

Highlights

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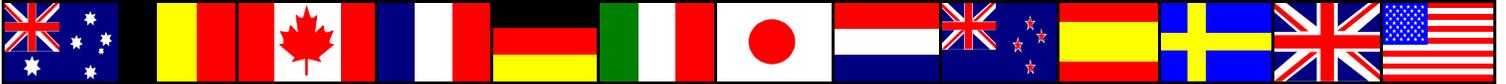
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The DOPPS Report

Newsletter of the Dialysis Outcomes and Practice Patterns Study

Volume III, Issue 1 October, 2001



This issue of the DOPPS Report is dedicated to the memory of Dr. Fernando Valderrábano

DOPPS Overview

The Dialysis Outcomes and Practice Patterns Study (DOPPS) is an on-going, international, longitudinal study that provides insight into the effects of clinical practice patterns in relation to patient outcomes. Practice patterns refer to the types of treatments and health care structures that constitute the medical care provided to hemodialysis patients at dialysis units. Particularly important patient outcomes for this study include mortality, hospitalization, vascular access failure, and quality of life. The international scope of DOPPS provides investigators with a unique opportunity to study broad variations in practice patterns.

New Countries Join DOPPS

Phase II of DOPPS will include six new countries, Australia, Belgium, Canada, the Netherlands, New Zealand, and Sweden. It is anticipated that countries from the first phase of DOPPS will continue to participate in Phase II. There is a clear need to understand the relationship between treatment practices and patient outcomes. Data collection in a range of countries will provide unique opportunities to assess practices and outcomes from widely variable sources with an eye to identifying treatment factors associated with better outcomes and improving patient care.

DOPPS Country Investigators: *Australia:* • Alex Disney, MD • Peter G. Kerr, MD; *Belgium:* • Michel Jadoul, MD • Norbert H. Lameire, MD; *Canada:* • Jean Ethier, MD • David C. Mendelsohn, MD, FRCPC; *France:* • Bernard Canaud, MD • Christian Combe, MD; *Germany:* • Jürgen Bommer, MD • Erwin Hecking, MD; *Italy:* • Vittorio Andreucci, MD • Francesco Locatelli, MD; *Netherlands:* • Raymond T. Krediet, MD, PhD • KML Leunissen, MD; *New Zealand:* • Mark R. Marshall, MD; *Spain:* • Luis Piera, MD • Fernando Valderrábano, MD; *Sweden:* • Björn Wikström, MD • Karl-Goran Prütz, MD; *United Kingdom:* • Roger Greenwood, MSc, MD, FRCP • Hugh C. Rayner, MD, FRCP

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U.S. DOPPS Investigators: • Philip J. Held, PhD • Kenneth Chen, MS • David A. Goodkin, MD • Marcia L. Keen, PhD • Donna L. Mapes, DNSc, MS • Bradley J. Maroni, MD • Friedrich K. Port, MD, MS† • Robert A. Wolfe, PhD† • Eric W. Young, MD, MS†

† Indicates investigators subcontracted with the University of Michigan

DOPPS is a worldwide hemodialysis study coordinated by the University Renal Research and Education Association (URREA). DOPPS is supported by an unrestricted grant from Kirin-Amgen. URREA Web Site: www.urrea.org E-Mail: urrea@urrea.org

The Phase II Protocol

Facility Participation

Phase II of DOPPS will involve 20 hemodialysis facilities from each of the participating countries other than the United States (100 facilities will be enrolled in the U.S.). Facilities will be randomly selected in order to represent all geographic regions and all types of dialysis facilities in each country. Data on the practice patterns within each facility will be collected through a series of directed questionnaires designed to collect patient-specific and facility-specific information.

Reducing the Data Collection Burden

Based on valuable feedback from Phase I, we will streamline the data collection process to substantially decrease the workload for the study coordinators. Some of the changes that have been made to facilitate data collection include:

- Improving layout, presentation, and packaging of all questionnaires
- Enabling completion of the patient census (CHC) electronically where feasible
- Instituting courier pickup of questionnaires in place of the Datafax system used in Europe
- Requiring informed consent only for selected patients, not all new patients entering the facility

In addition to the items listed above, **Table 1** provides a comparison between the Phase I and Phase II protocol in regards to patient selection and sample, data entry procedures, and changes to the current questionnaires.

The continuation and expansion of DOPPS is desirable and advantageous for several reasons. The expansion will enable investigators to:

- Collect data on research areas not fully studied in Phase I (e.g., pre-ESRD patient care, nutrition, and vascular access surgery)
- Collect additional longitudinal data on practice patterns and hemodialysis patient outcomes from the countries previously included in DOPPS
- Track dialysis practice patterns over time
- Improve study precision
- Provide greater statistical power

DOPPS Phase II

Although data collection has been on-going from Phase I, much effort has been devoted to the planning and development of Phase II. Following are just a few of the many tasks that will be necessary before the initiation of Phase II early next year. These tasks are:

- Obtaining approval from the applicable Ethical Committees to conduct the study
- Selecting and recruiting new facilities as needed in each country
- Refining the protocol for data collection
- Revising and translating the questionnaires for use in different countries

Feedback from Country Investigators and Study Coordinators from Phase I has contributed to the development of a new data collection protocol. A primary emphasis in redefining the data collection protocol was to reduce the work burden placed upon study coordinators. These insights and feedback have greatly facilitated planning and development of Phase II.

Table 1: Comparison Between the DOPPS Phase I and Phase II Protocol

Item	Phase I	Phase II
Patient selection	Random selection at study start and every 4 month interval to replace departed patients	Random selection of a prevalent patient sample at study start and recruitment of up to 15 incident patients during the study, no replacement of departed patients during the year
Target patient sample	Steady state of an average of 30 Patients per facility (mix of prevalent and incident patients)	20-40 prevalent patients selected at study start and first 15 consecutive incident patients
Patient Consent	Consent obtained from all chronic HD patients at the unit	Consent obtained only from selected DOPPS patients
Data Entry	Datafax system in Europe	Courier pick-up of forms
Patient Questionnaire	At study start and annually; 45 minutes for completion	At study start and annually; time for completion shortened to 20-30 minutes using the shorter KDQOL-36 and the CESD-10 (Center for Epidemiological Studies Depression Scale-short form)
Medical Questionnaire	At study start	At study start
Interval Summary	Every 4 months	A reduced amount of clinical information will be collected every four months
Unit Practices Survey	At study start and annually	Month four and annually
Medical Director Survey	At study start and annually	Month four and annually

Worldwide Presentations

This year, nine DOPPS abstracts have been accepted as poster presentations at the 2001 ASN/ISN conference in San Francisco, CA, USA. **Table 2** is a complete listing of the abstract titles and first authors. DOPPS Investigator, Dr. Friedrich Port, will present DOPPS analyses at the International Federation of Renal Registries (IFRR) post education course held before the start of the ASN conference. Also, DOPPS investigator Dr. Eric Young will present “Hemodialysis Practice Patterns and Outcomes in the Seven Countries of DOPPS” at ASN’s Basic and Clinical Science Symposium.

DOPPS analyses continue to be presented world-wide at major renal meetings. These meetings were well attended and the DOPPS research has generated a great deal of discussion and enthusiasm in the renal community. **Table 3** is a list of symposia and conferences which feature DOPPS research.

Table 2: DOPPS Abstracts Presented as Poster Sessions at ASN/ISN 2001

DOPPS Abstracts	Authors
Analgesic Use Among Hemodialysis (HD) Patients: Potential for Drug Related Problems	GR Bailie, et. al.
Association between Vascular Access Failure and Use of Specific Drugs: The Dialysis Outcomes and Practice Patterns Study (DOPPS)	EW Young, et. al.
Association of Blood Flow Rate (BFR) and Treatment Time (TT) with Mortality Risk (RR) in Hemodialysis (HD) Patients Across Three Continents	FK Port, et. al.
Beta-Adrenergic Antagonist Utilization Among Hemodialysis (HD) Patients	JL Bragg, et. al.
Higher Catheter Use Within Facilities is Associated with Increased Mortality and Hospitalization: Results From DOPPS	RL Pisoni, et. al.
Outcomes and Treatment Patterns of Elderly Hemodialysis (HD) Patients	ML Keen, et. al.
Patient Characteristics and Facility Practices Affecting Tunneled Catheter Use Among Incident Hemodialysis (HD) Patients in the United States and Europe: Results from DOPPS.	C Combe, et. al.
Predictors of Staffing Practices in Hemodialysis (HD) Facilities: Dialysis Outcomes and Practice Patterns Study (DOPPS)	DL Mapes, et. al.
Underutilization of HMG-CoA Reductase Inhibitors (HMG-CoAIs) among Hemodialysis (HD) Patients: A Potential Drug-Related Problem	NA Mason, et. al.

Table 3: DOPPS Research Presentations at Major Renal Meetings in 2001

Meeting	Location	Date
Central Vein Accesses for Hemodialysis Conference	Montpellier, France	February 1
Annual Conference on Dialysis	New Orleans, LA	February 21
International Conference on Geriatric Nephrology and Urology	Lisbon, Portugal	March 21
ISO-QoL Conference	Tokyo, Japan	April 14
National Kidney Foundation Meeting	Orlando, FL	April 17
American Nephrology Nurses Association (ANNA)	Las Vegas, NV	April 21
International Congress of Uremia Research (ICUR)	Nara, Japan	April 26
Necker Nephrology Meeting	Paris, France	May 9
Japanese Society of Nephrology	Tokyo, Japan	May 27
AFIDTN (French Congress, Nurses Association)	Nantes, France	May 31
2nd International Congress on Vascular Access	London, UK	May 31
Nephrology New Brunswick Regional Meeting	New Brunswick, Canada	June 1
Catalan Society of Nephrology	Cataluña, Spain	June 7
American Society for Artificial Internal Organs	New York, NY	June 8
British Renal Symposium	Manchester, UK	June 8
Italian Society of Nephrology	Crotone, Italy	June 8
Japanese Society of Dialysis Therapy	Osaka, Japan	June 22
European Dialysis and Transplant Association	Vienna, Austria	June 26
Australian & New Zealand Society of Nephrology	Darwin, Australia	September 5
International Society of Blood Purification	Tokyo, Japan	September 7
European Dialysis & Transplant Nurses Association	Nice, France	September 22
Spanish National Congress of Nephrology	Barcelona, Spain	September 28
French Society of Nephrology Congress	Montpellier, France	October 1
German Nephrology Congress	Muenster, Germany	October 1
German Dialysis Meeting	Berlin, Germany	November 30

Country Variations in Selected Socioeconomic Factors

Four socioeconomic factors were investigated to understand their variation across the DOPPS countries and also their relationship to characteristics of hemodialysis patients. These factors were employment, disability status, mode of transportation to the dialysis facility, and living arrangements. The analyses shown used a prevalent sample of patients from participating facilities in each of the seven countries in DOPPS Phase I.

Country variations in the employment and disability status of hemodialysis patients less than 60 years of age, is shown in **Figure 1**. Disabled patients were defined as unable to engage in any substantive gainful activity by reason of physical or mental impairment. Japan displays the highest percentage of employed hemodialysis patients and the lowest percentage of disabled patients. The large disparity between the countries in numbers of disabled patients may be differences in the social or cultural definition of patients categorized as being “disabled.”

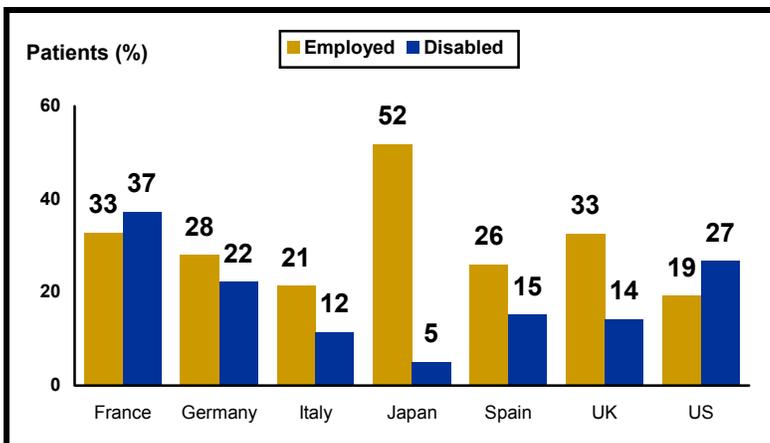


Figure 1: Employment and Disability Status by Country

Typically, disabled patients are more likely to utilize services of a social worker if unable to assist themselves. Based on responses from the Unit Practices Survey, the percentage of facilities which provide a social worker on a regular or as needed basis, varies greatly in each country, ranging from 100% of facilities in the United States to 47% in Italy (**Figure 2**).

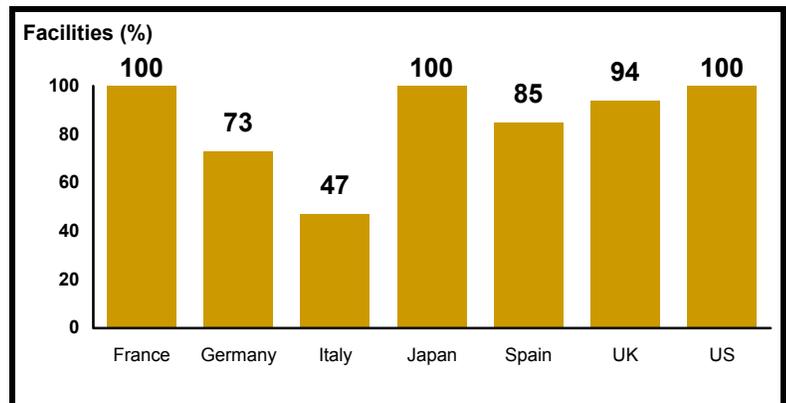


Figure 2: Access to a Social Worker by Country

In the U.S., the role of the social worker is to aid in the patient’s well being with services such as psychosocial assessment, patient and family counseling, and renal disease education. Other patient services include job placement, nursing home care, insurance coordination, homemaker assistance, and coordination of services with other care providers. Even though access to social workers varies greatly among the DOPPS countries, it does not necessarily mean these services are not performed or made available to patients in the countries reporting less access to social workers. In these countries, these patient services are often provided by the nursing staff or by another caregiver at the facility.

Another of the services provided by the social worker is to arrange transportation to and from the dialysis facility for those patients who cannot drive or make other arrangements themselves.

Using data from the Patient Questionnaire, **Figure 3** shows the wide variation between countries in the mode of transportation to and from the facility. These differences could be attributed to a number of factors in participating DOPPS countries. When asked on the patient questionnaire, “How do you usually get to dialysis?,” almost half of the dialysis patients in Japan answered that they drove themselves. In contrast, nearly half of the dialysis patients in the U.K. reported utilization of transportation provided by the facility. Interestingly, the amount of time it took to travel to the dialysis facility did not appear to be associated with the mode of transportation chosen by patients.

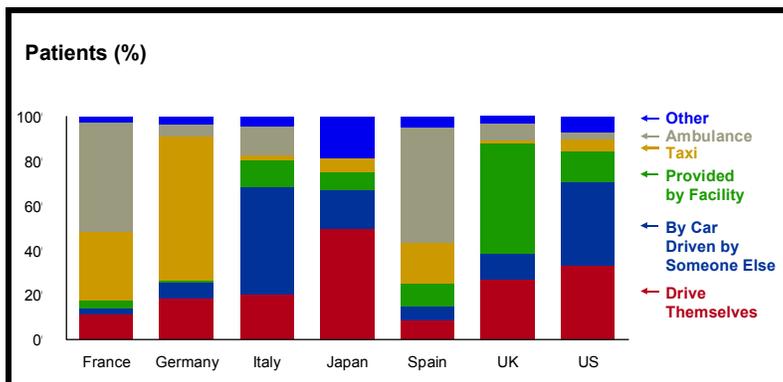


Figure 3: Transportation to Facility by Country

Economic factors, rather than travel time or necessity, seem to provide the best explanation for observed differences in the patient’s mode of transportation to the dialysis facility. The high percentage of patients transported by ambulance in some of the countries may be explained by subsidized ambulance services or other financial incentives in these countries.

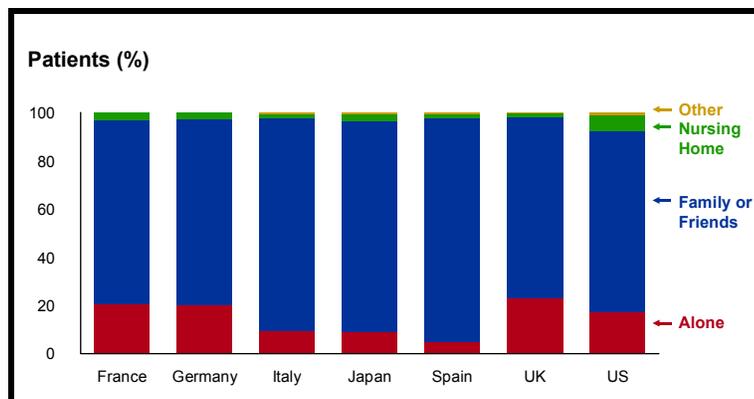


Figure 4: Living Arrangements by Country

Hemodialysis patients who live alone are typically perceived as being more independent and able to work and drive. On the other hand, the dialysis patient in the nursing home is often perceived as needing more assistance with daily living and may be classified as “disabled.” To our surprise, differences in living arrangements did not appear to correlate with either the patient’s disability status or preferred method of transportation to dialysis. In fact, the percentage of patients in nursing homes is quite similar for all seven countries (**Figure 4**), with the U.S. having the highest percentage (6.5%).

Closer examination of both economic and cultural factors within these countries might provide further insight into some of their differences. Further research is needed to more clearly define any relationship between these socioeconomic factors and facility practice patterns or patient outcomes.

Technical Notes:

- All DOPPS data in the figures presented were obtained from the Medical Questionnaire (MQ), the Patient Questionnaire (PQ), and the Unit Practices Survey (UPS) collected from 1996-2000.
- Figure 1: From the question asked on the MQ “Employment status at enrollment date”
- Figure 2: From the question asked on the UPS “Frequency of Social Worker counseling”
- Figure 2: Sample size (number of facilities): FR=16; GR=11; IT=17; JP=44; SP=13; UK=18; US=145
- Figure 3: From the question asked on the PQ “How do you usually get to dialysis?”
- Figure 4: From the question asked on the MQ “Living status at enrollment”
- Employment data from patients <60 years old

Questions & Answers

Frequently Asked Questions from Participating DOPPS Facilities

Q: When will Phase II begin ?

A: Data collection for Phase II of DOPPS is scheduled to start for all countries in early 2002. Facilities recruited to be in the study will receive all necessary information, instructions, and forms prior to the start of data collection.

Q: How are the dialysis facilities selected to participate in DOPPS?

A: Selection is made from a randomized list of facilities currently caring for 25 or more hemodialysis patients. Selection is designed to obtain a sample that is representative both by type of facility (satellite, hospital, etc.) and geographic location.

Q: Will our facility be compensated for participating in the study, and if so, how and when will we get paid?

A: Within each country, facilities are compensated for completed forms returned to the DOPPS Coordinating Center. The medical director or administrator at your facility will receive a *Payment Information Form* that specifies how compensation is to be made, to whom, and where the payments are to be sent. When forms are returned to the DOPPS Coordinating Center, a voucher is created and submitted for payment.

Q: How are patients selected and enrolled into DOPPS? Will patient information be kept confidential?

A: Within each participating hemodialysis facility, a random sample of patients will be selected. The information provided to the DOPPS Coordinating Center, DOPPS staff, and Quintiles staff will not include any identifying information (i.e. name or date of birth). Patients will only be identified by a "census" number so that all information is collected and stored in an anonymous fashion without any linkage to patient names. Only the study coordinator at the facility will know the names of the patients that correspond to their census numbers in order to distribute and complete the questionnaires. The Patient Questionnaire is completed by the patient and is returned to the study coordinator in a sealed envelope.

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