



The DOPPS Practice Monitor (DPM): Emerging trends in clinical dialysis care (August 2010 to August 2011)

Updated: January, 2012

Emerging trends in US dialysis care are included in the latest update to the DOPPS Practice Monitor (DPM), a public website (<http://www.dopps.org/DPM>) of the Dialysis Outcomes and Practice Patterns Study (DOPPS) at Arbor Research Collaborative for Health. Based on a national sample of US hemodialysis patients and facilities, the DPM provides the earliest nationally representative, publicly available data to report contemporary trends in dialysis care. In August 2011, we reported trends in US dialysis care through April 2011. We now report data through August 2011.

Background – Ongoing Changes in the US Dialysis Environment

The DPM was originally launched to report trends in dialysis care before, during, and after implementation of the new Prospective Payment System (PPS). The PPS, launched in January 2011 as an initiative of the Centers for Medicare & Medicaid Services (CMS), is intended to control dialysis costs through bundled payments (that is, fewer separately billable medications and services). Another important payment change is the Quality Incentive Program (QIP) beginning in 2012. The QIP is the first Medicare program that links provider or facility payments to performance based on achievement of specific quality measures.

Since our last update, the FDA-approved prescribing information for erythropoiesis-stimulating agent (ESA) use was revised in June 2011. Previously, the label recommended a hemoglobin target range of 10-12 g/dL. The June 2011 update removed the target range, advising physicians instead to start ESA therapy at hemoglobin less than 10 g/dL and to reduce or interrupt the dose when the hemoglobin approaches or exceeds 11 g/dL. The FDA said the changes are based on clinical trials showing that using ESAs to target hemoglobin greater than 11 g/dL in patients with CKD provides no additional benefit and increases the risk of adverse cardiovascular events such as stroke. The new prescribing information provides language to individualize maintenance dosing and recognizes the benefit of limiting the need for blood transfusions.

In July 2011 shortly after release of the new ESA label, CMS released a proposed rule for the QIP to eliminate the payment penalty for hemoglobin less than 10 g/dL, but keeping the penalty for hemoglobin above 12 g/dL. This was incorporated into the final rule for the 2013 QIP (which has a 2011 performance period).

To follow effects of these policy changes, we summarize here data in our national sample, trends separately in large/medium-chain and small-chain/independent facilities, and trends in black and non-black patients. The comparison by race is in response to a 2010 US Government Accountability Office report which highlighted that black patients, who have above-average dialysis costs, may be especially likely to experience changes in care with Medicare's new dialysis payment system.



Interpretation of DPM findings

Details about the DPM facility sample, as well as data demonstrating comparability to national data (e.g., CMS data and ELabs), are in the “Study Sample and Methods” document accessible from the DPM home page. We’d like to emphasize several points with respect to interpretation of DPM findings:

- For early trends, additional follow-up is warranted to understand if findings persist over time.
- Trends require confirmation with national data when eventually available.
- Trends in clinical care may not necessarily affect patient outcomes, and careful evaluation to understand the effect on patient outcomes, if any, is warranted.
- DPM data are aggregated across dialysis organizations and facilities. Dialysis organizations and facilities are not identified individually. Aggregated trends may not reflect trends in individual dialysis organizations or facilities, and are not intended to provide oversight of performance in individual dialysis organizations or facilities.

Notable changes over this August 2010 through August 2011 period, as well as trends in areas with higher likelihood of change due to changing incentives and oversight, are summarized in this document. An interim "data refresh" is expected in February 2012 and will provide additional data collected through August 2011. The next major update of the DPM website is expected in April 2012 and will provide data through December 2011.

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Trends in Clinical Practice

Summary

Over the August 2010 to August 2011 time period, many hemodialysis practices have remained stable; examples include nutrition measures and hemodialysis treatment time and dose. Trends in the following areas are noted:

Anemia: Hgb levels have decreased since the June 2011 ESA label update. While the mean hemoglobin level declined by 0.12 g/dL over 10 months from August 2010 to July 2011, it declined in August 2011 by another 0.10 g/dL to 11.26 g/dL. The percentage of patients with hemoglobin levels greater than 12 g/dL declined sharply (from 28% to 23%) in July/August 2011, while the percentage with hemoglobin levels less than 10 g/dL increased slightly from 8.5% to 10% and the percentage with hemoglobin levels less than 9 g/dL remained under 3%. Mean prescribed erythropoietin (epoetin) dose (among patients receiving epoetin) decreased 15% from August 2010 to August 2011, with the greatest decline occurring in June-August 2011. Epoetin doses at the higher end of the dose range have decreased most notably. Overall IV iron use has increased over the August 2010 to August 2011 time period, though has recently stabilized. In keeping with greater IV iron use, serum ferritin levels (indicative of iron stores) have continued to rise. Serum ferritin concentration exceeded 500 ng/mL among 65% of patients, exceeded 800 ng/mL among 34% of patients, and exceeded 1,200 ng/mL in 11% of patients, in August 2011.

Mineral bone disorder: In our last report, we noted a 29% increase in serum PTH levels through April 2011, and differences by race were noted. Since then, PTH levels have remained stable or declined slightly in both black and non-black patients. In August 2011, 22% of black patients and 12% of non-black patients had very high PTH values (defined here as PTH >600 pg/mL). The percentage of hemodialysis patients for whom PTH is measured has declined slightly since August 2010. There have been no clear changes in serum calcium or serum phosphorus levels.

Clinical Outcomes: Preliminary data indicate that the 30-day annualized hospitalization rate has increased somewhat from August 2010 to August 2011. The DPM does not report yet on trends in red blood cell transfusions, as dialysis units are often unaware of transfusions occurring in the inpatient setting. Additional efforts to comprehensively monitor trends in transfusions are warranted. To date mortality rate has not changed appreciably, though further follow-up time is warranted and we will continue to track this critical outcome.

Future monitoring of these trends, confirmation with national data when eventually available, and understanding their effect on clinical outcomes, if any, are warranted.

A more detailed overview, as well as trends by dialysis organization size and race, are provided below. Graphics, underlying data tables, sampling and weighting techniques, and other calculation methods are provided at <http://www.dopps.org/DPM>. Selected graphics are reproduced here. Research papers describing the DPM methods [*Robinson et al, Am J Kidney Dis (2011) 57: 822-831*] and an overview of findings through April 2011 [*Robinson et al, Am J Kidney Dis (2012); In press*] have been published.

Anemia

Lab values

- Hemoglobin (Hgb):
 - **Nationwide:** Mean hemoglobin levels among all patients declined by 0.12 g/dL over 12 months from August 2010 to July 2011, and then decreased by another 0.10 g/dL in August 2011 to 11.26 g/dL. Median hemoglobin levels followed a similar pattern during this time period. The percentage with Hgb >12 g/dL decreased from 31.4% to 28.0% through June 2011, and then had a sharper decline to 22.6% in August 2011. The percentage with Hgb >13 g/dL decreased from 8.7% in August 2010 to 6.4% in August 2011. The percentage with Hgb <10 g/dL increased from 8.5% to 10.0%, and the percentage with Hgb <9 g/dL remained stable (2.8-2.9%).
 - **Dialysis organization size:** Mean hemoglobin levels declined in large/medium-chain facilities from 11.52 in August 2010 to 11.37 g/dL in April 2011, and then declined further to 11.26 g/dL in August 2011. Mean hemoglobin levels among small-chain/independent facilities decreased from 11.49 g/dL in January 2011 to 11.24 g/dL in August 2011. The percentage with Hgb >12 g/dL decreased by 10-11% in both large/medium-chain facilities and small-chain/independent facilities. The percentage with Hgb <10 g/dL was similar in large/medium-chain and small-chain/independent facilities.
 - **Race:** In August 2010, mean hemoglobin levels were 0.07 g/dL higher in blacks than in non-blacks. From August 2010 to April 2011, mean hemoglobin levels decreased more rapidly in blacks than non-blacks (0.19 g/dL versus 0.06 g/dL). By August 2011, the hemoglobin levels in both groups were similar. The percentage with Hgb >12 g/dL decreased by 10.3% in black and 8.2% in non-black patients, and the percentage with Hgb <10 g/dL increased slightly and were comparable in both groups.
- Serum Ferritin:
 - **Nationwide:** Median serum ferritin (most recent value within 3 months) increased from 555 ng/mL in August 2010 to 598 ng/mL in April 2011 and then to 647 ng/mL in August 2011. The 90th percentile of ferritin values increased from 1049 ng/mL in August 2010 to 1235 ng/mL in August 2011. The percentage with ferritin <200 ng/mL did not change substantially (varying from 8-12%), while the percentage with ferritin >800 ng/mL increased from 26.0% to 34.1%, and the percentage with ferritin >1200 ng/mL increased from 6.5% to 11.2%. The percentage of patients with a quarterly measurement of ferritin decreased from 91.8% in August 2010 to 85.3% in August 2011.
 - **Dialysis organization size:** The percentage with ferritin >800 ng/mL remained relatively stable in large/medium-chain facilities at ~29-30% through June 2011, but increased to 35.0% in August 2011. Among small-chain/independent facilities, a smaller increase was observed. The percentage of patients with ferritin <200 ng/mL decreased in large/medium-chain facilities (from 12.4% in August 2010 to 7.9% in August 2011), while among small-chain/independent facilities the percentage remained at 10-11%.
 - **Race:** No substantial differences in trend by race.
- Transferrin saturation (TSAT):
 - **Nationwide:** There was no substantial change in median TSAT levels (~28%) through June 2011, and a slight increase is observed in July/August 2011. The percentage with TSAT <20% declined from 20.0% in August 2010 to 17.3% in April 2011, and later to 15.4% in August 2011. The percentage with TSAT >50% was relatively stable at 7-9%.



- **Dialysis organization size:** No substantial differences in trend by dialysis organization size.
- **Race:** No substantial differences in trend by race.

Medications

- Erythropoietic stimulating agent (ESA) use and route:
 - **Nationwide:** No substantial change in the percentage of patients prescribed ESA over 1 month (~88-90%). ESAs used included epoetin, as well as darbepoetin in a minority of facilities.
 - **Dialysis organization size:** Subcutaneous administration increased from <2% to 10-15% in small-chain/independent facilities, versus little change in large/medium-chain facilities (~1% of patients). This was principally due to a change to the subcutaneous route for most patients in a small number of small-chain/independent facilities.
 - **Race:** Subcutaneous administration increased from 1.2% to 3.8% in non-black patients versus little change in black patients (<1% of patients), as facilities switching to subcutaneous administration served mostly non-black patients.
- Prescribed IV epoetin dose:
 - **Overall:** Mean prescribed epoetin dose (among patients receiving epoetin) decreased by 15%, from 21,100 units/wk to 17,900 units/wk, from August 2010 to August 2011, with the greatest decline in June-August 2011. The percentage of patients prescribed epoetin doses >50,000 units/week decreased from 11.6% in August 2010 to 6.5% in August 2011.
 - **Dialysis organization size:** The mean prescribed epoetin dose has remained ~35% lower in small-chain/independent facilities compared to large/medium-chain facilities, with proportionally similar declines by dialysis organization size. The percentage of patients prescribed epoetin doses >50,000 units/week decreased from 12.9% to 6.7% in large/medium-chain facilities versus no substantial change in small-chain/independent facilities (~2%).
 - **Race:** Black patients continue to be prescribed ~15% higher epoetin doses than non-black patients on average. No substantial differences in trend by race over this time period.
- Administered IV epoetin dose:
 - **Preliminary data (not currently available for small DO/independents) :** Mean administered epoetin dose decreased from 19,900 in August 2010 to 18,800 units/week in April 2011 (5.8%), falling further to 15,900 units/week in August 2011 (20.4%). Additional data are expected, and therefore these numbers will change somewhat at the next interim update. Preliminary data indicate that the discrepancy between average prescribed and administered epoetin dose was due to a decline in number of administered epoetin doses per month. Whether this practice change is due to a decrease in the prescribed frequency of dosing, an increase in dose holds, and/or an increase in number of missed treatments requires further evaluation.
- IV Iron use:
 - **Nationwide:** The percentage of patients prescribed IV iron over 1 month increased from 56.9% in August 2010 to 78.1% in June 2011, then declined to 71.0% in August 2011.
 - **Dialysis organization size:** Among large/medium-chain facilities, the percentage of patients prescribed IV iron over 1 month increased from 55.7% in August 2010 to 80.7% in June 2011, then declined to 73.7% in August 2011. Among small-chain/independent facilities, the percentage of patients prescribed IV iron



over 1 month increased from 60.8% in August 2010 to 71.3% in April 2011, then declined to <60% in August 2011.

- **Race:** No substantial differences in trend by race.
- IV Iron dose:
 - **Nationwide:** A slight trend toward higher mean monthly iron dose (averaged over a 3-month period) was observed from 270 mg/mo in August 2010 to 305 mg/mo in August 2011. However, the median dose remained relatively unchanged during this same time period.
 - **Dialysis organization size:** IV iron dose was similar by dialysis organization size. No substantial differences in trend were noted.
 - **Race:** IV iron dose was similar by race. No substantial differences in trend were noted.
- Oral iron: No substantial change - prescribed for approximately 5% of patients.

Mineral & Bone Disorder

Lab values

- Serum PTH:
 - **Nationwide:** Overall, the mean PTH level (most recent value within 3 months) rose from 339 to 427 pg/mL from August 2010 to April 2011 (an increase of 26%), with an increase in median PTH from 246 pg/mL in August 2010 to 318 pg/mL in April 2011 (an increase of 29%). Since then, PTH levels remained stable or declined slightly from April 2011 through August 2011. The percentage of HD patients with any PTH measurement over 3 months was 95-96% in August 2010-December 2010 but declined steadily to 92% in August 2011.
 - **Dialysis organization size:** From August 2010 to April 2011, median PTH values increased both in large/medium-chain facilities and in small-chain/independent facilities, by 35% and 16% respectively.
 - **Race:** From August 2010 to August 2011, mean PTH values increased by 18-19% in both black and non-black patients, although the increase among black patients occurred somewhat sooner and from a higher starting point than for non-black patients. From August 2010 through April 2011, the prevalence of very high PTH values (defined here as PTH >600 pg/mL) increased from 17% to 27% in black patients, but declined to 22% by August 2011. In non-black patients, the proportion with PTH >600 pg/mL increased from 9% in August 2010 to 14% in April 2011 before declining to 12% by August 2011.
- Serum phosphorus: No clear change to date.
- Serum calcium: No clear change to date.

Medications

- IV vitamin D analogs:
 - **Nationwide:** The percentage of patients prescribed an IV vitamin D analog in the prior month increased from 75.1% in August 2010 to 79.2% in June 2011, with a slight decline to 77.4% in August 2011.
 - **Dialysis organization size:** In large/medium-chain facilities, the percentage of patients prescribed an IV vitamin D analog increased from 77.4% in August 2010 to 84.2% in June 2011, but declined to 80.5% in August 2011. A substantial fraction of these facilities switched IV vitamin D analog product from paricalcitol to doxercalciferol in late 2010. By contrast, the percentage of patients prescribed an IV vitamin D analog in the prior month declined in small-chain/independent facilities from 67.4% in August 2010 to <60% by August 2011.
 - **Race:** The percentage of patients prescribed an IV vitamin D analog in the prior month increased slightly among black (from 84.7% to 89.9%) and non-black (from 70.9% to 74.7%) patients from August 2010 to June 2011, with both groups declining about 2% through August 2011.
- Administered IV vitamin D analog dose:
 - **Preliminary data (not currently available for small DO/independents)** Among patients receiving IV vitamin D, monthly paricalcitol-equivalent dose increased through August 2011.
- Oral vitamin D:
 - **Nationwide:** Use of oral vitamin D analogs increased from 4% August 2010 to 7% in August 2011.
 - **Dialysis organization size:** A modest increase in oral vitamin D analog use among large/medium-chain facilities was observed, but the increase was slightly higher among small-chain/independent facilities.
 - **Race:** Greater rise in non-black (from 4% to 8%) versus black patients (remained 3-4%).



- Cinacalcet:
 - **Nationwide:** Slight increase in use from 24.4% to 26.5% from August 2010 to August 2011.
 - **Dialysis organization size:** Use in large/medium-chain facilities remained steady at 27-28%, whereas use in small-chain/independent facilities increased from 16.9% in August 2010 to 20.1% in May 2011.
 - **Race:** Use in black patients increased slightly 34.0% in August 2010 to 35.9% in May 2011 but declined to 33.8% in August 2011. Use in non-black patients increased from 20.5% in August 2010 to 23.0% in August 2011.
- Phosphate binders: The percentage of patients prescribed a phosphate binder over 1 month remained stable at 85-87%. Among patients who were prescribed a phosphate binder, the percentage of patients prescribed a calcium-containing binder and sevelamer together steadily increased from 13% in August 2010 to 17% in August 2011, with the percentage of patients prescribed a calcium-containing binder alone showing a corresponding decrease.



Other Practice Areas

Preliminary analyses have not indicated clear trends in other practice areas including dialysis session length, single-pool Kt/V, serum albumin levels, use of cardiovascular medications, and others.

Clinical Outcomes

Preliminary data indicate that the 30-day annualized hospitalization rate has increased approximately 1.8%/month from August 2010 to August 2011. Additional follow-up time to evaluate this trend and understand causes, if the trend persists, is needed. No significant trends in other patient clinical outcomes (mortality, transplantation, withdrawal from dialysis, and transfer out of the dialysis unit) have been observed to date. The DPM will continue to monitor these trends.

As hemoglobin levels declined for some dialysis patients over the time period reported here, it is possible that the rate of red blood cell transfusions may have increased. The DPM does not report yet on trends in red blood cell transfusions, as most transfusions now occur in the hospital setting and dialysis staff are not always made aware of these events. Additional efforts to comprehensively monitor trends in transfusion rates are warranted.

International Comparisons

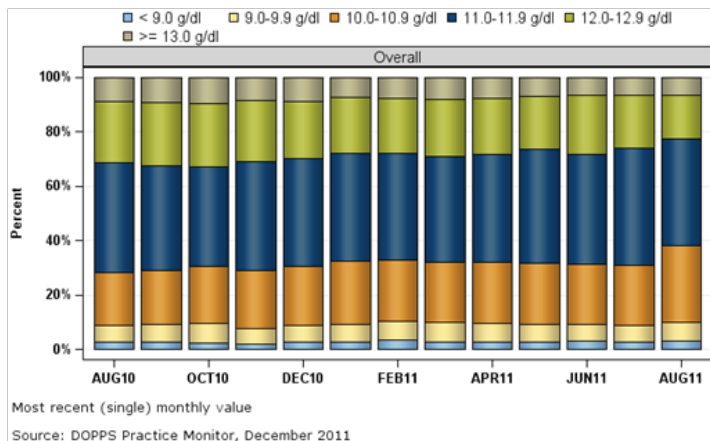
The DOPPS collects data from representative samples of dialysis facilities in 11 other countries, providing useful comparison data. In contrast to the United States, preliminary data indicate that PTH and hemoglobin levels were generally stable in Europe and Japan from August 2010 to at least April 2011. These comparisons suggest that the observed changes in the US data over this time period may reflect responses to new US-specific policy and payment changes, rather than other temporal trends. More recent international data, e.g. after the US epoetin label change, will be forthcoming shortly.

Figures

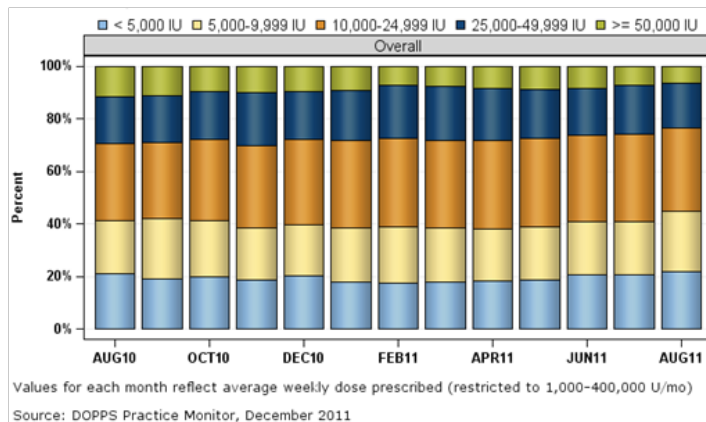
Additional graphics and underlying data tables are provided at <http://www.dopps.org/DPM>.

Figure 1 (A-D): Selected Anemia Trends (August 2010-August 2011)

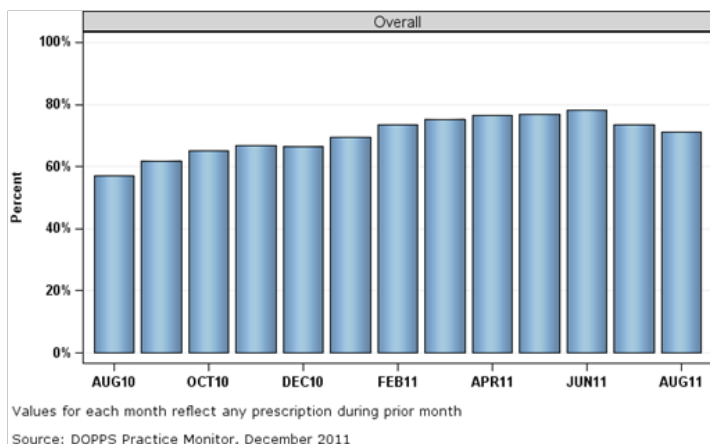
A) Hemoglobin (most recent)



B) Weekly IV epoetin dose prescribed (1 month average)



C) IV iron use, last 1 month



D) Serum ferritin (most recent)

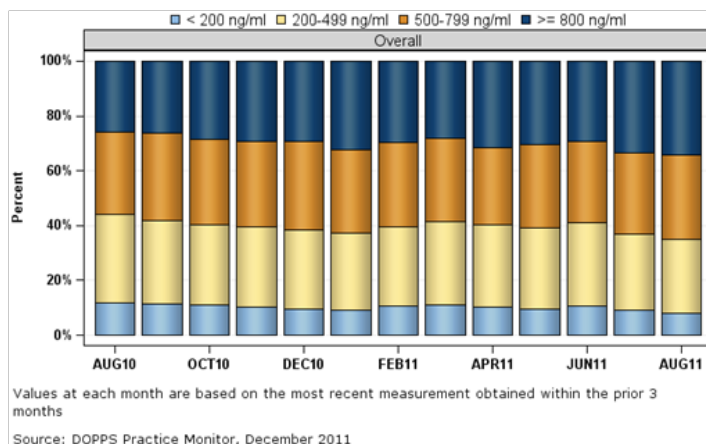


Figure 2: Selected Mineral and Bone Disorder Trends (August 2010-August 2011)

Serum PTH (most recent), by race

