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# The DOPPS Report

*The Dialysis Outcomes and Practice Patterns Study*

*Volume V, Issue 1 October 2003*



## Practices and Outcomes

Compliance with treatment, nutritional status, quality of life, vascular access

When people learn that they have End-Stage Renal Disease (ESRD) and will require chronic hemodialysis treatment, the question that often weighs heavily on their minds is, “How long am I going to live?” They also want to know how hemodialysis treatment will affect their quality of life.

For many of the world’s 900,000+ hemodialysis patients, dialysis therapy represents a new lease on life. For some, dialysis extends their lives for years - productive years of quality time with family and friends.

Unfortunately for many, life on dialysis is beset with unique treatment complications: vascular access failures, numerous hospitalizations, limited life quality, and perhaps most discouraging, a grim prognosis on life longevity.

Although dialysis patients face a high death rate, their health outcomes vary substantially across facilities and countries. In fact, death rates are lower for ESRD patients in

Europe and Japan than in the United States. And just as outcomes among dialysis patients vary greatly across the world and across regions of the United States, so do dialysis practices.

In view of these differences, researchers initiated the Dialysis Outcomes and Practice Patterns Study (DOPPS) in 1996 to look for the dialysis practices that promote longer lives, produce fewer hospital stays, improve quality of life, and provide better vascular access outcomes for patients.

The DOPPS has collected data on over 80,000 hemodialysis patients so far. As a result, DOPPS researchers have published, and continue to publish, many important articles showing how hemodialysis practices, patient behaviors, and policies affect patient outcomes.

These findings are timely and relevant to healthcare providers, policymakers, and patients around the world. This issue of *The DOPPS Report* highlights several recent findings regarding compliance with dialysis treatment, the relationship between nutritional status and patient outcomes, and factors associated with patient quality of life and vascular access outcomes. (continued on page 2)

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DOPPS is a worldwide hemodialysis study coordinated by the University Renal Research and Education Association (URREA).

DOPPS is supported by unrestricted grants from Amgen, Inc. and (for Japan) Kirin Brewery, Ltd.

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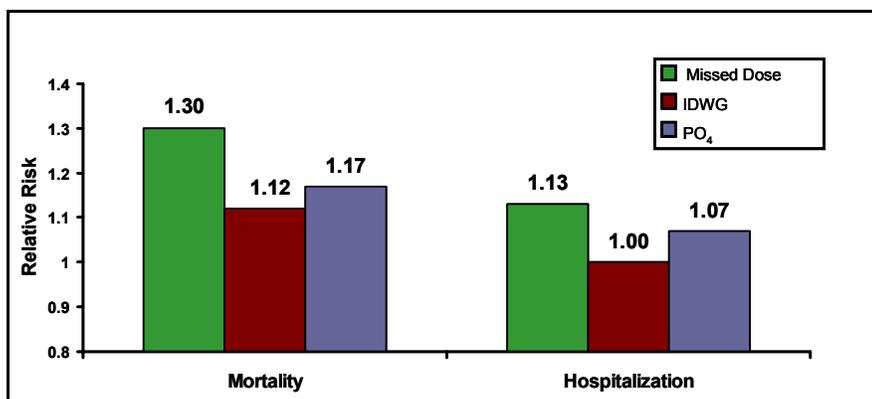
## Practices and Outcomes

Continued from page 1

Recent findings concerning **noncompliance** among hemodialysis patients show that facility practices and patient behaviors (regarding shortened or missed treatments) compromise dialysis therapy, and ultimately patient outcomes [1]. An analysis of DOPPS data revealed a much higher risk of death with such forms of noncompliance as missed dialysis treatments, excessive weight gain between treatments, and high serum phosphorous levels (**Figure 1**). Missed dialysis treatments and high phosphorous levels were also associated with increased hospitalization (**Figure 1**).

Similarly, facility practices and patient behaviors can affect **nutritional status**. DOPPS investigators recently found that lower initial measurements of body mass index (BMI), serum albumin, serum creatinine, and lymphocyte count are each associated with a much higher risk of death [2] (**Figures 2 and 3**).

While the importance of nutrition for ESRD patients has been known, long-term data from the DOPPS has also been able to show that a *change* in nutritional status over a period of six months could improve patient outcomes (**Figures 2 and 3**). Clearly, patient behaviors and nutritional monitoring practices are key to improving their nutritional status and outcomes.



**Figure 1: Noncompliance and Increased Risk of Mortality and Hospitalization**

- Missed Dose means missing one or more dialysis sessions per month (vs. not missing)
- IDWG = Interdialytic Weight Gain
- PO<sub>4</sub> = Phosphate levels > 7.5 mg/dL

All relative risk data significant at  $p = 0.05$  except IDWG for hospitalization. A relative risk above 1.0 suggests an increased risk of mortality or hospitalization.

When looking for possible reasons for noncompliance, DOPPS researchers found that patients treated in the larger dialysis facilities were more likely to miss or shorten their treatments. In larger facilities, patients also are more likely to gain excessive fluid between treatments.

The DOPPS research, however, also suggests that staffing practices seem to affect patient noncompliance with treatment. The likelihood of patients missing hemodialysis treatment is lower in dialysis units with a higher percentage of highly trained staff. Also, the number of patients who gain excessive weight between treatments tends to be lower if a dietitian is available to them.

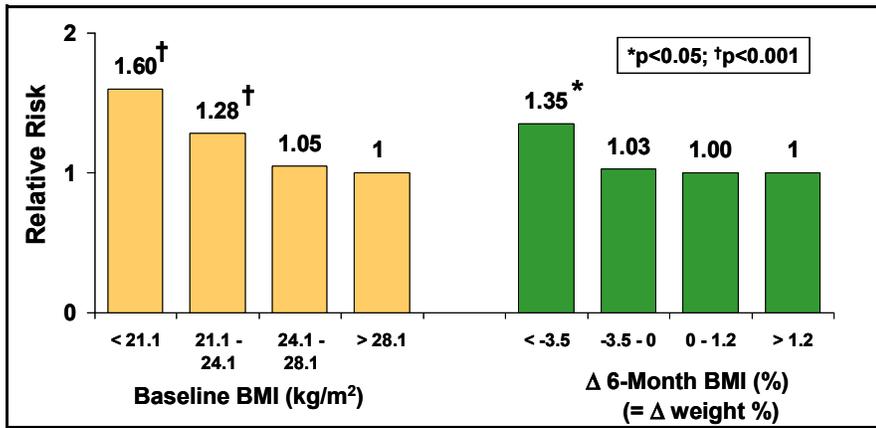
The DOPPS has reported a wealth of new information about patient **quality of life (QoL)**. QoL is an important outcome that describes the burdens afflicting patients with chronic medical conditions. Using the Kidney Diseases Quality of Life Short Form™, the DOPPS investigators looked at whether health-related QoL indicators are related to the risk of death and hospitalization [3].

The DOPPS data indicate a much higher relative risk of death and hospitalization for every 10-point lower mental and physical QoL score (**Figure 4**). These important associations with death and hospitalization are seen even after taking into account such patient characteristics as age and comorbid condition.

The unique, international nature of the DOPPS also allows researchers to make interesting comparisons of worldwide patient QoL. Patients in the US have the highest scores on

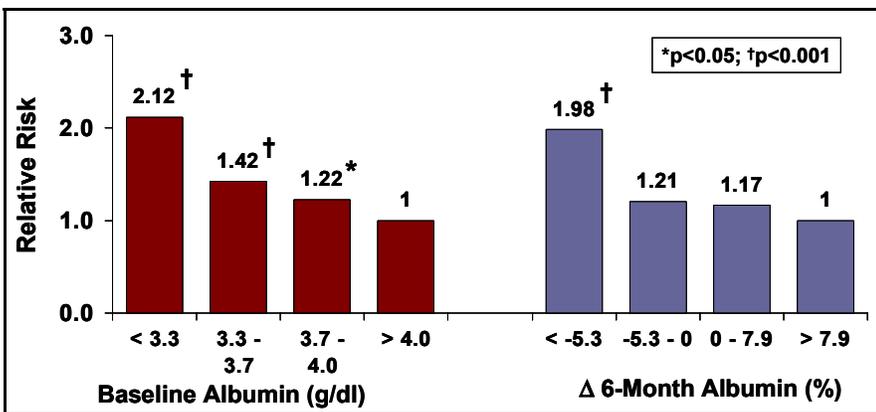
the mental health subscale when compared with patients in the five European DOPPS nations and Japan. Japanese patients report better physical ability; but they see their kidney disease as imposing a greater burden than do patients in the US and Europe (**Figure 5**).

Not surprisingly, hemodialysis patients in each DOPPS country report worse QoL than is seen in the general population of their countries [4]. Differences in socio-economic factors and patient characteristics explain few of the differences in physical ability. Other possible factors — such as quality of dialysis and related health care — deserve careful study.



**Figure 2: Mortality Risk is Inversely Associated with Baseline and Δ BMI**

\*BMI, Δ BMI, demographics, and comorbidity were included in Cox model on mortality (Δ = change). A relative risk above 1.0 suggests an increased risk of mortality.



**Figure 3: Mortality Risk is Inversely Associated with Baseline and Δ Albumin**

Albumin, Δ Albumin, demographics, and comorbidity all together in Cox model on mortality (Δ = change). A relative risk above 1.0 suggests an increased risk of mortality.

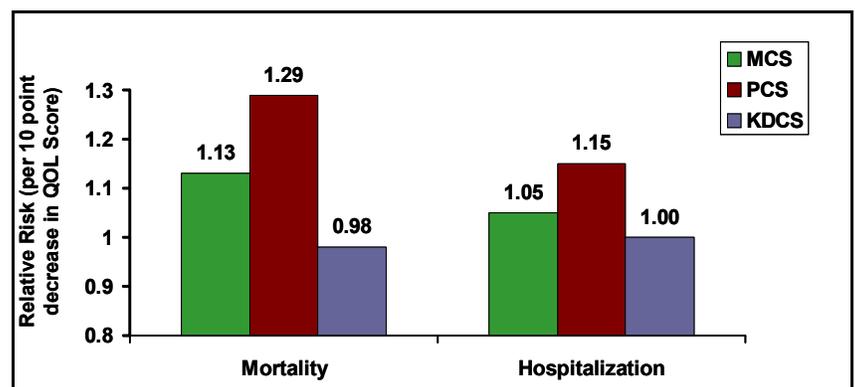
It is interesting and important, then, to see that in the US, only 79% of medical directors and 59% of nurse managers state that they prefer AV fistulae over synthetic grafts. In contrast, 100% of medical directors and nurse managers from DOPPS facilities in Europe and Japan prefer AV fistulae over synthetic grafts as the permanent access for patients starting hemodialysis in their units [6] (Figure 6).

In US facilities in which the medical director or nurse manager prefers a synthetic graft, DOPPS researchers found that patients are more than twice as likely to dialyze with a synthetic graft rather than an AV fistula. However, synthetic graft outcomes are not superior in facilities that prefer grafts to AV fistulae.

Grafts have a 40% higher failure rate than AV fistulae, regardless of a medical director's preference for synthetic grafts over AV fistulae. Furthermore, the risk of graft failure is nearly 60% higher than AV fistula failure in facilities representing the upper half of graft use in the US. The reasons for differences in vascular access preferences by dialysis units may involve issues that policymakers and providers should address.

Self-reported **depression** also goes along with higher risks of death and hospitalization for hemodialysis patients, even when taking their medical condition into account [5]. These new DOPPS data about death and hospitalization for depressed hemodialysis patients suggest that early detection and treatment of depression may help improve QoL, prolong survival, and reduce hospital admissions.

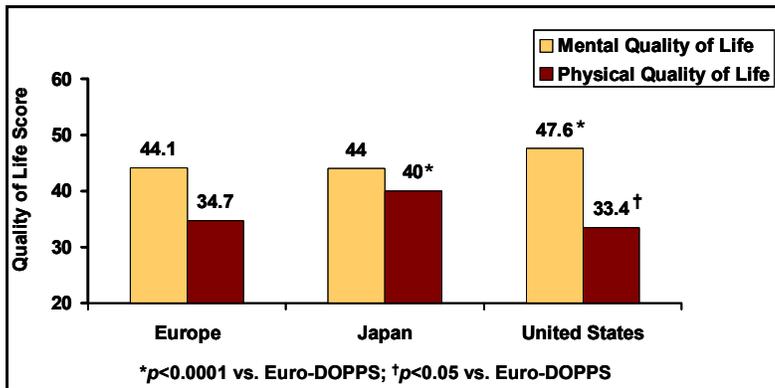
**Vascular access** practices vary greatly among the DOPPS countries and are highly associated with patient outcomes. For instance, it is generally known that synthetic grafts do not last as long as native arteriovenous (AV) fistulae and have more complications.



**Figure 4: Increased Risk of Death and Hospitalization Lower Quality of Life Score**

- MCS = Mental Component Score
- PCS = Physical Component Score
- KDCS = Kidney Disease Component Score

\*All relative risk data significant at  $p < 0.001$ . A relative risk above 1.0 suggests an increased risk of mortality or hospitalization.



**Figure 5: Mental and Physical Quality of Life in Europe, Japan, and the U.S.**

The DOPPS investigators have also looked at the relationship between vascular access survival and the use of certain drugs, including calcium channel blockers, angiotensin converting enzyme (ACE) inhibitors, aspirin, and warfarin. When studying the time from start of access placement until complete access failure, DOPPS analyses show a much greater survival of synthetic grafts for patients who took aspirin or calcium channel blockers [7]. Analyses also show a much better AV fistula survival for patients who took an ACE inhibitor.

These DOPPS results provide one of the largest and most detailed investigations of the relationship between specific medications and vascular access outcomes. These results also provide ideas for future drug studies aimed at understanding the possible use of medications to improve vascular access outcomes.

The DOPPS has found that many facility and patient practices go hand-in-hand to affect patient outcomes. The international and long-term nature of the DOPPS allows the renal community to learn about different ways to improve patient care.

As new data from DOPPS II become available, interesting trends in practice patterns and patient outcomes will no doubt arise. These trends will be studied to better understand how practices, policies, and guidelines affect patient outcomes. The ultimate goal of the DOPPS is to improve the longevity and quality of life for hemodialysis patients around the world.

For each of the publications referenced in this article, more information can be found in the publications section of the DOPPS website, [www.dopps.org](http://www.dopps.org).

Preference and Use	Europe	Japan	US
% of Patients Using AVF	81%	91%	24%
% of Medical Directors Preferring AVF	100%	100%	79%
% of Nurses Preferring AVF	100%	100%	59%

**Figure 6: Preferences and Use of Fistulas vs. Grafts as Permanent Access in New ESRD Patients**

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## DOPPS Background

Purpose, progress, and support

## News for DOPPS Coordinators and Medical Directors

In view of differences in patient outcomes of mortality and morbidity by country and by dialysis unit, researchers initiated the Dialysis Outcomes and Practice Patterns Study (DOPPS) in 1996. The goal of the DOPPS is to identify hemodialysis practice patterns that improve patient outcomes – specifically longer lives, fewer hospital stays, better quality of life, and improved vascular access survival.

The DOPPS is a prospective cohort study based on the collection of observational longitudinal data for a random sample of hemodialysis patients in twelve countries. Coordinated by the University Renal Research and Education Association (URREA) in Ann Arbor, MI, USA, the DOPPS is supported by unrestricted grants from Amgen, Inc. and (for Japan) Kirin Brewery, Ltd.

Since 1996, the DOPPS has yielded a wealth of nationally representative longitudinal patient data using a uniform international data collection protocol.

**DOPPS I:** Initiated in 1996, included:

- **Seven countries:** France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States
- **308 participating facilities** (101 in Europe, 65 in Japan, and 142 in the US)
- **17,000+ enrolled patients worldwide** (24,000+ years of longitudinal data)
- **Survival data for > 50,000 HD patients** (69,000+ years at risk)

**DOPPS II:** Initiated in 2002, includes:

- **Twelve countries:** Original seven plus Australia, Belgium, Canada, New Zealand, and Sweden
- **340 facilities targeted for participation** (20 in Australia/New Zealand, 20 in Canada, 140 in Europe, 60 in Japan, and 100 in the US)
- **10,000+ enrolled patients worldwide** (7,000+ years of longitudinal data)
- **Survival data for > 35,000 HD patients** (24,000+ years at risk)
- Facility recruitment and data collection is still underway and is scheduled to conclude in spring 2004

The DOPPS devotes special focus to selected unit practice patterns and major patient outcomes. **Observed practices** include administrative, anemia Rx, dialysis practice, cardiovascular risk, mineral metabolism, physician, nursing and technician, nutritional, social services, vascular access. **Observed major outcomes** include mortality, hospitalization, vascular access survival, and quality of life.

### Vascular Access Survey

Many of you are aware that we have distributed a new DOPPS questionnaire to the surgeon, nephrologist, or other physician responsible for placing the majority of vascular accesses in patients at your facility. This new questionnaire has been in development during DOPPS II, and with it, we hope to add to a body of information about vascular access (VA) obtained in previous DOPPS research.

As detailed under “Practices and Outcomes,” we have discovered that there are geographic differences in VA utilization and outcomes from previous DOPPS research. To understand why there are geographic differences in VA selection, this questionnaire investigates the variations in surgical practice and VA preference. We are also investigating how variations in surgical technique may determine VA outcomes – specifically VA selection and survival. Questions in the survey specifically address the training received for VA placement, post-training experience, pre-, intra-, and post-operative technique, the surgeon’s attitude regarding the different VA types, and reimbursement levels for the types of vascular accesses placed.

### Facility Feedback Reports

All participating DOPPS facilities will be receiving Facility Feedback Reports in the upcoming months. The Facility Feedback Report is prepared as an intra-country comparison indicating how statistics for your facility compare to the average for all DOPPS dialysis units in your country. We provide you with measurements for patients listed on the Cumulative Hemodialysis Census, specifically covering patient demographics (age, gender, race), diabetes as the primary cause of ESRD, and adjusted mortality risk.

We also include measurements on patients for whom a Medical Questionnaire and Interval Summaries were completed. For these patients, we cover demographics, comorbid conditions, adjusted mortality risk, hospitalization, quality of life, and vascular access use. For the patients who were new to hemodialysis when enrolled in the study (i.e. incident patients), we provide you with specific information on pre-ESRD care and vascular access use.

## Trend Data

### Changes in practice since start of DOPPS

The longitudinal design of DOPPS is invaluable because it allows identification of trends within many areas of hemodialysis (HD) therapy, many of which are considered to be indicators of important practice patterns. Within the last six years, DOPPS data reveals interesting variability and trends in patient comorbidities, vascular access use, and other key areas of HD practice.

Preliminary data from DOPPS I (1997-1999) to DOPPS II (2002-2003) reveal time trends useful in assessing the improvement of HD treatment for patients in DOPPS countries. Comparing a cross-section of prevalent patients from DOPPS I with patients from DOPPS II, we are observing the following trends:

- A higher percentage of patients worldwide have diabetes as the cause of ESRD
- An increase in mean hemoglobin and an increase in Erythropoietin (EPO) use
- A greater percentage of patients are receiving IV iron
- A decreased percentage of patients with a Kt/V < 1.2
- No substantial change in the percentage of patients with serum phosphorus levels > 5.5 mg/dl
- An increase in the percent of patients using an AV fistula in the U.S. and most countries, however the percentage of patients using catheters has also increased

## Impact of DOPPS

### Public health policymaking

DOPPS analyses are assisting health policy makers worldwide:

- Policy makers around the world are increasingly calling upon the wealth of international data from the DOPPS to help develop and guide policies
- DOPPS data are frequently used as a source of comparison data for other large studies of dialysis care around the world
- For a number of registries in DOPPS countries, the DOPPS is used for data validation and as a source for supplementary data

## DOPPS Presentations

In the past three years, over 150 presentations of DOPPS findings have been given worldwide, including ninety-six DOPPS abstracts presented at major renal meetings such as the American Society of Nephrology (ASN), the European Dialysis and Transplantation Association (EDTA), the National Kidney Foundation (NKF), and the International Congress of Transplant Society (ICTS).

At the June 2003 meeting of the World Congress of Nephrology in Berlin, DOPPS analysts and investigators presented nine abstracts from DOPPS data and featured research at two symposia. A joint symposium held with members of the ERA-EDTA registry prompted much discussion on the state of hemodialysis care in Europe. DOPPS data were particularly useful in assessing compliance with the European Best Practice Guideline/Dialysis Outcomes Quality Initiative (EBPG/DOQI).

The November 2003 meeting of the American Society of Nephrology will feature one symposium, two oral presentations, and fourteen abstracts with findings from the DOPPS. The Sunday plenary session will feature new international results from the DOPPS. Drs. Friedrich Port and Luis Piera will chair this symposium on international practice and outcomes results with DOPPS co-investigators from five countries addressing mineral metabolism, cardiac drugs, lipid-lowering drugs, vascular access, and health-related quality of life. For additional upcoming DOPPS international presentations, please refer to **Table 1**.

## DOPPS Results

### Manuscripts and publications

DOPPS has earned an international reputation and its continuation with DOPPS II has broad support from the worldwide renal community. Results from the DOPPS are being disseminated worldwide through numerous international presentations and scientific publications. DOPPS country investigators, advisory board members, and members of the URREA/Amgen study committee worked together in the past year to analyze and publish DOPPS results.

- Twenty-two DOPPS manuscripts have been published since 1999
- In 2003 alone, ten manuscripts have been published (please refer to **Table 2** for the manuscript citations)
- Five additional manuscripts have been accepted and are currently in press

**Table 1: Upcoming DOPPS International Presentations**

Meeting	Location	Date
International Society of Geriatric Nephrology and Urology	Atlanta, Georgia	October 9, 2003
French Speaking Society of Nephrology	Bordeaux, France	October 10, 2003
Congress of the Spanish Society of Nephrology	Palma de Mallorca, Spain	October 15, 2003
American Society of Nephrology	San Diego, CA	November 12, 2003
Hemodialysis Practices and Outcomes in Japan and Around the World: DOPPS	Tokyo, Japan	December 13, 2003
International Conference on Dialysis	Rio Grande, Puerto Rico	January 30, 2004
American Nephrology Nurses Association Statewide Meeting	Texas	February 6, 2004
Nephro-Asia Congress	Singapore	February 9, 2004
Annual Dialysis Conference	San Antonio, TX	February 9, 2004
Mexican Society of Nephrology	Guadalajara, Mexico	March 26, 2004
National Kidney Foundation Clinical Meeting	Chicago, IL	March 1, 2004
Vascular Access Symposium	Cincinnati, OH	March 19, 2004
National Kidney Foundation Clinical Meeting	Chicago, IL	April 28, 2004
European Dialysis and Transplantation Association / World Congress of Nephrology	Lisbon, Portugal	May 15, 2004
Canadian Society of Nephrology Annual Meeting	Toronto, Ontario, Canada	May 27, 2004

**Table 2: Citations for DOPPS Manuscripts Published in 2003**

- Fukuhara S, Lopes AA, Bragg-Gresham JL, Kurokawa K, Mapes DL, Akizawa T, Bommer J, Canaud BJ, Port FK, Held PJ: Health-related quality of life among dialysis patients on three continents: The Dialysis Outcomes and Practice Patterns Study. *Kidney Int* 64:1903-1910, 2003.
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## What is Unique About the DOPPS?

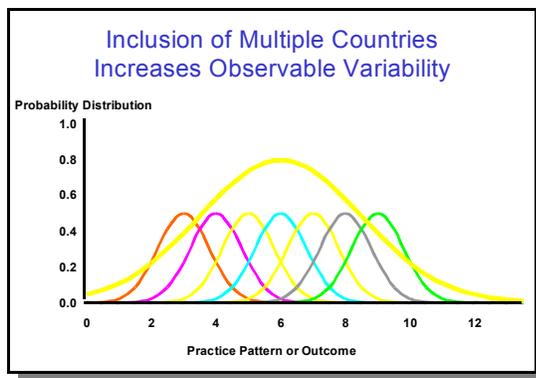
### A Longitudinal Design

The DOPPS is longitudinal and will collect information on units and patients in twelve countries using a common protocol over time. With a focus on the full range of unit practice patterns that may relate to clinically important outcomes, the outcomes measures will be adjusted for patient comorbidities and adjusted to a greater extent than previously possible in other studies.

### An International Scope

The international scope of the DOPPS provides greater variability in practice patterns and outcomes than can be observed in one country. This increased variation along with the study's large sample size leads to a greatly enhanced ability to understand the relationships between various treatment effects and patient outcomes.

The efforts of the DOPPS to obtain a representative, random sample of facilities and patients within each country allows for practice patterns within a participating country to be described.



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### Available online...

- ✓ Learn of the latest news from the DOPPS
- ✓ Find information on upcoming DOPPS research and presentations
- ✓ Conduct keyword searches for DOPPS research results
- ✓ Access and download PowerPoint presentations and abstracts of published DOPPS research
- ✓ Submit requests for DOPPS data

## DOPPS: A Team Effort

- Over 600 medical directors and study coordinators support the DOPPS at our participating facilities worldwide.
- It is estimated that a DOPPS II study coordinator will devote an average of 285 hours assisting with data collection over a two-year time period.
- Study coordinators continually maintain a comprehensive census of every hemodialysis patient in their facility. The census provides important information on mortality rates and patient characteristics.
- Every four months, DOPPS coordinators collect data on an average of 42-45 randomly selected patients. The information collected covers a variety of areas, including vascular access, hospitalization, outpatient events, selected laboratory values, hemodialysis prescription, and delivered dialysis dose.
- Each year, coordinators distribute a questionnaire to selected patients. This questionnaire is designed to capture information on the patients' quality of life.
- Medical directors and nurse managers at each of the DOPPS facilities devote considerable time each year to complete written surveys obtaining information about unit practices.

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