

Data Sources and Methods for DOPPS Annual Report

| DOPPS Phase | Study Period | Countries |
|--------------------|---------------------|---|
| DOPPS 1 | 1996-2001 | United States |
| | 1998-2001 | Europe (France, Germany, Italy, Spain, United Kingdom) |
| | 1999-2001 | Japan |
| DOPPS 2 | 2002-2004 | Same as DOPPS 1, plus Australia, Belgium, Canada, New Zealand, and Canada |
| DOPPS 3 | 2005-2008 | Same as DOPPS 2 |
| DOPPS 4 | 2009-2011 | Same as DOPPS 3 |

Sampling Methods

Facility sample

Within each country, facilities were randomly selected in strata of geographical region and facility type according to the frequency of facilities within each stratum. At least 20 patients had to be receiving chronic hemodialysis therapy in order for a facility to be eligible for study participation. The DOPPS I US facility sample was additionally supplemented with facilities selected from the upper and lower tails of an estimated standardized mortality ratio (SMR) distribution.

Patient sample

In all phases of the DOPPS, an initial cross-section of prevalent patients was obtained when a facility joined the study. However, sample replenishment protocols varied by phase.

DOPPS I used a continuous-replenishment strategy in which sampled patients who either died or otherwise departed the facility were immediately replaced via random selection among patients who started dialyzing in the facility since the previous selection. Three prevalent patient cross-sections are defined in the Annual Report for DOPPS I. They are based on patients alive and dialyzing in the facility as of 1) December 31, 1997 (US only); 2) June 30, 1999 (All DOPPS I countries); or 3) January 1, 2001 (US and Japan only).

DOPPS II did not replenish the patient sample when a patient departed the study. However, in addition to the initial prevalent patient sample, each facility purposively recruited up

to the first 15 incident patients entering the facility during the course of the study. Incident patients were defined as initiating hemodialysis within 30 days of study entry. One prevalent patient cross-section is defined for DOPPS II, comprised of the original random prevalent sample drawn from each participating facility.

Additional details of the DOPPS I and DOPPS II sample methodologies have been published previously¹⁻².

DOPPS III used an annual-replenishment strategy in which sampled patients who died or otherwise departed the facility were replaced on the facility's anniversary of study start via random selection among patients who started dialyzing in the facility since the previous selection. Two prevalent patient cross-sections are defined for DOPPS III. The first is comprised of the original random prevalent sample drawn from each participating facility. The second is comprised of 1) previously sampled patients who remained in the facility through the facility anniversary date and the 2) replenishment patients randomly selected on the facility anniversary.

DOPPS 4 (launching in 2009) will use an thrice-annual replenishment strategy in which sampled patients who became deceased or otherwise departed the facility will be replaced (on average) every four months during the study via random selection among patients who started dialyzing in the facility since the previous selection. Prevalent patient cross-sections will be defined as for DOPPS III.

Weighting

The patient sample was obtained via simple random sampling within each facility. However, practical concerns (e.g. poor patient health or refusal to consent) may result in a final analysis sample which is not completely random.

To correct for non-response in computing nationally representative estimates, we used a logistic regression that included variables collected from all patients dialyzing in a facility to compute the predicted probability that a patient would have provided consent and contributed data to the study. The reciprocal of this patient-specific predicted probability serves as a post-stratification weight used for most results.

Additional post-stratification weights were computed for the DOPPS III US facility sample, based on geographic region and facility type. These facility-level weights were multiplied with the patient-level weights for each patient within these facilities to obtain a final weight.

Data Sources

DOPPS applies a common protocol with standardized questionnaires to capture detailed longitudinal patient-level information, as well as dialysis facility practices and processes of care. The DOPPS Annual Report utilizes data obtained from the following DOPPS questionnaires:

Cumulative Hemodialysis Census (CHC)

Each facility maintains a roster of all chronic hemodialysis patients actively dialyzing in the unit. This roster is updated continuously, and serves as the patient sampling frame.

Medical Questionnaire (MQ)

Upon being selected and consented into the DOPPS, a comprehensive baseline survey for each patient, encompassing pre-ESRD care, history of comorbid conditions, aspects of prescribed and delivered hemodialysis therapy, recent laboratory values, medication use, and other measures, is obtained.

Interval Summary (IS)

Every four months while a patient is enrolled in the DOPPS, a subset of data from the initial Medical Questionnaire survey is updated - including laboratory values, hospitalizations, and changes in vascular access - so as to obtain a time course of these characteristics for longitudinal analysis.

Patient Questionnaire (PQ)

Upon being selected and annually thereafter during the DOPPS study, each study patient is asked to complete a questionnaire regarding his/her quality of life, quality of care, and other personal aspects of life on dialysis.

Medications Inventory

Upon selection into the DOPPS and every four months afterward, a current prescription list that includes dose strength and frequency information is obtained for patients.

Data Entry and Software

Anonymous raw data are collected via a proprietary web-based application (DOPPSLink) or keypunched in-house from paper forms. Range and consistency checks are performed on all data. Statistical analyses are performed using SAS 9.2 (SAS Institute, Cary, NC).

References

- ¹E. Young, et al. (2000). "The Dialysis Outcomes and Practice Patterns Study (DOPPS): An international hemodialysis study." *Kidney Int*, 57 Suppl. 74s, pp. S74-S81.
- ²R. Pisoni, et al. (2004). "The Dialysis Outcomes and Practice Patterns Study (DOPPS): Design, data elements, and methodology." *Am J Kidney Dis*, 44, pp. 7-15.