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 hemodialysis care using a complex sample design. Selected aspects of the DPM study design and calculation methods, are summarized below for readers of the DPM. 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 nationally representative or registry data.

Facility Sample Frame

In each DOPPS country, the facility sampling frame is composed of dialysis facilities treating at least 20 adult in-center hemodialysis patients (≥18 years of age). Facilities are randomly selected within pre-specified strata of different HD facility types:

(A) Facility type – Dialysis units are categorized according to their type, which may vary by country. For example, central vs. satellite, hospital-based or free-standing, public vs. private.

(B) Geographic Location – Dialysis units in each country are assigned to a geographic region based on commonly-used boundaries. Adjacent regions may be aggregated if the number of expected facilities sampled in a region is too small.

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

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 also is 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

Patient sampling weights and post-stratification weights are applied to report data that are representative at the national level. 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.

How Data are Reported in the DPM

Demographic and comorbidity data will be reported annually. Vascular access use will be reported every 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. Use of several classes of cardiovascular and anti-hypertension agents will be reported once every four months. Doses will be 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. The proportion of patients with serum ferritin and parathyroid hormone measurements 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 US DPM website: http://www.dopps.org/DPM/Understanding.pdf.

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 9.2 (SAS Institute, Cary, NC).