Sickness brought me this
Thought, in that scale of his:
Why should I be dismayed
Though flame had burned the whole
World, as it were a coal,
Now I have seen it weighed
Against a soul?

William Butler Yeats
“A Friend's Illness”
Advancing comorbidity in the ESRD population—particularly as it relates to the burden of diabetes, cardiovascular disease, and infectious complications—has led to an evolution in ways to improve short- and long-term outcomes. In the 1990s, discussions on quality of care were focused on delivered dialysis, anemia management, and vascular access. Recently, however, the National Kidney Foundation has built on the strong base of its initial K/DOQI guidelines, expanding these guidelines into wider areas of care and adding new momentum to concerns over cardiovascular disease as the major cause of death in ESRD patients.

On the next page we illustrate progress toward some of these guidelines. Data from CMS’s Clinical Performance Measures (CPM) project show that, as measured by Kt/V and URR, 90 percent of hemodialysis patients are receiving adequate therapy. Seventy-four percent of those on peritoneal dialysis are meeting the therapy target of a Kt/V of 2.0 or greater per week; this target, however, is currently being reviewed by the K/DOQI workgroups. Vascular access complications continue to be a central area of concern; with associations repeatedly shown among the use of native fistulas, the best long-term function, and the fewest complications, K/DOQI guidelines recommend that at least 50 percent of new patients, and 40 percent of prevalent ones, use this type of access. But while fistula use has grown in each population, we are still far from reaching both these target levels and the levels now achieved in Europe and Asia. We are, however, closer to meeting the target for anemia—a focus of treatment since the introduction of epoetin in the summer of 1989. Eighty-three percent of patients now meet or exceed the target hemoglobin level of 11g/dl.

While albumin level is traditionally used as marker of visceral protein stores, it is also a marker of inflammatory load; albumin synthesis is reduced and levels fall in response to infectious complications, and investigators have noted that the heavy inflammatory load of patients with kidney disease is associated with low albumins. Under K/DOQI guidelines the albumin of all patients should reach the lower limit of normal; currently, however, only 36 percent meet this target. It is not clear if this objective can be reached without a major effort directed at the inflammatory load carried by patients with chronic kidney disease.

On the next spread we examine diabetic care in the ESRD and general Medicare populations. The measurement of glycemic control—a cornerstone of diabetes management—has steadily improved, with 74 percent of dialysis patients, and 67 percent of those with a transplant, now receiving at least one glycosylated hemoglobin test each year. Forty-five percent of
the diabetic ESRD population now receive four or more tests, a measure of significant progress. Since the actual level of glycemic control is not reported in the Medicare data, more detailed assessment will require primary data collection.

With cardiovascular disease the leading cause of death in both diabetic and non-diabetic populations, lipid monitoring is also central to diabetes care. Fifty-eight percent of diabetic ESRD patients received at least one lipid test in 2002—quite different from the 75 percent level achieved in the general Medicare population.

Prescription drug therapy for diabetes and its complications is an important gauge of treatment intensity. The use of hypoglycemic agents other than insulin has been central to the improvement of glycemic control, with newer insulin sensitizers and secretagogues shown to be particularly effective at improving control in more complex patients. And clinical trials with ACE inhibitors, ARBs, and beta blockers have established their efficacy in the treatment of heart failure and as renoprotective agents. In this chapter we introduce new data on drug therapy in diabetic patients and for cardiovascular disease; in Chapters One and Three we also look at therapy in the CKD and incident ESRD populations.

Overall trends in anemia management are illustrated in the Précis; here we focus on management at the provider level. Individual providers appear to titrate epoetin doses to achieve specific hemoglobin levels; those with average levels of 11–12 g/dl, for example, give doses that maintain patients in this range. In general, when hemoglobin levels are low or high, doses are adjusted so that in subsequent months these levels move toward the K/DOQI target range of 11 g/dl or greater. Some for-profit providers maintain a large proportion of patients at 12 g/dl or above, suggesting a different approach to anemia management. Hemoglobin levels consistently below 11 g/dl tend to occur in EPO-resistant patients, including those with infections, cancer, chronic blood loss, AIDS, inflammatory kidney disease, and cardiovascular disease.

New data show that the use of a dialysis catheter as the initial form of vascular access appears to be growing, and that patients with this access have the highest URRs. These higher ratios may be related to recirculation, or to the longer treatment times necessitated by reduced blood flow rates or collapsing within the extracorporeal circuit.

In patients with catheters as their initial access, replacement with another catheter occurs at five times the rate of replacement with an internal access, and the rate of infectious events is 1–1.5 episodes per patient year. In patients whose initial access is a fistula, replacement with a catheter occurs up to twice as often as replacement or revision of the fistula. Replacement and revision rates are, as expected, much higher in patients with arteriovenous grafts, as are rates of declotting and angioplasty procedures; infection rates, however, are lower, which may reflect the increased early use of catheters in patients who later receive fistulas. Patients who initiate on peritoneal dialysis have PD catheter replacement rates of 0.8 per patient year, and peritonitis rates of up to 1.2; data on these complications may provide insight into the increased rates of infectious complications seen in this population (see Chapter Six for more information), and into the higher event rates of peritoneal dialysis patients in their second year of therapy.
Glycosylated hemoglobin (HbA1c) testing

[5.2] Geographic variations in the percent of patients receiving HbA1c testing

Prevalent ESRD patients

General Medicare patients

100
80
60
40
20
0

Percent of patients

ESRD (prevalent)

4+ tests
3 tests
2 tests
1 test
No tests

Race/ethnicity

Age

White
Black
N Am
Asian
Hispanic

All
18-30
31-40
41-50
51-60
61-70
71-75

Dialysis
Transplant

Prevalent ESRD patients

General Medicare patients

71.6+ (80.5)
64.1 to <71.6
57.6 to <64.1
50.4 to <57.6
below 50.4 (34.5)

82.5+ (85.6)
79.1 to <82.5
75.3 to <79.1
69.5 to <75.3
below 69.5 (55.5)

71.6+ (76.7)
64.1 to <71.6
57.6 to <64.1
50.4 to <57.6
below 50.4 (44.7)

Lipid monitoring

[5.5] Geographic variations in the percent of patients receiving lipid testing

[5.6] Lipid testing in ESRD & gen. Medicare pts

Prevalent ESRD patients

General Medicare patients

100
80
60
40
20
0

Percent of patients

ESRD (prevalent)

4+ tests
3 tests
2 tests
1 test
No tests

Race/ethnicity

Age

White
Black
N Am
Asian
Hispanic

All
18-30
31-40
41-50
51-60
61-70
71-75

Dialysis
Transplant

Prevalent ESRD patients

General Medicare patients

71.6+ (80.5)
64.1 to <71.6
57.6 to <64.1
50.4 to <57.6
below 50.4 (34.5)

82.5+ (85.6)
79.1 to <82.5
75.3 to <79.1
69.5 to <75.3
below 69.5 (55.5)

71.6+ (76.7)
64.1 to <71.6
57.6 to <64.1
50.4 to <57.6
below 50.4 (44.7)
lycosylated hemoglobin testing (HbA1c) is more common in the general Medicare population than in ESRD patients (Figure 5.2). In 1992–1993 only one in five diabetic ESRD patients received any testing; by 2001–2002, however, the number had grown to 76 percent, close to the level in general Medicare patients (Figure 5.3). Forty-five percent of diabetic ESRD patients now receive four or more tests annually—an improvement, but still a significant distance from fulfilling the guidelines of the American Diabetic Association, which recommend that all patients with complex disease burdens receive at least four tests per year. Testing rates are slightly higher in dialysis patients than in those with a transplant (Figure 5.4). And for reasons currently unclear, the youngest patients are least likely to receive testing.

Except for areas in the Upper Midwest, the Northeast, Florida, and the West Coast, more general Medicare patients nationwide receive lipid testing than ESRD patients (Figure 5.5). Seventy-five percent of diabetics in the general Medicare population receive some lipid monitoring, compared to 58 percent of ESRD patients (Figure 5.6). Testing rates are dramatically different between the modalities—81 percent of diabetic transplant patients are tested, compared to only 55 percent of those on dialysis (Figure 5.7). And rates differ as well for Native Americans, with only 34 and 57 percent of dialysis and transplant patients receiving a lipid test.

In 1997 Medicare increased the benefits for diabetics to include glucose testing supplies. Both the ESRD and general Medicare populations have expanded their use of this benefit over the last five years; nationwide, however, general Medicare patients are more likely to receive these supplies (Figure 5.8). In the diabetic ESRD and general Medicare populations, 62 and 58 percent of patients, respectively, receive no prescription for blood glucose tests or reagent strips, and only 11 and 8 percent are prescribed supplies sufficient for testing two or more times per day (Figure 5.9). Transplant patients receive diabetic testing supplies more frequently than those on dialysis, while the lowest prescription rates occur in patients age 18–30 and in those of Native American descent (Figure 5.10).
Prescription drug therapy for diabetic patients

Clinical care

5.11 Cumulative percent of diabetic patients receiving insulin, by age

5.12 Cumulative percent of diabetic patients receiving metformin, by age

5.13 Cumulative percent of diabetic patients receiving thiazolidinediones, by age

5.14 Cumulative percent of diabetic patients receiving secretagogues, by age

5.15 Cumulative % of diabetic CVD pts receiving ACE inhibitors or ARBs, by age

5.16 Cumulative % of diabetic CVD patients receiving beta blockers, by age
or analyses of prescription drug use we have used the Medstat MarketScan database of Employer Group Health Plan (EGHP) patients.

Approximately 60 percent of diabetic ESRD patients receive insulin, compared to only 25–37 percent of non-ESRD patients (Figure 5.11). This may be because ESRD patients are rarely prescribed metformin (the risk of lactic acidosis increases with the degree of kidney impairment), because diabetes is more advanced and difficult to control in ESRD patients, or because the ESRD population has a different mix of Type 1 and Type 2 diabetes. Insulin use has remained stable in both ESRD and non-ESRD patients, despite the addition of several oral agents to the market.

The percentage of non-ESRD patients with diabetes who take metformin has increased substantially (from 31 to 40 percent in patients age 20–44, and from 42 to 49 percent in those age 45–64; Figure 5.12). Metformin was used in less than 2 percent of ESRD patients in 2002.

Only 7–16 percent of diabetic ESRD patients receive thiazolidinediones (rosiglitazone, pioglitazone), a number substantially lower than the 22–31 percent of their non-ESRD counterparts (Figure 5.13). It is interesting that these drugs are not being used more frequently in the ESRD population, as they are not contraindicated in ESRD patients, and can be used either with or without insulin to improve the sensitivity of tissues to insulin. Secretagogues, such as sulfonylureas, nateglinide, and repaglinide, are also used more frequently in the non-ESRD population (34–47 percent) than in patients with ESRD (9–17 percent; Figure 5.14).

Figures 5.15–19 show the cumulative percentage of diabetic patients with cardiovascular disease (CVD) receiving key cardiovascular-related drugs. It is important to note that the subpopulation of diabetic patients with CVD and age 20–44 is quite small, and thus conclusions cannot be drawn about this group. The percentage of patients receiving ACE inhibitors/ARBs, beta blockers, and lipid-lowering agents increased overall from 2000 to 2002 in both ESRD and non-ESRD patients. ACE inhibitor/ARB use is lower in ESRD than non-ESRD patients, while the reverse is true for the use of beta-blockers (Figure 5.15).

The use of calcium channel blockers (CCBs) is also greater in the ESRD population; this may reflect the effectiveness of dihydropyridone CCBs in treating hypertension in ESRD patients, and merits further investigation. Use of CCBs in older non-ESRD patients has fallen, while it has remained stable in their ESRD counterparts (Figure 5.17).

The use of lipid-lowering agents is greatest in non-ESRD patients, despite the fact that all ESRD patients are considered to be at the highest risk of coronary disease, warranting aggressive lipid-lowering therapy (Figure 5.18). The general use of anticoagulants (low-molecular weight heparins and coumadin) has decreased slightly in ESRD patients, but still remains greater than in non-ESRD patients.

(Figures 5.11–19) prevalent EGHP patients with ESRD, age 20–64. Two-year study period includes a one-year selection period, used to define comorbidity, & a one-year observation period, used to count prescription drug therapy. Months shown are months in the observation period.
The cumulative percent of dialysis patients taking ACE inhibitors or ARBs grew consistently during all study periods, and was slightly higher in the later years. The most noticeable increases have taken place in females and diabetics (Figure 5.20). Less than 43 percent of diabetic patients received lipid-lowering agents in 2002, despite being at high risk for atherosclerotic heart disease. Use of diuretics appears to be declining, which may reflect increasing vintage within the dialysis population.

In dialysis patients with congestive heart failure, use of ACE inhibitors, ARBs, and beta blockers generally increased, and 61–64
(5.22) Cumulative percent of prescription drug use in prevalent dialysis patients with CVD, by age, gender, & diabetic status

(5.23) Cumulative percent of prescription drug use in prevalent dialysis patients with hypertension, by age, gender, & diabetic status

percent of patients with diabetes have a prescription for these drug classes (Figure 5.21). Digitalis preparations are used in less than 16 percent of patients with CHF, and nearly 28 percent of those with diabetes as well received diuretic therapy in 2002.

In dialysis patients with CVD the use of ACE inhibitors/ARBs has remained steady since 2001 (Figure 5.22). Rates are slightly higher in diabetics compared to non-diabetics. Patients with diabetes had the highest use of lipid lowering agents in 2002.

There has been a noticeable increase in the use of ACE inhibitors or ARBs since 2000 in various groups of patients with hypertension (Figure 5.23). In females and diabetic patients, for example, use of these agents grew 15–16 percent between 2000 and 2002. The use of beta blockers in the diabetic patients has also increased markedly, from 35 percent in 2000 to 48 percent in 2002.

Figures 5.20–23 prevalent EGHP dialysis patients, age 20–64. Two-year study period includes a one-year selection period, used to define comorbidity, & a one-year observation period, used to count prescription drug therapy. Months shown are months in the observation period.
In order to reach hemoglobin levels recommended by the National Kidney Foundation’s anemia practice guidelines, dialysis units are encouraged to follow EPO dosing guidelines. Dosing patterns are clearly different among different providers (Figures 5.24–25). In patients who initiate dialysis with hemoglobins less than 10 g/dl and in those with hemoglobins less than 10 after six months, for example, Group 1 providers (Fresenius, DaVita, and Renal Care Group) appear to give higher doses of EPO compared to all other providers, as much as 20–35 units/kg/week.

In prevalent patients with average hemoglobin levels less than 10 g/dl, EPO dosing is similar in both groups of chain-affiliated units, at 428–429 units/kg/week; dosing is lowest in units that are independently owned, at 362 (Figure 5.26).

It appears that providers are adjusting EPO doses accordingly with hemoglobins, and that the percent of patients on IV iron rises with vintage (Figure 5.27). In most providers at least two-thirds of patients have hemoglobins of 11–12 g/dl (Figures 5.28–29). The percent of providers whose patients have hemoglobins of 12 g/dl or greater is highest in the Southwest and West, and mean EPO doses and IV iron use are highest in the eastern half of the country, (Figures 5.30–32).
(5.27) Provider-level anemia treatment, by patient-level hemoglobin (g/dl)

<table>
<thead>
<tr>
<th>Hemoglobin 12+ g/dl</th>
<th>Hemoglobin 11–&lt;12 g/dl</th>
<th>Hemoglobin &lt;11 g/dl</th>
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<tr>
<td>36.1+ (47.3)</td>
<td>31.9+ (41.3)</td>
<td>12.1+ (14.3)</td>
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<td>27.9 to &lt;36.1</td>
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<td>below 10.3 (3.4)</td>
<td>below 9.4 (2.7)</td>
<td>below 8.0 (1.4)</td>
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<tr>
<td>Insuff. data</td>
<td>Insuff. data</td>
<td>Insuff. data</td>
</tr>
</tbody>
</table>

(5.28) Distribution of hgb groups, by provider

(5.29) Distribution of hgb groups, by unit type

(5.30) Geographic variations in provider distribution, by unit-level mean hemoglobin

(5.31) Geographic variations in provider-level mean weekly EPO dose (in thousands of units), by unit-level mean hemoglobin

(5.32) Geographic variations in the percent of patients who receive iron, by unit-level mean hemoglobin
Persistently low hemoglobin levels are an area of concern, as they may reflect an increased burden of comorbidity, infectious complications, or erythropoietin resistance secondary to inflammation or hyperparathyroidism. Here we show the characteristics of patients whose hemoglobin level, on average, is less than 11 g/dl after the first six months of ESRD treatment.

Overall, hemoglobin levels in this group tend to rise slowly during these six months to just over 10 g/dl, with the lowest quartile at approximately 9.2 g/dl and the highest at 10.7 g/dl (Figure 5.33). Erythropoietin doses per week also tend to climb, with a median of approximately 28,000 units per week and an inter-quartile range of 18,000–40,000. At the end of six months, approximately 56 percent of patients with persistently low hemoglobins (less than 11 g/dl) have received iron.

Compared to patients with higher hemoglobin levels, those with low hemoglobins have greater dialysis catheter use, lower use of arteriovenous fistulas, and comparable use of arteriovenous grafts (Figure 5.34). These patients also appear to have more diagnoses of solid tumors and chronic blood loss, a greater likelihood of AIDS, inflammatory diseases, and cardiovascular disease in general, and a markedly greater likelihood of CHF (Figure 5.35).

Again compared to patients with hemoglobin levels of 11 g/dl and above, patients with lower levels have higher rates of infections and thrombotic complications—including sepsis and clotting—in the six months after initiation (Figure 5.36). The rate of septic episodes in those with lower hemoglobins, for example, is more than double that found in the higher hemoglobin group. Infection rates for all causes of infections are also greater in these patients.
Since infectious complications generate high cytokine levels, which in turn contribute to erythropoietin resistance, it is not clear whether anemia per se leads to these higher rates of complications, or whether the anemia is a consequence of persistent infectious events.

(Figure 5.37). Since infectious complications generate high cytokine levels, which in turn contribute to erythropoietin resistance, it is not clear whether anemia per se leads to these higher rates of complications, or whether the anemia is a consequence of persistent infectious events.
recent guidelines published by the NKF in their Kidney Disease Outcomes Quality Initiative concluded that clinical outcomes in hemodialysis patients could be improved with increased use of arteriovenous (AV) fistulas. Figures 5.38–40 provide information on access use at the initiation of hemodialysis.

Dialysis catheters remain the access of choice among providers, and their use appears to be on the rise despite NKF recommendations. Catheter use varies little among age, gender, racial/ethnic, and diabetic groups. AV fistulas are used in 30 percent of patients initiating dialysis (see Figure hp.8). Use is more frequent in males than in females, and 5–6 percent lower in blacks compared to patients of other racial/ethnic groups. Approximately 5 percent more non-diabetic patients receive AV fistulas than diabetics. As is the case with AV fistulas, use of AV grafts continues to fall (Figure 5.40). There is little difference in use between age groups, while 3.8 percent more males receive AV grafts than females. Use is higher in blacks and Hispanics, and slightly higher in diabetics than in non-diabetics.

Urea reduction ratio (URR) is a measurement of dialysis dose. NKF guidelines recommend a minimum URR of 65 percent ($K_t/V$ of 1.2). In 2001, 19.4 percent of patients with catheters had URRs below the target, while percentages below target for those with AV fistulas and AV grafts were 13.3 and 15.2, respectively (Figure 5.41).

Patients with dialysis catheters are nearly six times more likely to have their accesses replaced with another catheter than with an internal access, and rates of sepsis in these patients are one and a half times higher than rates of infection (Figures 5.42–45). Infection rates in patients with catheters are as much as two and a half times higher than those in patients with internal accesses, while rates of sepsis are 1.5–2.0 times higher. Peritoneal dialysis patients are four to five times more prone to suffer from peritonitis than from an infection or sepsis.

Examples of Figures 5.38–41 prevalent hemodialysis patients, CPM data; includes only patients who are also in the USRDS database, who begin dialysis prior to October 1 of the prevalent year, & whose first access is known. Year represents the prevalent year & the year the CPM data were collected. URR in Figure 5.41 represents the median value of the total (up to three) URR measurements reported in the CPM data. Figures 5.42–44 incident hemodialysis patients who are also in the CPM database, 1999–2001 combined; includes patients whose first access is the access addressed in the figure. First access determined from CPM data. Events & complications identified from claims during the first year after the first service date; events identified from Part B CPT codes, & infections/sepsis from Parts A & B ICD-9-CM codes. Figure 5.45 incident peritoneal dialysis patients who are also in the CPM database, 1999–2001 combined. Events & complications identified from claims during the first year after the first service date; events identified from Part B CPT codes, & infections/sepsis from Parts A & B ICD-9-CM codes.
(5.42) Rate of catheter events & complications in the first year of dialysis
in patients whose first access is a catheter

(5.43) Rate of AV fistula events & complications in the first year of dialysis
in patients whose first access is an AV fistula

(5.44) Rate of AV graft events & complications in the first year of dialysis
in patients whose first access is an AV graft

(5.45) Rate of PD catheter events & complications in the first year of dialysis
in patients whose first access is a peritoneal dialysis catheter

{5.42} Rate of catheter events & complications in the first year of dialysis
in patients whose first access is a catheter

{5.43} Rate of AV fistula events & complications in the first year of dialysis
in patients whose first access is an AV fistula

{5.44} Rate of AV graft events & complications in the first year of dialysis
in patients whose first access is an AV graft

{5.45} Rate of PD catheter events & complications in the first year of dialysis
in patients whose first access is a peritoneal dialysis catheter
Diabetic care

[Figures 5.2–4] Hemoglobin A1c monitoring in prevalent ESRD patients is less than that of the general Medicare population. Of those tested, ESRD patients tend to receive more measurements in a year. [Figures 5.5–7] ESRD patients are less likely than general Medicare patients to have lipid testing at least once per year, with 42 percent of patients receiving no tests. At least 80 percent of transplant patients have at least one lipid test each year.

Prescription drug therapy for diabetic patients

[Figure 5.11] Substantially more diabetic patients with ESRD receive insulin therapy than those without. [Figure 5.12] Diabetic ESRD patients rarely receive metformin because of the risk of lactic acidosis, but use in the general diabetic population has increased greatly. [Figures 5.15–16] The use of ACE inhibitors/ARBs and beta blockers has grown in both ESRD and non-ESRD patients. About 52 percent of older ESRD patients with CVD receive beta blockers, a slightly higher percentage than in their non-ESRD counterparts. [Figure 5.19] The use of anticoagulants is higher in CVD patients with ESRD than in those without, but has fallen since 2000.

Prescription drug therapy for cardiovascular disease

[Figure 5.20] Despite their high risk of atherosclerotic heart disease, fewer than 45 percent of diabetic dialysis patients with ESRD received lipid-lowering agents in 2002. [Figure 5.21] In dialysis patients with CHF, ACE inhibitor/ARB and beta blocker use has generally increased, but digitals preparations are used in less than 15 percent of these patients. [Figure 5.22] In the dialysis population with CVD, use of ACE inhibitors/ARBs, beta blockers and lipid-lowering agents is highest in diabetic patients. [Figure 5.23] Between 2000 and 2001, the use of ACE inhibitors/ARBs and beta blockers grew substantially in female and diabetic dialysis patients with hypertension.

Provider management of anemia

[Figure 5.27] Trends in hemoglobin levels over time show that patients with high or low hemoglobin levels converge towards the K/DOQI guidelines. Certain providers appear to target higher levels. Although EPO doses appear to fall by about 20 percent for patients with hemoglobins above 12 gm/dl, continued dose reductions do not appear to be present over a six-month period. Iron appears to be consistently given to 80–85 percent of patients.

Clinical characteristics of patients with hemoglobins less than 11 g/dl

[Figure 5.34] Compared to patients with higher hemoglobin levels, those with low hemoglobins have greater dialysis catheter use, significantly lower use of arteriovenous fistulas, and comparable use of arteriovenous grafts. [Figure 5.36] Patients with hemoglobin levels less than 11 g/dl have higher rates of infections and thrombotic complications—including sepsis and clotting—in the six months after initiation of therapy.

Vascular access events

[Figure 5.39] The use of dialysis catheters in incident patients has changed little, with catheters used as the first access in approximately 70 percent of new patients. [Figures 5.42–45] Patients whose first access is a dialysis catheter are almost 2.5 times more likely to have it replaced with a catheter than with an internal access. Infections and sepsis are common in these patients, much more so than in those who have an arteriovenous fistula as their first access.

Maps: National means & patient populations

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