

Evaluating the Consequences of Multidisciplinary Case Management for Patients with Chronic Renal Failure

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Multidisciplinary case management implies the organization of a cohesive team of experts in a specific disease area who are committed to and responsible for the care of a defined group of patients (1). The promise of case management is to provide more structured delivery of care for patients with complex, chronic conditions, and thereby improve their health outcomes and decrease the cost of care.

For more than 2 decades, the management of patients with end-stage renal disease (ESRD) has been organized according to what may be referred to as a disease-management model. Dialysis and transplant services have teams of physician specialists, dieticians, nurse managers, and social workers. This approach evolved in part because of the complexities of managing ESRD, which affects every organ system, and limits life expectancy and quality of life. Case management for ESRD care never underwent formal testing in randomized trials. It is doubtful that many experts would currently advocate such trials because the theoretical benefits of managing this complex and costly illness with a cohesive, team approach seem compelling when compared with its added costs.

Attention has turned to whether to adopt a team approach at an earlier stage of the disease, when patients are first diagnosed with chronic renal failure (2,3). What are the theoretical advantages of case management in these patients? First, as in many other chronic conditions (4), patients may not have been recommended, nor been adherent to, treatments that have been shown in randomized trials [ie, angiotensin-converting enzyme inhibitors (5) and intensive treatment of diabetes (6)] to stem the progression of renal failure. Second, almost 25% of patients are not seen by a renal specialist within 1 month of needing to initiate ESRD (7). It has been speculated that by seeing a renal specialist the patient is more likely to receive therapies proven to slow the progression of renal

failure (7). Also, there is consensus among renal specialists that patients should be referred within 6 months of their expected time to starting renal replacement therapy to assure placement of an optimal vascular access for hemodialysis (a native arteriovenous fistula instead of a vascular graft or temporary dialysis catheter) (8–10). Indeed, patients who have seen renal specialists are more than twice as likely to receive the more desirable native fistula (7). Also, planned instead of “emergent” initiation of dialysis is associated with fewer hospitalization days, decreased morbidity, and greater patient choice of dialysis modality (hemodialysis versus peritoneal dialysis) (2). Last, many patients with renal failure have other comorbidities, including hypertension, diabetes, and ischemic heart disease, whose management may benefit from a coordinated approach to care (7). In all, it is reasonable that a case-management approach may favorably affect several outcomes (2,3,8–12), including progression to ESRD, prevention of cardiovascular events, improved nutritional status, increased likelihood that the patient receives a native arteriovenous fistula, and greater patient choice in deciding between hemodialysis and peritoneal dialysis.

Harris and colleagues (13) undertook the first prospective, randomized trial of a multidisciplinary case-management intervention in renal disease. They enrolled 437 patients with chronic renal failure from an urban, academic, general medicine practice. Patients were randomly assigned to continue to receive care either through routine practice or through an investigative intervention with a 5-year follow-up period. The central part of the intervention was a 2-year enrollment in The Nephrology Case Management Clinic. Of importance, the medical interventions remained, for the most part, under the primary direction of the general medical physician in communication with the case management physician. Several members of the team focused on medical and dietary compliance, and the patients received instructions about low-protein, low-potassium diets. Overall, there were no significant differences in the primary outcome measures of change in renal function, use of health services, or mortality. The investigators suggest caution when considering whether to adopt a case-management approach for patients with chronic renal failure.

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The study highlights some of the challenges to determining the benefits, risks, and costs of such interventions. First, the study was initiated in the early 1990s when the benefits of specific treatments for stemming the progression of renal disease had not yet been established in clinical trials. Second, only recently has the importance of focusing on outcomes other than the rate of renal progression (eg, the type of vascular access the patient receives) been established. Third, the primary care physicians in this study maintained control over whether the renal team's recommendations were implemented; the study was not designed to address whether outcomes would differ if the renal team had been given authority for implementing its recommendations. For these reasons, in retrospect, it seems likely that the risk was high of *not* finding a difference between groups in the primary outcomes, if such a difference actually exists. The results are disappointing, not because they are particularly unexpected, but because there remains a substantial need to find ways to translate the health benefits of interventions, such as tight control of blood sugar in diabetes patients, proven to work in clinical trials into corresponding health benefits in non-trial situations.

We agree with the investigators that current evidence does not favor widespread adoption of case management for patients with chronic renal failure. However, success in science often is preceded by disappointments. The need has never been greater to continue investigating new systems of care that show promise to improve outcomes for patients with renal disease. Rather than dismiss case management for renal disease at this time, the issue is to decide what lessons were learned so as to design a better intervention. The next attempt should incorporate the newer concepts of reducing the risk of progression of renal disease, examine a broader range of outcomes, and consider the value of empowering the case-management team to implement its recommendations.

An additional issue in evaluating case-management programs is deciding what evidence is sufficient to recommend changing clinical practice. The randomized clinical trial is held as the gold standard of evidence because of high degree of internal validity in establishing a causal link between the intervention and the study outcomes. There are many examples in which associations found in nonrandomized studies did not hold up to the scrutiny of a randomized trial. For example, contrast the prior epidemiological findings with the results of the recently published HERS study on use of estrogen/progestin to prevent coronary events in postmenopausal women (14). By contrast, some of the difficulties with randomized trials are evident in this study. They are expensive and time consuming, the latter being particularly important in this instance because the scientific understanding of managing chronic renal disease had progressed during the time the trial was being conducted.

Also, when the main uncertainty is how to extend an effective intervention to new populations, controversy may evolve over the ethics of randomization (15). Case management has proven safe and effective for selected patient populations (16). As the authors imply, the main source of uncertainty for the use of case management in renal disease does not concern its safety compared with a less structured system, but whether its effectiveness is outweighed by its costs. Techniques based on the principles of cost effectiveness are being developed to help investigators design trials that will address these questions (17,18).

We remain cautiously optimistic about the potential of case management for patients with chronic renal failure. Investigators, managed care organizations, and potential sponsors, working together and learning from experience of the current study, should consider new designs for case management interventions. If an intervention has the right ingredients to improve outcomes for patients with chronic renal failure, a systematic evaluation in a prospective, cost-effectively designed clinical trial is most likely to provide the evidence needed to motivate organizations to adopt a new standard of care.

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