function correlates with worse outcomes. An estimate of the glomerular filtration rate (GFR) was selected as the best routine measure of kidney function in health and disease. It is also a convenient number because physicians and patients alike are familiar with the concept that the kidney is a filter. Since the normal GFR is about 120 to 130 mL per minute standardized to body surface area (per 1.73m²), estimated GFR approximates the percentage of kidney filtration function.

Stages 1 and 2 of CKD are characterized by the presence of markers of kidney damage. In stage 1, the GFR is normal or increased, while in stage 2 the GFR is already mildly reduced. Stages 3 and higher are defined by a GFR less than 60 mL/min/1.73m². A GFR of 60 mL/min/1.73m² represents the loss of approximately half of normal kidney function. A GFR of less than 60 mL/min/1.73m² is associated with an increased incidence and prevalence of complications of kidney disease, such as anemia, bone disease, malnutrition, and reduced functioning and well-being. In addition, the dose of many drugs needs to be adjusted for a GFR less than 60 mL/min/1.73m². CKD stage 4 is characterized by a GFR of 15 to 30 mL/min/1.73m². Stage 5, which is also termed kidney failure, applies to a GFR of less than 15 mL/min/1.73m² or treatment by dialysis.

It is important to note that kidney failure is not iden-
tical to end-stage renal disease (ESRD). ESRD is not a clinical diagnosis but an administrative term used for determining eligibility for Medicare benefits. ESRD is applied to individuals who are on dialysis or have undergone kidney transplantation. Thus, individuals with very low kidney function but who are not yet on dialysis are excluded by the ESRD definition, while individuals after kidney transplantation who have good transplant kidney function are included. On the other hand, stage 5 or “kidney failure” describes the last stage of CKD, which corresponds to very low kidney function or the need to be maintained on dialysis. Recipients of a kidney transplant do not have kidney failure unless they have a GFR less than 15 mL/min/1.73m² or have needed to resume dialysis.

Treatment of CKD by a stage-appropriate action plan

The guidelines endorse the importance of the traditional approach to kidney disease, which necessitates elucidating the exact cause of CKD in order to target specific diseases with specific treatments. Table 3, on page 6, depicts three types of the disease: diabetic kidney disease, nondiabetic kidney disease, and diseases in the transplant recipient. At the same time, the guidelines emphasize that it is equally important to treat individuals with CKD with a stage-appropriate action plan that is independent of the actual type of CKD. Making a specific diagnosis for kidney disease and the initiation of disease-specific treatments may necessitate consultation or co-management by a nephrologist; to a great extent, however, non-nephrologists can institute a stage-appropriate action plan. This is an important issue for developing disease management programs, because — during the early stages of CKD — the vast majority of patients receive most of their medical care from primary care physicians, who typically treat the patients’ hypertension and diabetes. The sheer number of individuals with CKD dictates that primary care physicians become familiar with CKD and assume an active role in its treatment.

### TABLE 1 Stages of chronic kidney disease

<table>
<thead>
<tr>
<th>Stage</th>
<th>GFR (mL/min/1.73m²)</th>
<th>Prevalence</th>
<th>Recommended action†</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Kidney damage with normal or elevated GFR</td>
<td>≥90</td>
<td>5.9</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Kidney damage with mildly reduced GFR</td>
<td>60–89</td>
<td>5.3</td>
<td>3.0</td>
</tr>
<tr>
<td>3 Moderately reduced GFR</td>
<td>30–59</td>
<td>7.6</td>
<td>4.3</td>
</tr>
<tr>
<td>4 Severely reduced GFR</td>
<td>15–29</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>5 Kidney failure</td>
<td>&lt;15 or dialysis</td>
<td>0.3</td>
<td>0.1</td>
</tr>
</tbody>
</table>

GFR = glomerular filtration rate.
*Percentage of population comprising 177 million adults, age ≥20 years.
†The action plan for every stage includes the recommendations for each of the preceding stage(s).

SOURCE: K/DOQI 2002

### TABLE 2 Markers of kidney damage

<table>
<thead>
<tr>
<th>Abnormal urine findings</th>
<th>Abnormal findings on imaging studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proteinuria</td>
<td>Renal artery stenosis</td>
</tr>
<tr>
<td>Red blood cell casts*</td>
<td>Asymmetry of size</td>
</tr>
<tr>
<td>White blood cell casts*</td>
<td>Cysts</td>
</tr>
<tr>
<td>Coarse granular casts</td>
<td>Obstruction</td>
</tr>
<tr>
<td>Tubular epithelial cells</td>
<td>Scarring</td>
</tr>
<tr>
<td>Fat</td>
<td>Small size</td>
</tr>
<tr>
<td></td>
<td>Masses</td>
</tr>
</tbody>
</table>

*Findings of hematuria or pyuria on dipstick should prompt careful examination of urine sediment for cellular casts that point to the kidney as the site of damage.
especially in the disease’s early stages.

The action plan for each stage of disease includes the action plan outlined for preceding stages. With increasing severity of CKD, the management becomes more complex. In stages 1 and 2, the clinician needs to identify the type of kidney disease, institute measures to slow its progression, treat comorbid conditions, and reduce the risk of CVD. For the patients in stage 3 with a GFR of 30 to 59, the clinical action plan also includes the evaluation and treatment of complications of reduced kidney function. Once the GFR falls below 30, an additional important task is to prepare the patient for a smooth transition to renal replacement therapy. With a GFR of less than 15 mL/min/1.73m², patients have to be monitored carefully and should be initiated on kidney replacement therapy when uremic symptoms set in.

The NKF recommends referral to a kidney disease specialist when the GFR approaches 30 mL/min/1.73m², because preparation for renal replacement therapy should begin at that point. For the earlier stages, the guidelines do not specify referral criteria, because physicians have varying degrees of comfort and competence and should be able to decide themselves when it is best to refer their patients. The guidelines recommend calling in a specialist (e.g., a nephrologist, cardiologist, or nutritionist) whenever the clinical action plan cannot be prepared, the prescribed evaluation of the patient cannot be performed, or the recommended treatment cannot be carried out.

**Estimated GFR as the best measure of kidney function**

As outlined above, the level of GFR is an important number for assessing the level of kidney function and for staging CKD. The CKD guidelines recommend that kidney function be assessed via a GFR estimated from a prediction equation. Serum creatinine often is used in clinical practice as an indicator of kidney function. Creatinine is a product of dietary meat intake and muscle catabolism. The serum creatinine level depends on a person’s diet, age, weight, sex, and race. Serum creatinine should not be used alone to assess kidney function, because it fails to identify many patients whose GFR is reduced despite normal serum creatinine values.

By the time a patient’s serum creatinine rises above the normal...
reference range of the laboratory, the patient already could have lost 50 percent of kidney function. Neither should creatinine clearance measured in a 24-hour urine collection routinely be used to estimate kidney function. Twenty-four hour urine collections are fraught with collection errors. Also, 24-hour creatinine clearance measurements systematically overestimate GFR when the filtration rate is reduced, because tubular secretion of creatinine is increased (Figure 3). While measurement of creatinine clearance using timed urine collections usually does not improve the GFR estimate beyond that provided by prediction equations, clearance measurements may be necessary to estimate the GFR for patients who are at the extremes of age and body size, severely malnourished or obese, or for patients experiencing other special circumstances.

Estimated GFR can be computed from equations that incorporate the serum creatinine in addition to other variables. Two examples for prediction equations in adults are the Cockcroft-Gault equation and the MDRD (Modification of Diet in Renal Disease) Study formula (Table 4). The former is easier to compute, but the latter does not require the patient’s weight as a variable, and it is more accurate for patients whose GFR is less than 90 mL/min/1.73m².

Physicians can calculate the estimated GFR by the MDRD Study formula on a Web-based GFR calculator «http://www.kidney.org» or with software available for handheld devices or PCs. In the future, clinical laboratories should directly report an estimated GFR with each creatinine requested to facilitate the interpretation of kidney function by clinicians. An additional challenge regarding the precise assessment of kidney function by GFR stems from the fact that, at the present time, the results for serum creatinine vary widely across clinical laboratories. Thus, to improve precision of estimated GFR, which is derived from the serum creatinine, standards have to be developed to improve calibration of serum creatinine assays.

**Slowing CKD progression**

Treating hypertension is probably the most important intervention to slow the progression of CKD and prevent development or progression of CVD. Hypertension is both a risk factor for CKD as well as a complication of it. It should be noted that the target blood pressure in patients with CKD is less than 130/80 mm Hg (JNC-7 2003). Additionally, angiotensin-converting enzyme inhibitors (ACE inhibitors) or angiotensin-receptor blockers (ARBs) should be used in the treatment of individuals with diabetic kidney disease or those with a spot-protein-to-creatinine ratio greater than 200 mg/g, even if they are not hypertensive. This is because these agents delay the progression of kidney disease independent of lowering blood pressure. Follow-up laboratory tests after an individual has been started on an ACE inhibitor or an ARB may reveal an increase in creatinine or a decrease in GFR, which can alarm the physician to the extent that the patient is taken off the medication. Nevertheless, with careful monitoring, an initial decline in GFR up to 25 percent can be tolerated without cessation of these blood pressure agents, because maintaining a patient on these medications will increase his or her chances of deriving long-term benefit.

### Reducing cardiovascular disease risk

Another important consideration in the management of CKD is that having CKD puts an individual into the highest risk group for CVD. Thus, modifiable cardiovascular risk factors should be measured and treated. In keeping with the recommendations of the National Cholesterol Education Program’s most recent guidelines, the low-density lipoprotein cholesterol goal for CKD patients recommended by the K/DOQI guidelines is less than 100 mg/dL. Statins are recommended as preferred agents to reach that treatment goal (K/DOQI 2003).

### Evaluating CKD complications

As the GFR falls below 60 mL/min/1.73m², the number of kidney disease-related complications increases

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**TABLE 4  GFR prediction equations**

<table>
<thead>
<tr>
<th>Equation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cockcroft-Gault equation</strong></td>
<td>$C_G (\text{mL/min}) = \frac{(140 - \text{Age}) \times \text{Weight}}{72 \times S_C} \times (0.85, \text{if female})$</td>
</tr>
<tr>
<td><strong>Four-variable (abbreviated) MDRD Study formula</strong></td>
<td>$\text{GFR (mL/min/1.73m}^2\text{)} = 186 \times (S_C)^{-1.154} \times (\text{Age}^{-0.203} \times (0.742, \text{if female}) \times (1.212, \text{if black})$</td>
</tr>
</tbody>
</table>

GFR = glomerular filtration rate.

$C_G$ = creatinine clearance.

$S_C$ = serum creatinine in mg/dL.

Age in years; weight in kg.

MDRD Study = Modification of Diet in Renal Disease Study.
Anemia, bone disease, calcium and phosphorus imbalances, hyperparathyroidism, malnutrition, neuropathy, and reduced functioning and well-being all are seen more frequently below this GFR and are associated with worse outcomes. The guidelines recommend that all patients with a GFR less than 60 mL/min/1.73m² should be evaluated for these complications periodically. For anemia, evaluation should include measurement of hemoglobin. The K/DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease outline the work-up if anemia is present as well as the use of iron and erythropoietin. For evaluation of bone disease and disorders of calcium and phosphorus metabolism, parathyroid hormone (PTH), phosphorus and calcium levels are the biomarkers most commonly used. There are no convincing data to suggest that there is benefit to obtaining bone biopsies or bone densitometry routinely. More specific treatment recommendations will be given in the forthcoming K/DOQI Clinical Practice Guidelines on Bone Metabolism and Disease in Chronic Kidney Disease. Similarly, the K/DOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure recommend assessment of nutritional status in all patients with advanced CKD, as well as counseling or specialized nutrition therapy if decreased dietary intake or malnutrition are found.

**Testing individuals at increased risk for CKD**

Management of CKD actually begins at “stage zero” — that is, in patients who have risk factors for CKD but who still have normal kidney function and no evidence of kidney damage. Primary care providers have a unique role in primary prevention and early detection in these individuals. Hypertension and diabetes should be treated in these patients. Also, these individuals should be periodically tested for CKD. Routine evaluation consists of an estimated GFR, calculated from a serum creatinine, and urine tests for protein, red blood cells, and white blood cells.

While it is normal for small amounts of protein to be excreted in the urine, persistently elevated urinary protein excretion is a marker of kidney damage. Albumin in the urine is the earliest marker of kidney damage that is due to diabetes, hypertension, and glomerular diseases. Albumin-sensitive tests are 10 times more sensitive than standard protein tests. Because persistent albuminuria can signify CKD, even when GFR is still normal, the testing for albuminuria in individuals with risk factors for CKD has great importance for early identification of CKD. The U.S. Public Health Service Task Force recognizes hypertension and diabetes as risk factors for CKD, but the NKF goes further and recommends testing for patients in all groups at increased risk (Table 5). The NKF hopes the task force will reconsider its recommendations, based on the high prevalence of patients in CKD stages 1 and 2, as identified by repeated albuminuria testing (Table 1).

Routine testing can be performed on a spot-urine sample and does not warrant a timed urine collection. Adults at increased risk for CKD should be tested with

**TABLE 5 Individuals at increased risk for CKD**

<table>
<thead>
<tr>
<th>Risk Factors for CKD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Age &gt;60 years</td>
</tr>
<tr>
<td>Family history of kidney disease</td>
</tr>
<tr>
<td>Autoimmune disease</td>
</tr>
</tbody>
</table>

**FIGURE 4 Prevalence of patients by number of abnormalities by level of GFR (NHANES III)**

- Hypertension*
- Unable to walk 1/4 mile
- Serum calcium <8.5 mg/dL
- Hemoglobin <12.0 g/dL
- Serum albumin <3.5 g/dL
- Serum phosphorus >4.5 mg/dL

*≥140/90 or antihypertensive medication.  
p-trend <.001 for each abnormality.

**SOURCE: K/DOQI 2002**
an albumin-sensitive dipstick or with an albumin-to-creatinine ratio in a spot-urine sample sent to the laboratory (Figure 5). Endocrinologists frequently use albumin urine dipsticks to test for microalbuminuria in patients with diabetes. Albumin-sensitive dipstick tests are more expensive than regular protein urine dipstick tests. Therefore, testing in adults at increased risk can begin with a routine urine-protein dipstick test. This serves the purpose of simultaneously testing for red and white blood cells with a multitesting strip. Nevertheless, a negative urine-protein result needs to be confirmed by an albumin-specific test. A positive albumin dipstick test or a positive protein dipstick test needs to be confirmed with a quantitative test in a spot-urine sample (albumin-to-creatinine or protein-to-creatinine ratio). The NKF guidelines recommend that individuals with risk factors for CKD who have no evidence of microalbuminuria on spot-urine screening should be retested at periodic intervals. Those who test positive for microalbuminuria or proteinuria on repeated occasions should be evaluated for CKD.

In the work-up for CKD, a more elaborate laboratory panel of serum electrolytes (sodium, potassium, chloride, bicarbonate) should be added, a urine sediment should be examined under the microscope, and the kidneys should be imaged, usually by ultrasound.

**K/DOQI guidelines — a framework**

In summary, the K/DOQI guidelines provide a framework for the diagnosis, staging, and evaluation of CKD. They recommend a stage-appropriate action plan that is independent of the type of kidney disease and that can be taught to and carried out by non-nephrologists. Interventions should address both CKD and CVD — and their risk factors. In later stages, complications of decreased kidney function have to be addressed, and preparation for renal replacement therapy should be undertaken, if appropriate. An estimated GFR calculated from a prediction equation, which incorporates the serum creatinine (as opposed to relying only on serum creatinine), is the best measure for assessing kidney function in routine clinical practice. The guidelines recommend the routine provision of estimated GFRs by clinical laboratories, together with serum creatinine values, to facilitate the identification and staging of individuals with CKD. Improving early recognition of patients with CKD necessitates laboratory testing of individuals at increased risk. An albumin-specific method for testing spot-urine samples will detect kidney damage earlier than standard urine-protein tests. Early identification widens the window of opportunity to put effective interventions to work, which will benefit patients and may prove to be cost-effective for managed care organizations in view of the high cost of care for ESRD.

**References**

Many managed care organizations overlook important opportunities that exist to improve care and to control costs through disease management (DM) initiatives targeting chronic kidney disease (CKD) and its progressive disease state, end-stage renal disease (ESRD). This article will examine practical ways to manage CKD, given the economic challenges facing most MCOs. Although most managed care professionals appreciate the long-term benefits of successfully managing chronic illnesses, these DM benefits compete against other short-term priorities, such as meeting requirements for the Health Plan Employer Data and Information Set (HEDIS). In the coming years, the success of CKD DM will become clear as these programs demonstrate measurable utility and value to MCOs.

CKD management: a question of resources

For many health plans, assessing CKD as an isolated disease state that must be managed is difficult. CKD is a complex condition, touching on many other disease states, and it therefore brings unique process challenges to MCOs. Because DM often is run as a compliance measure, created and managed to meet the National Committee for Quality Assurance (NCQA) and HEDIS requirements, many MCO DM programs are geared to narrow data needs. In the real world, chronic diseases tend to flow into each other rather than exist as distinct entities. Successful management of chronic diseases therefore necessitates that the MCO embrace the entire spectrum of a disease. For instance, CKD, as a component of a chronic disease state, should be included in any diabetes or hypertension program. Unfortunately, this long-term, encompassing approach frequently is at odds with an MCO’s short-term, compliance-driven data requirements.

Due to this conflict between long- and short-term needs, every MCO will need to make critical decisions regarding resource allocation and the prioritization of CKD management. Currently, management of CKD is not a HEDIS requirement, which presents a considerable obstacle to widespread DM intervention; it is reasonable to assume that CKD management may need to become a mandated HEDIS requirement in order to consistently garner the precious resources within a plan.

So, if the primary barrier to CKD DM is simply getting the attention of MCOs, a secondary barrier is the availability of resources that can be used to put a program in place. Those who implement DM at the plan level must concern themselves with the basic issue of budget and the critical question: does DM represent an administrative overhead cost?

When DM exists to comply with HEDIS or other measurements, the answer to that question is “yes.” Nevertheless, the budgetary process often is not kind to additional, non-HEDIS-specific measures. When the reality of limited resources meets DM ideals, a more creative approach is demanded of the MCO. For instance, sending out a new mailing to raise disease-state awareness might cost the plan $45,000 or more — a significant amount in budget-constrained times. On the other hand, the health plan could implement a disease-state awareness campaign by making use of existing educational tools. For example, letters that the plan already has slated to send out to its members who have diabetes might be written to include information about glomerular filtration rate (GFR) testing and the importance of this score to the patient’s long-term health. A strategy such as this effectively stretches DM budget dollars, allows small, specific CKD measures to be introduced, and raises the awareness level of both members and providers.

To capture the attention of an MCO and to initiate the process of managing CKD, a strong case must be made for early, appropriate intervention. The critical questions that need to be answered for the MCO are: Where in the ongoing CKD process is it appropriate to intervene? What types of outcomes (clinical and economic) can the MCO expect to see?
CKD intervention points

In determining the point at which intervention is appropriate for CKD, it is helpful to consider the description offered by Theodore F. Hatch, ScD, of the relationship between an organism and the environment (Esmen 1984). Figure 1 adapts Hatch’s description to provide a graphic representation of the cost of disease versus its severity, and it demonstrates the specific potential intervention points in the treatment of CKD — categorized as primary, secondary, and tertiary prevention.

In the primary prevention stage, an opportunity exists to prevent dysfunction. During this stage, patients have a tremendous capacity to return to normalcy or good health. This primary stage offers an opportunity to help the patient manage his or her condition, delay disease progression, or even reverse its effects.

In the secondary stage, the objective is the prevention of progression; in the tertiary stage, the objective is prevention of disability. Within the tertiary period, the CKD patient is progressing toward dialysis and transplant, with the attendant complications and costs (Figure 2). The primary goal is to prevent the progression of CKD in the first place and to maintain the at-risk individual in a homeostatic realm.

In this model, assisting the patient to move toward treatment-compliant behavior is essential. In the primary prevention stage, especially, patient-centered care that is focused on education and empowerment is key. Generally, patients become extremely motivated if they are made aware that they may become disabled if the disease is not brought under control. Although contemplating disability may be frightening, often it is that prospect that effectively prompts a patient to consider altering behavior that is damaging. Without a doubt, obtaining a change in patient behavior is always extremely challenging, but if MCOs select and focus on certain pieces of important information (such as GFR scores) about which patients and providers can be educated, that initial action opens up opportunities for meaningful change.

Figure 3 represents another modification of Hatch’s material and shows the relative importance of early, appropriate testing —
in terms of slowing both disease progression and the escalating costs.

The economics of CKD management

It is as important to change physicians’ habits as it is to change patient behavior. While it is difficult to alter entrenched behavior, this is not because the physicians are uneducable but is linked to the lack of incentive to follow CKD DM guidelines. An MCO may suggest specific actions, but if reimbursement is not sufficiently addressed, the desired behavior is unlikely to follow.

For CKD DM to succeed, it is essential that the facts about managed care be taken into account. The reality is that physicians are coping with larger caseloads and greater economic pressures and do not have an economic incentive to pursue many of the practices that would result in early identification and management of patients at risk for CKD. Instead, these patients often go unrecognized until they develop ESRD — at which point, dialysis becomes a necessity.

In the same way, MCOs must deal with CKD in the shadow of their economic imperatives. For instance, the health plan will notice if the provider is ordering what is deemed to be an excessive number of tests; and, because the plan might not have guidelines for CKD pretesting or prevention, there are misperceptions about what is appropriate or how to measure the success of a treatment modality.

So, does the physician order a test that may be challenged by the MCO? Does the physician spend more time with a patient where coding and reimbursement might be challenged? Does the MCO spend the time and money necessary to develop and implement guidelines?

Before the MCO decides to spend budget dollars on a specific member population, there are other issues to be addressed. For instance, managed care plans tend to have a shortened time frame when they are seeking a return on investment (ROI) — either through savings or other benefits — based on a member’s benefit period. Health plans often are loathe to spend limited resources on health issues that are currently mismanaged, with the prevailing perspective being that by the time the patient begins to become well controlled, he or she will have moved to another plan; thus, the plan would be expending resources without reaping the associated benefits.

To overcome these economic and process barriers, CKD needs to be taken out of the realm of the short-term benefit period ROI and placed squarely in the public health arena. Once addressed as a public health issue, the focus is where it belongs — on clinical outcomes. Clinical findings must be used to demonstrate to MCOs how a CKD patient may be brought back toward homeostasis — dramatically delaying the progress of the disease toward the need for dialysis (with its cost and clinical implications).

As a public health issue, CKD could be addressed by health plans as a group in a region, with all medical directors meeting to discuss ways to raise awareness and to generate opportunities to work together (from a nonproprietary standpoint). Blue Cross attempted this approach in Jacksonville, Fla., and the plan found some success in raising awareness. Although CKD patients do migrate from plan to plan,
In a high-risk situation, the incremental costs of check-test is a good starting point at which to screen patients. The benefits of risk stratification. The identification of a GFR to know that the K/DOQI guidelines exist. One would hope that primary care physicians would have been educated that the additional laboratory costs actually assist in standing that early identification and management is vital to the health plan. One could easily make the case that the additional laboratory costs actually assist in keeping other — higher costs — lower in the long term. By educating the provider and member concerning the importance of the GFR score in anticipating CKD, the

Clinical data as an educational opportunity

The K/DOQI guidelines are a valuable starting point for MCOs. The key point for the health plan is the education of its providers concerning the identification of individuals based on susceptibility or risk factors, as well as how to apply the K/DOQI guidelines properly. From a health plan perspective, a provider would not be expected to know the specifics of the guidelines, but he or she would be expected to know that they exist and to have a set point at which the guidelines are to be applied — a point at which they may be provided with an incentive to reference the guidelines.

Educating providers concerning the value of GFR testing in the overall management of CKD patient is important. Most health plans do not manage to this level of proscribing the tests that are ordered by the physician. At Blue Cross Blue Shield of Florida, for example, the plan does not try to limit individual members’ tests. Instead, the plan focuses on raising the physicians’ awareness level, so that tests are ordered appropriately. Nevertheless, one difficult outcome for the MCO of a campaign to raise CKD awareness could be that every patient, regardless of risk factors, is being screened, which results in escalating costs. The ultimate goal, then, rather than simply to ensure that providers have an improved understanding of the disease state, is to foster understanding among primary care physicians of the risk factors and of the importance of targeting their patient population.

Ideally, then, in any scenario where clinical investigation has recognized a decreased GFR, one would hope that primary care physicians would have been educated to know that the K/DOQI guidelines exist. Part of the education initiative is to creative an effective rationale for appropriate testing and the tangible benefits of risk stratification. The identification of a GFR test is a good starting point at which to screen patients. In a high-risk situation, the incremental costs of check-

The health information call-line vendor/Blue Cross experience

Blue Cross Blue Shield of Florida is attempting to link case-management and disease-management awareness to its efforts with respect to population-based disease management. To that end, Blue Cross is using a contracted health information call-line vendor, which will provide a 24-hour/7-day telephonic interface for one of its new product lines, with potential expansion into more traditional lines of business, including HMOs. This nurse call line does not steer individuals to particular treatment parameters; they view themselves as a coaching organization. Blue Cross members call the health information call-line vendor when they want to know more about their disease state. In the case of chronic kidney disease, education might take the shape of emphasizing the importance of the glomerular filtration rate (GFR) score for the at-risk member.

In the Blue Cross model, however, the effort does not stop with the passive education of the member. Blue Cross is linking the call made to the health information call-line vendor to developed protocols, whereby they can identify an individual who has a need or a request to be a part of case management. The plan then brings that member into a managed situation, whereby more active or aggressive interventions can be brought to the fore.

One of the challenges that Blue Cross faces is determining which patients would benefit most from case management. Because there are not sufficient numbers of case managers to handle all the plan’s members, protocols need to be developed to help create the dividing line between a population base and those individuals who need management (in coronary heart failure, diabetes, or asthma, for example). As part of this protocol creation, management of some members ceases because it is not making a significant difference in their care.

When the effort to get individuals into a DM program is controlled internally, it is a more direct process to get “voluntary” cooperation from the member. Yet another challenge faced using an external health information call-line vendor — or any vendor, for that matter, — is assuring compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In other words, an MCO has to make certain that personally identifiable medical information (PIMI) is properly maintained and confidential, and that all guidelines for voluntary participation in programs are followed.
MCO is focused on a relatively discrete clinical diagnostic goal that is not complicated and is easily attainable.

**Conclusion**

For CKD DM to succeed in the managed care marketplace, DM advocates must address specific key issues. First, the problem of CKD must be made important to the plan (which is dealing with many competing priorities), creating both economic and clinical rationales for appropriate intervention. Second, realistic ROI scenarios must be drawn up, whereby the plan understands the long- and short-term implications of CKD DM. Implementation must be made relatively simple, with attainable goals such as GFR screening and the early identification of at-risk members. Additionally, implementation must address reimbursement and ensure that physicians have sufficient incentives for complying with K/DOQI guidelines. Fourth, education of both provider and member will ensure the program’s success; educational initiatives that address the legitimate issues of both physician and patient will speak to their needs.

Finally, for CKD DM to succeed in managed care, MCOs will need to see the disease state and its key measures included by HEDIS. In these days of limited resources and an increasingly narrow focus on short-term goals, MCOs may want to do the ‘right’ thing — but they may only do what is necessary. CKD DM advocates must help MCOs to bridge the gap between what is correct and what is necessary.

**REFERENCES**


Chronic Kidney Disease Management: Challenges and Opportunities

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Senior Vice President, RMS Disease Management

Innovative medical management techniques for chronic kidney disease (CKD) and end-stage renal disease (ESRD) represent opportunities for MCOs to treat these conditions appropriately and efficiently. CKD and ESRD affect approximately 11 percent of the U.S. adult population (Coresh 2003). This article discusses CKD disease management (DM), the barriers to its use or success, and the keys to creating a program that yields maximum medical improvement for the patient. DM represents a proven methodology for this underserved medical population — one that, when properly implemented, should result in improved outcomes and cost savings through well-timed and coordinated interventions.

Why CKD?
An economic imperative

The overarching objectives for a CKD DM program are relatively straightforward:

1. Improve outcomes and reduce costs of CKD
2. Properly organize the transition to dialysis
3. Delay progression to ESRD

These are attainable objectives and, as argued below, are critical from a cost-control point of view.

From a managed care perspective, there are significant economic reasons to apply DM principles to CKD and ESRD. Since 1972, Medicare coverage has been extended to patients of any age with ESRD. Patients with ESRD constituted only 0.5 percent of the Medicare population in 2000, but they utilized 5.8 percent of its budget during that year (USRDS 2002). In 1991, however, the ESRD program consumed 4.9 percent of the Medicare budget. Between 1991 and 2000, the overall Medicare budget increased 82 percent, from $120 billion to $219 billion, while the portion devoted to ESRD increased by 129 percent, from $5.4 billion to $12.7 billion. This increase in ESRD spending is due primarily to the growth in this patient population. In addition, non-Medicare ESRD-related care expenditures have grown to $5.2 billion.

At the individual plan level, the costs related to ESRD can escalate rapidly. ESRD costs, per patient per year, are estimated to be between $50,000 and $100,000. Table 1 shows the budget ramifications for health plans of differing membership levels, using USRDS figures of 650 ESRD patients per million individuals (650 is an average of all populations; the range is 250 per million to 1,200 per million, depending on the population’s demographics). These prevalence rates may vary depending on health plan product lines.

Figure 1 dramatically illustrates the importance of improving CKD care. In the 2 years prior to starting dialysis, these Medicare patients cost approximately $800 to $900 per month. There then is a gradual increase, until the patient starts dialysis with Medicare; at this point, costs escalate tremendously, to between $11,000

<table>
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<td>Annual cost per patient</td>
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<td>$50,000</td>
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SOURCE: BRUCE 2001

Table 1 Annual ESRD-related costs

Figure 1 Annual ESRD-related costs
and $12,000 per month, as patients become acutely ill and are hospitalized for initiation of dialysis care.

The opportunity exists for DM to lower the cost associated with CKD patients through education and care planning, to delay this progression, and to organize the transition to dialysis—all of which significantly improve clinical outcomes and lower costs. Projections estimate that DM techniques can reduce the costs related to this patient population by as much as 15 to 20 percent through proper management of comorbidities. Data from the Robert Wood Johnson Foundation (Figure 2) show that within the entire Medicare population, costs dramatically escalate for patients with multiple comorbidities. CKD patients often have anemia, hypertension, cardiovascular disease, and peripheral vascular disease; appropriate management necessitates organized coordination of care.

An additional benefit related to early and appropriate intervention is that there are numerous patients (some estimates are as high as 30 percent to 40 percent) who do not survive to the point of dialysis or transplantation. This mortality is associated with patient complications and additional hospitalizations. It should be reduced substantially by ensuring that at-risk patients are identified early and then appropriately managed.

**Current medical management strategies**

Many health plans use what could be termed a classic approach to DM. In this process, the MCO first reviews claims information and works internally or with outside vendors to identify at-risk patients for specific disease states. Once these members are identified, classic DM institutes telephonic case management, with a focus on member education. Care managers provide information to members about evidence-based care guidelines, to avert recurrent heart failure or the complications of diabetes.

The challenge of the classic DM model is that there often is limited physician communication or integration. For example, telephonic case management might help to educate patients about their treatment, yet the physicians who treat these patients for hypertension, heart failure, and/or diabetes may not be closely integrated into the process. In general, these programs work well for patients who require less complicated care, but a lack of physician coordination and communication becomes more of an issue when patients have multiple comorbidities; they may, as a result, receive conflicting care plan instructions from their DM nurse and the principal care physician.
Traditional DM interventions such as reminder calls for diabetes patients regarding nephrology testing, low-density lipoprotein (LDL) tests, hemoglobin A1c tests, and eye examinations have worked well to prompt the patient to request critical tests from his or her physician.

**Advanced care management**

Utilizing advanced care management for complex conditions such as CKD and ESRD — those with multiple comorbidities — telephonic case management is augmented by nurses working in the field with physicians to develop and implement a comprehensive care plan. To differentiate advanced care management from traditional disease management, it is useful to note its core components:

- Comprehensive assessment of patients regarding multiple comorbidities
- Field-based nurses focused on implementing the physician’s care plan
- Primary source data collection
- Network development to identify those providers interested in managing chronically ill patients
- Facilitation of local continuous quality improvement (CQI) processes with the attending providers

In addition, the Chronic Care Model, developed by Edward Wagner, MD (MacColl Institute for Healthcare Innovation at the Center for Health Studies, Group Health Cooperative), offers a template and a list of criteria that are necessary for the proper management of chronic care illnesses (Figure 3). Wagner stresses linkages between information systems, appropriate caregivers, and community connections to achieve the best possible outcome. The integration discussed in Wagner’s work and promoted in the advanced care management methodology is essential in chronic care, especially with CKD, where the danger is that serious comorbidities do not receive sufficient attention.

**Focus on patients with multiple comorbidities**

Medical spending on patients with multiple comorbidities is radically higher than spending on patients with a few comorbidities. As illustrated in Figure 2, there is a rapid increase in spending with patients that have multiple comorbidities, demonstrating a particularly dramatic increase at five comorbidities. In applying this trend to CKD, it could be supposed that the majority of renal failure patients in stages 3, 4, and 5 have three to five comorbidities.

CKD could be viewed as chronic cardiovascular disease with numerous associated conditions: coronary disease, heart failure, peripheral vascular disease, stroke, or diabetes, as well as renal insufficiency. Although usually thought of as a renal disease, CKD is most likely an indicator for the presence of these comorbidities.

**Field-based nurses implement physician’s care plan**

In this advanced care management process, the nurse often goes into the home to assess patients who are at high risk. After an extensive assessment, including 6 months of medical history, the data are entered into a renal-specific care management software program. These data are shared with the attending physician and become the driving force in the creation of a care plan.

**Collection of primary source data**

In contrast to the classic DM approach, where clinical outcomes data are received from patients, the advanced care model for patients with more complex needs uses primary-source information from physician charts, hospital records, and laboratory reports.

**Network development**

To implement improvement in the health care system, one needs to create a more organized delivery system for patients with chronic diseases. It is important to identify providers who are interested in managing patients with chronic illnesses. Some providers would rather focus on the care of healthier patients than work with the chronically ill patients. For example, many vascular surgeons prefer to perform peripheral vascular surgery or carotid endarterectomies on more stable patients than work with vascular access for dialysis patients. The key to the success of a model for chronic care management is to identify those providers (physicians, surgical centers, etc.) interested in being available and responsive to the needs of a specific population.

**Facilitate CQI processes**

Implementing a CQI process is important for obtaining physician buy-in. Sharing outcomes data with physicians in conjunction with the MCO establishes a forum that includes the participating doctors. The CQI philosophy extends to bringing providers and representatives from provider groups together with the MCO to assess processes and identify areas for improvement within the system. Among the issues that might be discussed are referral management and ensuring a smooth delivery system without restrictions relative to access to care. In addition, dissemination and implementation of guidelines for care are more easily accomplished in this type of forum.

**The CKD challenges**

Proper management of CKD and ESRD necessitates strategies to overcome specific barriers. First, MCOs need to implement methodologies for identifying at-risk patients. Second, there are limited educational tools regarding management of multiple comorbid condi-
tions in the at-risk patient with progressing renal disease. Third, there is a paucity of data regarding the effects of care coordination (in terms of glucose control, blood pressure control, anemia management, angiotensin-converting enzyme inhibition, and dietary instruction) in slowing the patient’s progression to renal failure. Fourth, multiple providers who care for these patients often are not aware of each other’s plans or interventions. Fifth — and a major challenge to the proper management of CKD — the patient is absent a single and primary health care point of contact for the direction of care. It is critical to identify who will be the “captain of the ship” and act as the coordinating force for the patient’s care.

Another CKD concern is suboptimal education relative to renal replacement therapy (RRT). This is a late-referral issue, as many patients are neither referred to nephrologists nor educated prior to dialysis. For example, most patients have dialysis initiated on an emergency basis with an internal jugular catheter and have not been educated about their choices of therapy (i.e., peritoneal dialysis, transplant, or hemodialysis). A much better, preemptive option for a patient choosing hemodialysis is to place an autologous arteriovenous fistula and start dialysis in the outpatient setting. This approach is also safer with respect to avoiding the sepsis and central vein stenosis that often accompany the internal jugular catheter lines.

Finally, there is a lack of data needed to drive improvement. In a CQI loop, all necessary actions revolve around analyzed data. In the advanced care model, providers who are interested in caring for CKD patients are identified, communication between key players is facilitated, outcomes data are collected, reasons for the patient’s hospital admittance are understood, and then the correct process must be fashioned to improve the delivery system. A software system that has been designed to collect the appropriate information is essential for effecting this change.

The CQI process will drive studies concerning the effectiveness of different systems of care delivery. By collecting outcomes and performance measures and presenting these to community providers, health plans can improve models of care for these complicated, expensive, and challenging patients. Among the issues being studied are the role of nurse-driven care and — given the shortage of nephrologists — using nephrologists as care-team leaders for the ever-expanding renal-failure population.

Barriers to CKD management

Despite all the evidence that coordinated care would result in both better clinical outcomes and lower costs related to CKD, there are significant obstacles to implementation. In the real world, a CKD DM initiative needs to overcome challenges relative to specific issues such as:

- Lab data/glomerular filtration rate (GFR) issue. Support is needed from the large national laboratories to calculate and report GFR, rather than serum creatinine alone, as part of standard laboratory reporting.
- Where to focus CKD care. Aside from the challenges of identifying CKD patients in a health plan’s claims file, another problem area for CKD care managers is gaining a clear understanding of the right intervention for the right patient at the right time. In other words: Which of the 10 to 19 million affected patients stand to benefit most from intervention? Once there are more outcome data with respect to management of this population, this question will be more easily answered.
- Cost/benefit data. A better understanding is needed regarding the benefit of using advanced care management models. Do these more formal approaches to management of the chronically ill patient benefit providers and health plans? Is there an economic opportunity for physicians to work more closely with these DM organizations and incorporate their services into their practices? Is there a good return on investment for the health plan?
Should the health plan build these programs internally or hire outside companies to provide these services? These questions need to be answered through testing the use of these care models. Early results of ESRD advanced care management are quite positive, with an 8- to 10-percent reduction in overall costs and a significant reduction in patient mortality (Nissenson 2001). The RMS experience with CKD management, with Florida Medicaid, led to more than a 15 percent cost reduction after the first year, so it appears that this model can be extremely effective for CKD, as well.

**Determining the captain of the ship.** Nephrologists probably are best suited to support the CKD patient, because they already manage patients with multiple co-morbidities. The mitigating factor here is the shortage of nephrologists. As the ESRD patient population grows, the number of patients that a nephrologist sees could soar from its current high of 70 to 80 ESRD patients to an unwieldy 130 ESRD patients per nephrologist. Experience suggests that a nephrologist can manage 65 to 70 patients with success (defined as coordinating medications, understanding the patient’s family dynamics and needs, and providing regular visits in the dialysis unit) before the workload becomes overwhelming.

For CKD, the other potential captain, the primary care physician, often is providing the principal care for the patient. Coordination of care between primary care physicians and nephrologists is essential as renal failure progresses, and at an agreed-upon point in time, the patient’s primary care should be transferred to the nephrologist.

Nephrologists tend to view primary care physicians as referring patients too late, which results in poor transition to dialysis or dialysis started on an emergency basis. Primary care physicians perceive that the nephrologists’ schedules are overloaded and that they may not want to take on additional patients or, if the patient is seen, the value of the consult might be questioned (numerous tests may be ordered, but with limited patient education).

Additionally, it was thought that Health Insurance Portability and Accountability Act privacy requirements would make coordination potentially more difficult. This, however, has not proven to be the case, as DM companies and MCOs have found that most members do not opt out of programs out of concern that information about their health issues will be misused. Thus far, at least, HIPAA has not proven to be an issue.

**Physician compensation.** The economics of health care also is central to improving the coordination of care. Currently, physicians are paid less if the rate of hospitalization is reduced. Improved patient education will eventually lead to fewer office visits. If nephrologists are willing to lead the improvements in CKD management, then pursuant to Recommendation 10 of the Institute of Medicine report, *Crossing...*
the Quality Chasm, we need to work with MCOs and the CMS to “remove barriers that currently impede quality improvement, and to build in stronger incentives for quality improvement.” This will assist in obtaining physician buy-in and support — without which, these initiatives would be likely to fail.

Conclusion

For the CKD and ESRD populations, DM techniques can have a major effect, reducing the rate of escalation in treatment costs and improving patient outcomes. Advanced care management offers a team-oriented approach to the coordination of treatment that previously had been fragmented. In addition, this type of approach allows health care providers the opportunity to get ahead of the CKD/ESRD continuum and to anticipate and delay the cruel progression of the disease.

References


Targeting CKD Stages 3 and 4 For Disease Management

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anaged care organizations evaluate disease management (DM) initiatives for chronic kidney disease (CKD) within the pressurized context of today’s managed care world, where health care programs of all kinds are competing for attention as resources shrink. Given the plethora of DM opportunities today, an important question is: Why choose CKD?

CKD is defined as renal disease that can be described in stages (see Table 1, on page 5 of Dr. Uhlig’s article) from initial laboratory indications of early renal deterioration to a definitive point where renal function has declined such that a patient must receive some form of renal replacement therapy. Renal replacement therapy can take the form of hemodialysis, peritoneal dialysis, or kidney transplant. CKD progression is measured by function of the kidneys, known as glomerular filtration rate (GFR). The classification of the term CKD is the result of work done by the National Kidney Foundation (NKF) to bring a disciplined order to the diagnosis, identification, and treatment of patients across the continuum of renal deterioration and its complications, such as anemia, heart disease, and bone disease.

When first offering DM programs, managed care organizations focused on conditions with high prevalence rates, such as asthma, cardiovascular disease, and diabetes. Now, the DM industry is moving beyond these areas to address the next generation of disease states. In evaluating potential new targets, health plans look for disease states where members can be readily identified, where there is the potential to affect the inappropriate utilization of health care resources, and, importantly, where the quality of care and the quality of the member’s life can be improved. Within this context, DM advocates need to provide a strong rationale for a CKD program, as they would for any DM initiative.

Indeed, there are compelling reasons for a health plan to turn its attention to CKD. This article examines the opportunities presented by CKD DM, the health plan viewpoint when evaluating DM opportunities, and the considerations when implementing such a program.

Through a heightened understanding of the challenges that MCOs typically face, CKD DM advocates can align their objectives more effectively with those of the health plan to ensure success relative to long-term medical and economic outcomes. Finally, this article highlights the positive partnership between Aetna and Optimal Renal Care, a DM company, in a program targeting end-stage renal disease (ESRD).

Why CKD?

Advancing knowledge about the management of CKD makes this a time of great opportunity for CKD DM. Still, a managed care professional must ask: Why choose CKD when many other DM opportunities compete for priority attention?

CKD is an attractive target for management for a number of reasons. If the disease is managed well and aggressively, its progression may be positively altered. Additionally, appropriate actions can increase a member’s quality of life and functional status while decreasing the overall cost of care. Moreover, CKD is a condition that has many comorbidities, such as diabetes, which means that a well-designed CKD DM program can integrate and create powerful synergies with other DM programs.

The National Kidney Foundation’s (NKF) publica-
tion of the Kidney Disease Outcomes Quality Initiative (K/DOQI) guidelines presents an important opportunity for health plan DM leaders to reengineer the health care system to better care for CKD members. These guidelines help MCOs to define the disease state and identify the co-existing conditions that need to be managed through all stages of CKD, from early onset to dialysis or ESRD. K/DOQI provides MCOs with a road map for provider and member education, as well as appropriate interventions and the timing of such interventions.

The business case for CKD DM

Despite the introduction of K/DOQI and increasing provider and public awareness, challenges remain relative to attracting an MCO’s attention. Some of these challenges are inherent to any new DM program, others are more specific to CKD; all, however, are important.

Initially, it is essential to raise awareness among the plan’s key decision makers about the disease and the opportunity to manage it effectively. The plan’s readiness will determine the extent to which a DM company will successfully implement a program that increases the quality of care in a cost-effective manner. Defining the nature of CKD and ESRD, along with the associated costs and utilization, fosters plan recognition that the CKD population will not get better or self-correct. Rather, as these patients move through CKD stages 1 to 3, disease progression becomes more rapid and dramatic.

Early and appropriate intervention can delay the CKD members’ progression to dialysis, with all the attendant health, care-coordination, and cost issues. MCO recognition of these issues is essential to successfully implementing a DM strategy for managing the potentially explosive CKD costs associated with a growing member population.

It is also useful to note that due to changes in the Medicare entitlement program, MCOs have primary financial responsibility for ESRD patients for longer periods of time before they migrate to Medicare. In recent years, this period of responsibility has increased from 18 to 30 months; the expectation is that this window may soon expand to 36 months. Thus, the plan bears ESRD member costs for a greatly extended period of time.

CKD is an expensive population to treat, with a poor quality of life; these members will go through a prolonged period of expensive, high-technology care and, ultimately, succumb to their condition, or they will survive the experience of the onset of CKD stage 5 (dialysis) and begin an expensive therapeutic process that is made more costly by the fact that it is not well managed prior to dialysis initiation.

FIGURE 1 Chronic kidney disease management activities before “going live”

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Marketing/Operations</th>
<th>Program</th>
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<tr>
<td>Chronic kidney disease (CKD) management launch-strategy sessions</td>
<td>Communications — letters</td>
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<tr>
<td>• Health plan</td>
<td>• Health plan (internal)</td>
<td>CKD WORKFLOW</td>
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<tr>
<td>• Physician champions (post ID)</td>
<td>• Health plan (external via newsletters)</td>
<td>(“Go live”)</td>
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<tr>
<td>CKD member-ID process (multimethod)</td>
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<tr>
<td>• Laboratory data</td>
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<td>• Creatinine, urine glucose, and/or protein</td>
<td>Meetings/presentations announcing program:</td>
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<td>• Glomerular filtration rate</td>
<td>• Nephrologists</td>
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<tr>
<td>• Local nephrologist network</td>
<td>• Care map</td>
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<tr>
<td>• Primary care practitioners (tips card)</td>
<td>• Primary care practitioner tips card</td>
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<tr>
<td>• Community-based education programs</td>
<td>• CKD management workflow</td>
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<td>• Optimal Renal Care</td>
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<td>Primary care practitioner tips card</td>
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<td>• Health plan-specific</td>
<td>• Recruit lead physicians</td>
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<td>Establish CKD management workflow</td>
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<td>Education</td>
<td>• Develop working group</td>
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<td>• Formalize CKD class materials:</td>
<td>• Provide feedback via continuous quality improvement process and ongoing communication</td>
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<td>• PowerPoint slides</td>
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ESRD = end-stage renal disease
Optimal Renal Care uses the term **predialysis** to describe a finite period during which the member in a CKD program transitions into dialysis (Figure 2). The objective of the transition is to help the member as he or she begins dialysis, through an easily understood and customized treatment-action plan, such as ensuring vascular access so that the dialysis experience is as easy as possible. Based on the needs of the member, often this will result in the start of dialysis in an outpatient setting, instead of the traditional pattern of initiating dialysis in a hospital in a crisis mode. Ensuring that the member’s dialysis experience does not begin in a crisis fashion increases the likelihood of DM success and slows the progression of ESRD, with its attendant complications and costs.

**Considerations in implementing a CKD program**

The ability to identify CKD members accurately is a critical factor in making the decision to target the disease...
state. It is essential that identification and outreach to the members (from the MCO, the DM company, or the treating physician) be as targeted and as selective as possible. Medical claims and laboratory data, when available, may be used to identify at-risk members. In early-stage CKD, patients often do not have frequent acute episodes, making their identification by an MCO through claims more difficult.

Ideally, to provide a definitive and specific identification, the patient’s GFR test score should be collected and reported via laboratory tests. Currently, few patients are having these critical tests done and even fewer laboratories typically report these data. Nevertheless, laboratories now are becoming more amenable to reporting this test result, along with serum creatinine. In the absence of a reported GFR from a laboratory, the formula to arrive at the GFR is achieved using the patient’s age, sex, race, and weight. With the addition of GFR in laboratory data, MCOs will have a methodology for definitive identification of at-risk members for early intervention and, most importantly, one that will delay the otherwise rapid progression of the disease to dialysis.

After the CKD patients are identified, the MCO’s medical affairs and information technology departments need to manage its members with a seamless, unified, and targeted approach, so a process needed to be established whereby DM companies understand at what points in the DM process a member transfers from one DM company program to another. Given that ESRD members usually present with multiple comorbidities that would, without coordination, cause them to participate in multiple DM programs, it was determined that eligibility for Aetna’s ESRD DM program takes precedence over eligibility for other DM programs (so that the member is managed by one program). To ease the transition between DM programs, Aetna created a clear DM decision tree that describes member eligibility for the ESRD DM program. In the ESRD DM program, the trigger for member eligibility is the initiation of dialysis.

One early challenge during the launch of the ESRD program was gaining physician support. Many physicians initially viewed this program as either an intrusion into their practice or as a means to monitor their practice patterns; the only way to gain their trust was for Optimal Renal Care to back up its promises with action by becoming established as a resource to advance the outcomes and well being of their patients. If the physicians feel antagonistic toward a DM program, and if the physician champions are not advocating the program in the community, then the program is likely to be unsuccessful.

As part of the Aetna–Optimal program, Optimal created specific algorithms, based on a plan’s market, the distribution of members in delivery markets, and the availability of nephrologists. The customization also includes a primary care practitioner “tip card.” The objective of these cards is to provide information to members specific to their individual health needs and to serve as an important reminder tool for the primary care physician. The cards also are designed to empower members by helping them gain insight into their condition and the ways that they can have a positive impact on their care.

Aetna and Optimal Renal Care identified specific performance standards by which the program’s success can be measured, including enrollment rates, testing, and effectiveness of dialysis.

Measures also include quality of care, functional status, provider and member satisfaction, as well as a financial return on the program investment. The ESRD program began in a subset of Aetna members and, once its safety was demonstrated, was extended to include the Medicare +Choice population. Bolstered by a positive experience with Optimal in ESRD DM, the availability of GFR laboratory data, and the recognition of CKD’s overlapping comorbidities, Aetna is exploring implementing a CKD DM program.
to understand the CKD treatment algorithm to determine how to allocate resources. There is a strong link between using these data to identify plan members accurately and using an algorithm that can be implemented with relative ease. In developing a process for the MCO that is as close to a turnkey operation as possible, the DM company can more readily answer the MCO’s major question: How will this DM program affect my resources? This necessitates streamlining the implementation process so that it can be outlined step-by-step, thus allowing the MCO and its providers to understand how care management will integrate with member education and, importantly, reduce the resource intensity of implementation (for the plan). Figure 1, on page 22, illustrates a typical plan where key elements and audiences are listed alongside the anticipated action plan. Figures 2 and 3, on page 23, demonstrate the workflow; customization of the workflow to meet each MCO’s needs is essential.

**Demonstrating return on investment**

For any MCO, a CKD DM program needs to effectively demonstrate a return on investment (ROI) and an improvement in clinical outcomes. A powerful way for a DM company to work with an MCO is to be able to identify its dialysis population and perform a claims review. An examination of data from 20 health plans found the average cost of an ESRD patient in the 12 to 18 months prior to the onset of dialysis to be between $22,000 and $39,000. Additionally, it is not unusual for a member to experience a spike in claims cost in the range of $8,000 to $10,000 per member per month in the 3 months immediately preceding dialysis initiation. These expensive patients are relatively easy to identify. When an MCO sees these data, it then has hard numbers to place next to an at-risk member population, and the case for CKD DM becomes easier. Because each member is so costly for the health plan, modest cost reductions, when seen in aggregate, become significant.

Given the high cost of treating ESRD, it is reasonable to propose that a DM program has the potential to reduce costs by as much as 5 percent to 10 percent, by delaying the onset of dialysis and managing the transition to achieve a smoother entry into dialysis. In Optimal Renal Care’s experience, a health plan can obtain an ROI in the range of 1.25:1 to 1.75:1. This is a sufficient return on such a population.

**Conclusion**

MCOs and DM companies must set out attainable goals for a CKD program to succeed. An approach that is based on claims review allows for a fuller understanding of the member’s condition and his or her medical costs. By targeting the member in this way, the health plan is able to develop programs that have a greater impact on quality of care, quality of life, and functional status issues as well as more significant medical cost savings.

By focusing on claims-data analysis and DM program implementation issues, CKD DM advocates increase the likelihood that they are identifying the right subpopulation and linking CKD patients with the most appropriate care plan. DM advocates also need to focus on reducing the degree of difficulty these challenges present to MCOs by ensuring that the CKD DM process is easy to understand and communicate to decision makers, members, and providers. A successful program will demonstrate to the health plan that their CKD members are identifiable as well as manageable and that a well-designed intervention will result in a significant ROI.
MEDICARE ELIGIBILITY

JOHN P. DICKMEYER, MD: Chronic kidney disease patients incur a lot of costs in the first 30 months before they become eligible for Medicare end-stage renal disease coverage, which means that there is an ever-increasing incentive to see these patients earlier and to smooth the transition to dialysis, if not prevent disease progression.

PETER F. SAUER: That 30-month waiting period has been in place for 6 years now. There is significant discussion suggesting that the waiting period will extend to 36 months or more. I’ll ask the nephrologists in the room: What’s the typical life span for a diabetic end-stage renal disease patient?

KATRIN UHLIG, MD: It is within that range.

SAUER: Medicare can look at the claims for these expensive patients and project the significant expense associated with them. As a result, Medicare will continue to shift costs to private payers.

DICKMEYER: I recently heard a consultant say that he is confident that the bar that prohibits ESRD patients from entering into managed care will drop this year. This is the only population that is barred from enrolling in a Medicare+Choice program. This will lead to a need for MCOs to have efficient mechanisms in place to manage ESRD patients.

DAVID B. NASH, MD, MBA: So, that will take away the 30-month waiting program?

SAUER: No, these are two different things. The 30-month waiting period is for anyone under the age of 65. It is widely believed that, in the near future, Medicare will extend that coordination-of-benefit period to 36 months. Dr. Dickmeyer is referring to the prohibition of individuals over the age of 65 — who, if they have ESRD, are prevented from joining a Medicare+Choice program. What happens now is that if you are at least 65 and develop ESRD, you are not able to join a Medicare+Choice program. But if the bar were to be taken away, anyone who developed ESRD at 65 or older would be able to migrate into a Medicare+Choice program. It is going to be a significant issue for any carrier that has this type of Medicare+Choice plan, because now you only have to deal with those members who develop ESRD while they are in the Medicare+Choice program.

NASH: One of the issues that we have to sort out is the incentive structure relative to the timing of the intervention. In other words, at what time in the spectrum of the illness is it eco-

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The day’s faculty included:

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SAUER: And that’s a different question from the issue of when to identify the members in the general cohort as they progress to ESRD.

NASH: OK, so the ESRD label is a key political issue?

SAUER: ESRD is an administrative term. It is strictly based on the entitlement program under Medicare, Act I, of 1972. If you go anywhere else in the world, you don’t have that issue, which is why the National Kidney Foundation used the vehicle of the Kidney Disease Outcomes Quality Initiative to create a more precise definition in the K/DOQI guidelines that applies to the entire spectrum of kidney disease. ESRD is now part of the full spectrum of CKD, in that it is stage 5.

**CREATING A “COMFORT ZONE”**

SAUER: Stages 3 and 4 of CKD present a significant challenge to both payers and providers of care. For payers, the issue is to identify this population and to be able to put their arms around the actual expense of these members. For providers, it is about determining who will provide the actual care. One reaction is to send all these patients to nephrologists, but that will not work for a wide range of reasons. One of the challenges in the general management of CKD is to create a comfort zone for primary care physicians, so that they will take on the responsibility for the care of CKD patients in stages 3 and 4. This means that primary care physicians will need to treat anemia and other comorbidities that contribute to a patient’s progression to ESRD. The treatment of anemia and the administration of such pharmaceutical agents as erythropoietin are critical components in managing this population. Yet most primary care practitioners do not feel comfortable using these agents in managing the chronic kidney disease population. We know, however, that by treating the anemia aggressively, we deal effectively with such problems as left ventricular hypertrophy — a major cause of hospitalization in this population. In a study by Silverberg,* it was found that with early and aggressive anemia intervention, hospitalizations were dramatically reduced in ESRD patients. Most primary care practitioners have not had a great deal of experience with these treatment protocols. Yet, in the dialysis world, nephrologists do this all the time. The natural assumption, then, is that for their overall care, these patients should be referred to a nephrologist; it is not that simple, however.

It’s not that the nephrologists don’t want to treat these patients. The fact is, there is a significant shortage of nephrologists in the United States. In the past few years, the caseload of a typical nephrologist has gone up dramatically — a result of caring for ESRD patients. To ask these nephrologists now to take on the full care of CKD patients in stages 3 and 4 is rather unrealistic. That population is so large that primary care practitioners must assume a good deal of the responsibility for their care. If you look at the economics of the typical nephrology office, most nephrologists view care during the early stages of CKD as a loss leader. Most nephrologists will tell you that they generate the bulk of their income in the dialysis unit.

In fact, I don’t know a nephrologist who doesn’t want to take care of these patients. Every one of them wants to be able to do it; it’s just a matter of how well they are organized to expand the number of available nephrologists.

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NASH: In California, it’s probably an entirely different kettle of fish than here in Philadelphia. The payment system will drive this.

MICHAEL N. BAXLEY, MD: Sure, and what we are talking about, ultimately, is to give primary care physicians a greater comfort level relative to recognizing and managing the individual patient, and then knowing when a nephrology referral is appropriate.

NASH: There are at least two issues here — first, a better understanding of CKD, which entails appropriate clinical care and referral at the appropriate stage — and second, the incentive structure to drive that kind of behavior.

SAUER: It’s the economics and the availability.

NASH: OK, I would add the availability. But generally speaking, economics trumps clinical every day.

BAXLEY: Well, you bring up a good point, though, one that we are moving away from in the managed care world — capitating the primary care individuals. There is absolutely no incentive to manage these individual patients, whether we’re talking kidney disease, hypertension, or virtually whatever the case may be; there is an incentive to refer early. And, of course, these patients could drop through the cracks because of the availability issue and due to the other economic incentives that exist.

NASH: Here is where a Medicare demonstration project in chronic kidney disease would be great, and a global fee that would connect everybody nicely, and then how you manage. That is another issue. But there are a dozen Medicare disease management demonstration projects right now, and I don’t know if a single one pertains to chronic kidney disease.

SAUER: Actually, it is possible that there could be two demonstration models, a more global model and a fee-for-service project.

NASH: Well, that’s where the future is — looking at these

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early demonstrations of whether they are successful or not. As I come to understand the science better, it's becoming very clear to me that linking the incentives is the key to making this work.

**SAUER:** Actually, the future is about where the referral point is and also how we can create the opportunity for earlier management, not necessarily by nephrologists.

**NASH:** Correct.

### IDENTIFYING MEMBERS WITH CKD

**NASH:** What advice to give to managed care medical directors about identifying their members with CKD?

**BAXLEY:** You can do it both internally and externally. From the external perspective, you need to add the chronic kidney disease concept to any existing disease management programs. It may mean adding that piece of information to existing diabetes education programs. Internally, medical directors should start talking about the fact that disease management is more than just adherence to therapy; it’s approaching the chronic disease and all the comorbidities.

**DICKMEYER:** Awareness needs to be developed that this goes beyond population management, that this is more of a specific population with multiple comorbidities. I would talk about delivery-system improvement, through identification of key providers who are truly interested in managing this population. Over time, it would be important to look at whether your health plan is open to identifying a delivery system for a chronically ill patient population like this — and whether there is interest in gaining a better understanding of who can take this population on a day-to-day basis — because some plans are very interested in this concept and others aren’t. What’s the vision of your plan regarding delivery-system changes?

**BAXLEY:** After almost 50 years in existence, we just got an official chief medical officer at Blue Cross Blue Shield of Florida. One of the first projects that I am addressing with him is to create “centers of excellence” for various disease processes, whether we’re talking about gynecology, oncology, or obesity — whatever the case may be. A center of excellence for the management of chronic kidney disease could start identifying those key individuals in the community and looking at delivery systems to treat them. There also is the somewhat unpopular idea of possibly opening your pocketbook and seeing how you might be able to provide incentive to individuals to participate in such a program. You really don’t want a big network; you want a high-performing network to do this.

**DICKMEYER:** What I have heard from physicians across the country in the last 6 or 7 years is that they are interested in developing relationships with health plans to focus on the management of a chronically ill population, and that this alone — the referral and the relationship — is a strong incentive to build my business. It’s not only the dollars per patient but the opportunity for practice remodeling and growth of the practice referrals. Not every physician wants to deal with someone who has five comorbidities, but others are becoming more interested if they have the support, referrals, and tools.

**SAUER:** I would ask medical directors if they know how many ESRD members they have and what they’re costing them, and if they know what’s around the curve on those members. I would present it as another opportunity to affect your medical loss ratio in a very positive way. It’s an opportunity to do the right thing to improve quality outcomes, in what was described earlier as a silent issue. That’s because it is not one of the big identifier issues, it’s a very quiet one — quiet but loud. It encompasses all these other comorbidities. You want to be able to ask the chief medical officer and the chief financial officer whether they know what their ESRD population is and what it is costing them — and if they know where these members came from.

**DICKMEYER:** This is a good point, and I suspect that 6 years ago, commercial health plans didn’t know how many ESRD patients they had, but the fact that many now know means that ESRD and renal disease are on the radar screen.

**BAXLEY:** ESRD identification may be driven, at least in the Medicare-age population, by the increased Medicare reimbursement.

**SAUER:** You keep coming back to that increased reimbursement, but that applies only to your Medicare+..."
Choice population. In your commercial population, if you’re collecting a $400-a-month premium on a perfectly healthy patient, you are also collecting a $400-a-month premium on an ESRD patient who is costing you $7,000 a month in medical expenses.

**BAXLEY:** Therefore, in the non-Medicare population, you can talk about the disparity between cost of the ESRD patient and the monthly premiums.

**DICKMEYER:** And we are seeing health plans looking at dialysis contracts and developing strategies with regard to facility contracting.

**BAXLEY:** But, you may need to connect the dots. It is a silent situation; somebody needs to raise the awareness — internally as well as externally — about how these dots are connected.

**SAUER:** You need an external champion who understands that. That’s why you’ve got to ask medical directors: Do you know if you have a problem? If you have a million-member health plan with 500 ESRD patients, anybody who has studied this would say that for every ESRD member, there are three to five CKD members — most of whom you don’t know about. We have done numerous studies reviewing the data of an ESRD population, going back 12 to 18 months from dialysis onset, and we find members who just show up on dialysis. They may have only a short period of claims beforehand — where either no one was managing them for CKD or there were no claims — but they didn’t just get sick, unless an acute onset brought them to the point of requiring dialysis; they were ramping up to dialysis onset, but nobody was looking at it from the perspective that dialysis would be required at some point. Yet the fact that glomerular filtration rate was not being reported is a major issue. Without the GFR being reported, it is likely that the need for the application of therapies to slow deterioration of renal function is not being addressed fully. An example would be a patient who is a silent hypertensive. There are all these comorbid conditions occurring in the background, and the patient suddenly shows up in the emergency room as a dialysis patient. Then, if you go back and look at the predialysis population to compare the number of members in stage 4 CKD to those who make it to stage 5 and begin dialysis, you find that, in most cases, significantly fewer patients are on dialysis than were in the predialysis population. So, the question is: what happened to all the others? Where did they go? The claims for the member who did not cross over to stage 5 simply stopped.

**UHLIG:** I see several aspects that should be considered when designing programs for disease management of CKD. The cost associated with initiation of dialysis in patients who are poorly prepared for kidney failure is a very good reason for managed care organizations to focus on improving care delivered in CKD stages 3 and 4. The “captain of the ship” in the care of advanced stages of CKD really could be from any specialty, as long as this provider can dedicate the resources to coordinate and integrate the increasingly complex care management for these individuals.

The greatest benefit, from a societal standpoint, will derive from identifying individuals with CKD earlier and preventing progression to the later stages of disease that are associated with greater morbidity, mortality, and expenditure. Earlier detection of CKD, as well as improved care at earlier stages of CKD, requires buy-in and education of primary care doctors. Earlier recognition of CKD would be facilitated by more universal testing for albuminuria in individuals at increased risk and by routine laboratory reporting of estimated GFR, along with serum creatinine. Laboratory case-finding methods may be useful.

High turnover of members may make an MCO reluctant to invest in disease management programs that focus on testing of individuals who are at increased risk or on the treatment of early stages of the disease, because of the possibility that claims during late stages will not accrue during coverage by the same MCO. Yet, if one MCO does not identify and treat its patients with CKD early — and if its competitors also do not — then, down the road, it is going to hurt all of them. Encouraging solidarity and a proactive approach in addressing CKD early may appear idealistic, but compelling logic supports this approach.

CKD is not a new disease, but recognition of its epidemic scope is growing. There now is a need to develop and adopt universal clinical performance measures. Because the disease management programs for CKD are so young, there is a need to put them to the test and to rigorously evaluate both cost and quality. In addition, data from the evaluation of demonstration projects should be shared publicly and discussed to outline the best strategies to confine the epidemic. The National Kidney Foundation is extremely interested in collaborating with managed care organizations to implement CKD guidelines and to design and evaluate programs for CKD disease management.

**NASH:** We have covered a great deal of ground in our discussions, from identifying members with CKD to possibly creating a CKD disease management program — complete with fully aligned incentives. I greatly appreciate each of your contributions, and I would like to thank each of our distinguished faculty members personally for their participation.