DPM Sampling, Study Design, and Calculation Methods

Table of Contents

The Dialysis Outcomes and Practice Patterns Study (DOPPS) Practice Monitor (DPM) aims to report nationally representative trends in US hemodialysis care using a complex sample design. Details of the DPM study design, sampling approach, and facility sample characteristics have been published[1]. Selected aspects of the DPM study design and calculation methods, are summarized below for readers of the DPM.

This overview of DPM methods also includes information demonstrating that the DPM sample of US hemodialysis facilities yields results that are representative nationally and by facility type (dialysis organization size, rural/urban, free-standing/hospital-based), achieving coverage similar to the CMS sample frame at average values and tails of the distributions of key measures and patient characteristics. Close correspondence of DPM results with national ELab statistics for late 2010 is also shown near the end of this document.

Although great efforts are made to provide nationally representative statistics in the DPM, it is important to note that sampling variability, the use of survey weights, and calculation methods may produce results that differ slightly from other national data sources.

Facility Sample Frame – DOPPS 4 (2009-2011)

In each DOPPS country, facilities are randomly selected from a list of all dialysis facilities (i.e., sample frame) treating at least 20 adult in-center hemodialysis patients (≥18 years of age). For the US, this facility sample frame was based on the 2008 Dialysis Facility Compare database (DFC; REF: www3.cms.gov/DialysisFacilityCompare), created from CMS data by Arbor Research Collaborative for Health and the University of Michigan Kidney Epidemiology Cost Center. This DFC database contains demographic and quality-of-care measure data for all Medicare-certified dialysis facilities in the United States collected through the end of 2007. Data from the DFC were augmented with facility patient counts obtained from the July 2008 Annual Facility Survey database (AFS; REF: Form CMS-2744). A data use agreement with CMS provided access to CMS data.

Of 4,959 facilities listed in the DFC database, 4,343 (88%) served at least 20 chronic adult (≥18 years old) in-center hemodialysis patients and comprised the final sample frame of facilities eligible for DOPPS 4 study participation. The restriction to facilities treating at least 20 patients, due to resource limitations, is readily justifiable because these facilities served 97% of U.S. hemodialysis patients. From this sample frame, approximately 145 dialysis units were targeted for recruitment to meet the study's scientific goals.

Facility Sample Frame – DOPPS 5 (2012-2014)

The DOPPS 5 sample frame was constructed in the same manner, based on the 2011 Dialysis Facility Compare database. Of 5,642 facilities listed in the DFC database, 4,808 (85%) served at least 20 chronic adult (≥18 years old) in-center hemodialysis patients and comprised the final sample frame of facilities eligible for DOPPS 5 study participation. From this sample frame, approximately 140 dialysis units are targeted for recruitment to meet the study's scientific goals. As of the end of 2012, 88% of DOPPS 5 facilities also provided data during DOPPS 4.

Facility Sample Frame – DOPPS 6 (2015-2018) and DOPPS 7 (2018-2021)

The DOPPS 6 and DOPPS 7 sample frames were constructed on the basis of the October 2015 Dialysis Facility Compare database. The US DOPPS sample is comprised of ~35 facilities randomly selected from among each of the two largest dialysis organizations, and ~100 small- and medium-chain, independent, and hospital-based facilities utilizing the Visonex EHR software (Green Bay, WI). As of the end of 2015, 85% of DOPPS 6 facilities also provided data during DOPPS 5.

Facility Sampling Strata

Facilities were randomly selected within pre-specified strata of different HD facility types:

(A) DIALYSIS ORGANIZATION SIZE – Based on the number of units comprising a dialysis organization, dialysis units were classified as part of an LDO (large dialysis organization; ≥1,000 dialysis facilities), MDO (medium-size dialysis organization; 10-<1,000 facilities), and independent or SDO (small-size dialysis organization; <10 dialysis facilities). Notably, the LDO stratum is composed of only the two largest U.S. dialysis organizations. Also, we are unaware of a standard cut-point to distinguish SDO from MDO; the cut-point of 10 facilities was used to meet the needs of the DPM sampling design.

(B) HOSPITAL-based / NON-HOSPITAL-based – All dialysis units were categorized as either hospital-based or free-standing, non-hospital based dialysis units. Note that all hospital-based units in CMS data were SDO/independent facilities, based on the definition above.

(C) RURAL / NON-RURAL LOCATION – Dialysis units were grouped into 3 categories based on the 2004 census tract-based rural-urban commuting area (RUCA) codes available from WWAMI Rural Health Research Center at the University of Washington, Seattle, WA (http://depts.washington.edu/uwruca/index.php). Zip codes were used to assign facilities to a particular RUCA code. Facilities were grouped into the 3 categories of: (i) Remote Rural, defined as having RUCA code 7.0-10.6 (population <10,000) with >45 minutes travel time to the nearest urbanized area of ≥50,000 population), (ii) Non-remote Rural, defined as having RUCA code 7.0-10.6 (population <10,000) with <45 minutes travel time to the nearest urbanized area of ≥50,000 population), and (iii) Non-rural, defined as having a RUCA code <7.0 (i.e., population ≥10,000). Travel time of less than versus greater than 45 minutes to the nearest urbanized area of ≥50,000 population was taken from this same University of Washington data source. As of DOPPS 5, the categories of Remote Rural and Non-remote Rural were combined.

(D) GEOGRAPHY – Dialysis units were grouped into 4 regions: Central, East, South, and West. The boundary lines can be found by clicking on the "Understanding the DPM" link available on most DPM pages.

Patient Sampling – DOPPS 4

To reduce the data collection burden at recruited study sites, data are collected from 20-40 randomly selected chronic in-center HD patients at each participating study site, using a selection algorithm that selects a larger number of patients with increasing size of the dialysis unit to yield an overall average of around 30 study patients per facility. Patients departing the study (e.g., due to death, transfer to other facilities, switch to peritoneal dialysis or home HD, transplantation, or recovery of renal function) are replaced at four month intervals.

Replacements are determined by random selection of patients new to the facility since the prior selection, providing prevalent cross-sections that are representative of patients in each facility at every four month interval. Informed patient consent is obtained in accordance with local requirements.

Patient Sampling – DOPPS 5, DOPPS 6, and DOPPS 7

Patient sampling procedures remained the same as in DOPPS 4, but with a facility-specific target of 20-30 patients, and a study-wide target average of 27 patients per facility. However, DOPPS 5, 6, and 7 were also designed to obtain data from a larger cohort of incident HD patients (new to ESRD within 30 days of study entry) to further explore outcomes during the first year on HD therapy and thereafter. If fewer than 3 incident patients were selected during the standard ("prevalent") selection phase, additional incident patients may be randomly selected from eligible incident patients such that 3 incident patients were selected in total each round, if both (a) the number of incident patients currently in the sample is less than 10 and (b) no more than 15 incident patients have ever been selected during this phase.

Sampling Weights

Facility sampling weights, patient sampling weights, and post-stratification weights are applied to report data that are representative at the national and facility stratum levels. To obtain ≥20 facilities in each stratum category, over-sampling of facilities occurs in some categories. The fraction of facilities within each stratum that are participating in the DOPPS is termed the facility sampling fraction. The reciprocal of the facility sampling fraction serves as the facility sampling weight. Within each facility, data are collected on a random sample of patients. The fraction of all of the facility's chronic adult HD patients that are participating in the study is termed the patient sampling fraction. The reciprocal of the patient sampling fraction serves as the patient sampling weight. Additionally, post-stratification weights based on multiple regression are computed for each patient to correct for disproportionate consent rates among basic demographic variables collected on all facility patients.

DOPPS Data Elements

At study entry, patient data are collected which include demographics, detailed comorbidities, vascular access, medication use/dose, and laboratory values. Patient-level data are updated every four months including: laboratory values (recorded once monthly); medication use/dose (current medication list, as well as monthly use/dose for mineral metabolism and anemia-related medications); vascular access procedures, other clinical procedures, and hospitalizations; dates and cause of death; and reasons for study departure. Patient self-reported data (e.g., quality of life, depression symptoms, satisfaction with care, and others) are collected yearly. Facility survey data related to practice preferences, services offered, and

staffing are collected yearly from the facility medical director and nurse study manager. DOPPS data collection instruments are updated annually.

CMS Claims-based Data Elements

Medicare beneficiaries with 1+ outpatient ESRD service claim (billing type '72x') were assigned to the facility providing the most outpatient ESRD service claims to the beneficiary that month. To limit distortion due to discrete proportion effects, only facilities with 20+ assigned patients in a given month are shown. Transfusion events each month were identified by the presence of: (1) HCPCS codes P9010-P9011, P9016, P9021-P9022, P9038-P9040, P9051, P9054, and P9056-P9058, (2) claim value code 37, (3) ICD-9 procedure codes 99.03, 99.04, (4) or CPT code 36430. The maximum number of procedures per inpatient claim in this CMS dataset increased from 6 to 25 starting in 2011. Hospitalization events each month were identified by the presence of an inpatient admission claim for any reason.

How Data are Reported in the DPM

Demographic data, vascular access use, patient-reported data (MCS/PCS), and prescription of various cardiovascular and anti-hypertension agents will be reported every four to six months. Anemia and mineral bone disorder medication use will be reported monthly as a reflection of medication use either in the given study month and/or during the prior three months. Administered doses are reported for erythropoiesis-stimulating agents and intravenous iron. Routinely measured laboratory data will be reported for each month and as the mean of the last 2 to 3 monthly values. Less frequently measured laboratory data (e.g., PTH, ferritin) will be reported as the most recent monthly value and the mean of the last 1 to 3 monthly values. Process measures, such as the proportion of patients with non-missing lab values will also be reported for one-month and three-month periods.

Continuous variables (e.g., hemoglobin levels) will be presented as simplified box plots showing the median (50th percentile) value as a large dot, with auxiliary lines indicating the 10th-25th and 75th-90th percentiles. Categorical variables will be presented as column (two levels) or stacked column charts with clinically meaningful cut-points. Annotated examples of these types of charts are available on the DPM website: http://www.dopps.org/DPM/Understanding.pdf.

Emerging trends will be monitored for variables reported on the DPM website. Trends will be analyzed by several approaches, including longitudinal analyses. Additional modeling techniques including spline regression will be used to describe possible non-linear changes. Trends will be monitored at a national level, as well as within and between facility strata. A summary document provided with each DPM update will highlight notable findings.

Certain clinical data will not be provided on the website, but will form the basis for multivariable analyses and peer-reviewed publications. These include rates of clinical procedures and other events, facility survey data, and selected patient self-reported data.

Evaluating the Representativeness of the DPM facility sample – CMS, 2007

To assess the extent to which the sample of DPM facilities is representative of U.S. HD facilities overall, analyses have been performed comparing 2007 CMS data for 137 DPM facilities participating in the DOPPS in September, 2010 with the 2007 CMS data for all U.S. facilities treating at least 20 in-center chronic HD patients (n=4,343 facilities)[1]. Analyses were limited to chronic HD patients ≥18 years of age. Comparisons were performed for 8 patient characteristics or laboratory measures available in the CMS data. These items were chosen because they are part of the 2012 Quality Incentive Program, were identified as important in a recent GAO Report[5], or are otherwise expected to be potentially affected by the Prospective Payment System. Results of these analyses indicate the DPM is nationally representative of U.S. HD patients with nearly all of these tested measures, except for being under-represented in the percent of black HD patients (26% black patients in DPM vs. 36% in CMS data, overall). Although under-represented in overall percent of black HD patients, the DPM facility sample provides ample representation of the entire distribution of the facility percent of black patients and thus will be able to demonstrate changes or effects related to the percent of black patients within U.S. HD facilities. Additional details and results regarding these analyses are described in Robinson, et al[1].

Evaluating the Representativeness of the DPM sample – Elab, 2010

The ESRD Network 11 Elab project collects laboratory measurements from approximately 387,000 (97% of the US dialysis population) patients and therefore provides nearly complete national data against which DPM estimates can be validated. In June 2011, the Elab Project released their "National 2010 and Trends" report[4], which reports averages based on the mean of the laboratory values in October, November, and December 2010. The mean of up to three monthly values from October-December 2010 is also reported in the DPM (as "Dec 2010", where available), providing a similar methodology and enabling a fairer comparison. The following table represents the comparison of Elab and DPM estimates for demographic characteristics and laboratory variables in common.

Patient Characteristics	Elab 2010	DPM Dec 2010
Age, 18-54 yrs, (%)	30.2	29.2
Age, 55-74 yrs, (%)	48.1	47.9
Age, ≥75 yrs, (%)	21.7	23.0
Male, (%)	55.4	55.4

Patient Characteristics	Elab 2010	DPM Dec 2010
Black, (%)	37.6	30.8
Diabetic, (%)	54.6	62.1[a]

[a]Ascertainment of diabetes status differs between Elab and DPM; DPM incorporates use of diabetes-related medications as part of ascertainment in addition to indication of diabetes in medical record.

Laboratory Measures	Elab 2010	DPM Dec 2010
Mean Hemoglobin (Hgb), g/dL	11.5	11.5
Hgb <10 g/dL, (%)	6.6	5.5
Hgb 10-12 g/dL, (%)	68.4	71.1
Hgb >12 g/dL, (%)	25.0	23.3
TSAT ≥20%, (%)	87.0	87.6
URR ≥ 65%, (%)	91.1	92.6
S. Albumin ≥4.0 g/dL, (%)	39.1	40.3
S. Phosphorus, 3.5-5.5 mg/dL, (%)	55.3	58.0
S. Calcium, 8.4-9.5 mg/dL, (%)	64.1	64.9

Values shown are three-month averages for each measure.

Data Entry and Software

Anonymous raw data are collected from DOPPS study sites via either (1) electronic data transfer from databases, (2) data entry into a proprietary web-based application (DOPPSLink), or (3) paper forms keypunched in-house. Range and consistency checks are performed on all data. Statistical analyses are performed using SAS 9.4 (SAS Institute, Cary, NC).

References

[1] Robinson BM, Fuller DS, Dykstra DM, Albert JM, Gillespie BW, Tentori F, Turenne M, Port FK, Pisoni RL. (2011). "The DOPPS Practice Monitor: Rationale and Methods for an Initiative to Monitor the New US Bundled Dialysis Payment System." *Am J Kidney Dis*, 57, pp. 822-831.

[2] Young EW, Goodkin DA, Mapes DL, Port FK, Keen ML, Chen K, Maroni BL, Wolfe RA, and Held PJ. (2000). "The Dialysis Outcomes and Practice Patterns Study (DOPPS): An international hemodialysis study." *Kidney Int*, 57 Suppl. 74s, pp. S74-S81.

[3] Pisoni RL, Gillespie BW, Dickinson DM, Chen K, Kutner MH, and Wolfe RA. (2004). "The Dialysis Outcomes and Practice Patterns Study (DOPPS): Design, data elements, and methodology." *Am J Kidney Dis*, 44, pp. 7-15.

[4] ESRD Network 11 (2011). "National 2010 and Trends Elab Report". http://www.esrdnet11.org/Elab/elab_national_2010_and_trends_report.pdf; retrieved Nov 8, 2011.

[5] Centers for Medicare and Medicaid Services (2010). “CMS Should Monitor Access to and Quality of Dialysis Care Promptly after Implementation of New Bundled Payment System [GAO-

10-295]". Available at http://www.gao.gov/products/GAO-10-295. Accessed November 18, 2013.