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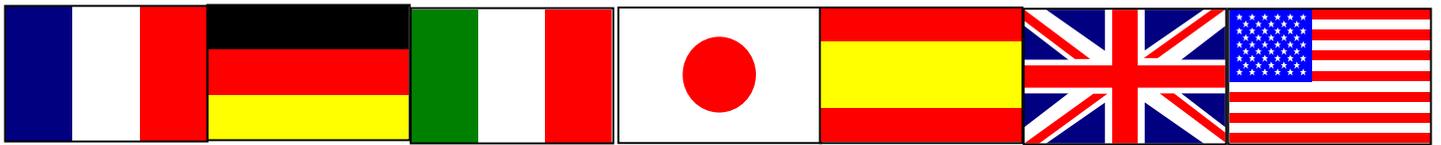
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The DOPPS Report

Newsletter of the Dialysis Outcomes and Practice Patterns Study

Volume 1, Issue 1

October 1999



DOPPS: An International Hemodialysis Study

Readers of “The DOPPS Report” are likely aware that DOPPS is an international study taking place in seven countries: France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States. With this in mind, we have decided to give the previously named International DOPPS the new and more appropriately descriptive name “Euro-DOPPS.” “Japan-DOPPS” will keep its name and DOPPS in the U.S. is now named “U.S.-DOPPS.” The official designation of each of the three projects comprising DOPPS is as follows:

Euro-DOPPS }
Japan-DOPPS } Combined as one study called “DOPPS”
U.S.-DOPPS }

Quintiles, an international contract research organization, oversees data collection in Europe and Japan. In the United States, data are collected by the DOPPS Coordinating Center at University Renal Research and Education Association (UR-REA) in Ann Arbor, Michigan.

Since DOPPS is really one study with a common protocol and shared objectives in each country, there is now one newsletter for the entire study instead of separate newsletters for Euro-DOPPS, Japan-DOPPS, and U.S.-DOPPS. This is the inaugural issue of “The DOPPS Report” as a newsletter for DOPPS that includes updates on all three DOPPS projects. This issue, and future issues of “The DOPPS Report,” will focus on informing readers about topics and events of mutual interest and relevance.

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

DOPPS is supported by a grant from Amgen. URREA Web Site: www.urrea.org, E-Mail: urrea@urrea.org

DOPPS: Representative Data

The data collected in seven countries for the DOPPS project constitute a large, powerful, longitudinal database of patient-specific and facility-specific information. Since data collection is based on a representative selection of facilities and patients, these data are representative of more than 75% of the estimated chronic hemodialysis population throughout the world.

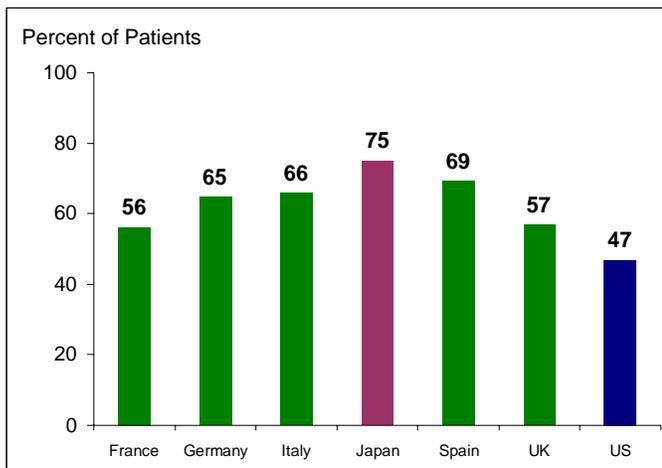


Figure 1. Percent of DOPPS Hemodialysis Patients Who are Married, by Country, 1997-1999.

More generally, the availability of valid, representative, longitudinal data permits analyses of practice patterns and their associations with mortality and other outcomes. These analyses take into account changes over time, patient characteristics, and patient demographics. Information on rates of marriage is one example of comparable patient-specific DOPPS data. As an example of representative, international data, **Figure 1** shows that the percentage of patients who are married varies from 47% in the U.S. to 75% in Japan.

Euro-DOPPS Update

Euro-DOPPS data collection is well underway; most facilities are in the third or fourth of seven total rounds of data collection. The 101 facilities participating in Euro-DOPPS have provided excellent support and cooperation. The rate of completion for each questionnaire is impressively positive.

The Euro-DOPPS Spring Meetings, held in each

participating country (France, Germany, Italy, Spain, and the United Kingdom), were an opportunity to present exciting preliminary data and exchange important information about data collection. We invited the Study Coordinator and Medical Director from each facility to attend. Each meeting was very well attended, with over 85% of facilities represented. The preliminary data presentation demonstrated that, by collecting information from a representative sample of patients, we can obtain important findings that will improve the well-being of all hemodialysis patients. We appreciate the support and effort of all involved in the Euro-DOPPS project and will continue to find ways to supply information to the participating facilities.



Figure 2. Geographic Distribution of Euro-DOPPS Facilities Enrolled as of March, 1999 (101 facilities, 3,000 patients).

Japan-DOPPS Update

In Japan, data collection started in February, 1999. Sixty-three facilities are now in either the first or second round of data collection. Returns in round one are very impressive. Patient Questionnaire return rates in the first round of data collection were near 97% of the 1800 patients included in the study. Medical Questionnaire return rates were similarly high. The quality of data collection in Japan is extremely impressive.

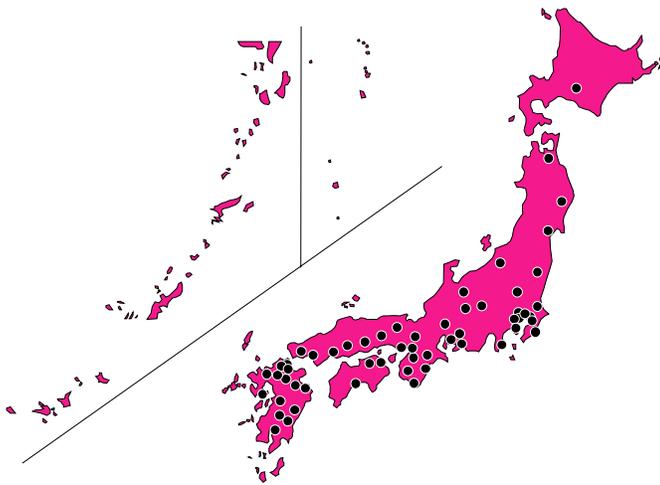


Figure 3. Geographic Distribution of Japan-DOPPS Facilities Enrolled as of June, 1999 (63 facilities, 1,800 patients).

In May, 1999, the Japan-DOPPS team met in Tokyo to review the procedures and logistics of data collection. Team members from URREA in Ann Arbor, Michigan, and Amgen in Thousand Oaks, California, had the privilege of visiting Japan and working side by side with the Japanese team. The U.S. team members thoroughly enjoyed their visit to Japan.

U.S.-DOPPS Update

In the United States, the continued dedication of Study Coordinators has led to substantial improvements in both the quality and quantity of data collected. Contributions from all 161 enrolled facilities in the United States has been a goal for U.S.-DOPPS since data collection started in 1996. We are pleased to have active participation (steady completion of study questionnaires) from most of the 161 enrolled facilities.

Each year, the DOPPS workshop at the ANNA (American Nephrology Nurses Association) convention provides an opportunity for the DOPPS Coordinating Center to share preliminary statistics from the data collected. This meeting facilitates a productive exchange of ideas and information about the process of data collection. On April 11, 1999 the

second annual DOPPS Workshop at ANNA was held in Baltimore, Maryland. We invited all DOPPS Study Coordinators to attend. As with last year's workshop, we awarded travel grants to a group of randomly selected Study Coordinators. This workshop will likely be held again at next year's ANNA meeting, and we hope that we can once again provide travel grants to a randomly selected group of Study Coordinators.

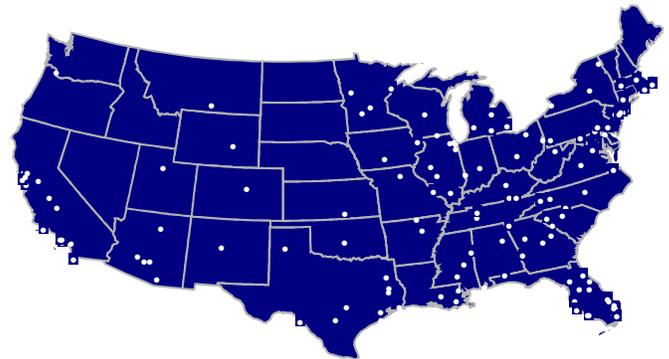


Figure 4. Geographic Distribution of U.S.-DOPPS Facilities Enrolled as of July, 1999 (161 facilities, 4,800 patients).

Research In Progress

We are very pleased to inform Study Coordinators and Medical Directors in all seven DOPPS countries about the advancements in DOPPS research that would not have been possible without their help and support. Last year, five abstracts were accepted for presentation at the American Society of Nephrology meeting. This year, 12 DOPPS abstracts were accepted by the ASN for poster presentation or free communication. These abstracts are the beginning of investigations in areas of renal research that will improve the welfare of kidney patients throughout the world.

Quality of Life

DOPPS is a prospective, observational study of the associations between hemodialysis treatment practices and patient outcomes. DOPPS focuses on

The following is a list of the 12 DOPPS abstracts that will be presented as either posters or free communications at the ASN meeting in November, 1999. We hope that many of you will get a chance to attend the presentations of DOPPS research during the meeting. We are eager to share these important preliminary statistics with our colleagues from around the world.

- Effectiveness of Nutritional Quality Improvement (QI) Activities (Young, et al.)
- Permanent Vascular Access (VA) Preferences and Outcomes (Young, et al.)
- Risk of Hospitalization and Length of Stay Among Hemodialysis (HD) Patients in the US and Europe (Young, et al.)
- Vascular Access (VA) Survival and Prior Access Placement (Young, et al.)
- Comparison of Vascular Access Use in the US and Europe: The Dialysis Outcomes and Practice Patterns Study (DOPPS) (Pisoni, et al.)
- Medicare Secondary Insurance Status Among Prevalent Hemodialysis (HD) Patients in the US (McCullough, et al.)
- Medication Insurance and Patient Out-of-Pocket Spending by Hemodialysis Patients in the US. (Orzol, et al.)
- Nutritional Indicators as Predictors of Mortality (Pifer, et al.)
- Permanent Vascular Access (VA) Procedures and Outcomes (Dykstra, et al.)
- International Variation in Comorbid Disease Among Hemodialysis (HD) Patients: Dialysis Outcomes and Practice Patterns Study (DOPPS) (Goodkin, et al.)
- Psychiatric Disease is Associated with Increased Mortality and Hospitalization Among Hemodialysis (HD) Patients (Goodkin, et al.)
- Quality of Life Predicts Mortality and Hospitalization for Hemodialysis (HD) Patients in US and Europe (Mapes, et al.)

the patient outcomes of mortality, hospitalization, vascular access, and quality of life. While mortality is of primary interest, there is increasing concurrence among renal researchers and health care providers that the quality of dialysis care cannot be measured

in terms of survival only. What matters to patients is not just whether they survive, but how well they are able to function and how satisfied they are with their daily lives. Since End Stage Renal Disease is a chronic condition that cannot be cured, it has a far-reaching impact on the lives of dialysis patients. Furthermore, the treatment itself (dialysis or kidney transplantation) has important consequences for patients and affects many facets of daily life.

Consequently, a study as comprehensive as DOPPS needs to include study objectives that focus on patient quality of life and well-being. The DOPPS project is designed to collect information that will contribute to improving the treatment and welfare of hemodialysis patients. This includes a focus on patient well-being and satisfaction that starts with the measurement of the patient's adaptation to chronic illness and ongoing treatment.

The DOPPS research plan is to measure the relationship between treatment practices and patient outcomes. While mortality describes the difference between patients who survive and do not survive, other outcomes such as frequency of hospitalization or quality of life can help describe the effectiveness of treatments among those who do survive. As we examine practice patterns using multiple outcome measures such as these, we can measure not only how a given practice changes a patient's chance of survival, but also how that practice affects the patient's adaptation to, and experience with, ESRD. It is also interesting to see the relationships among these different outcome measures. For example, how does a patient's functional adaptation, level of satisfaction, and sense of well-being affect hospitalization and survival? Do patients who report a better sense of well-being live longer or have fewer hospitalizations?

Since the assessment of personal satisfaction and well-being is subjective, quality of life is best measured by the patient. The measurement of quality of life needs to encompass multiple life domains including the physical, emotional, sexual, social, ability to work, and other concepts that impact a patient's sense of well-being.

In DOPPS, the Patient Questionnaire is the tool for measuring quality of life. The patient completes it (sometimes with assistance) at the time of study enrollment and again after each subsequent

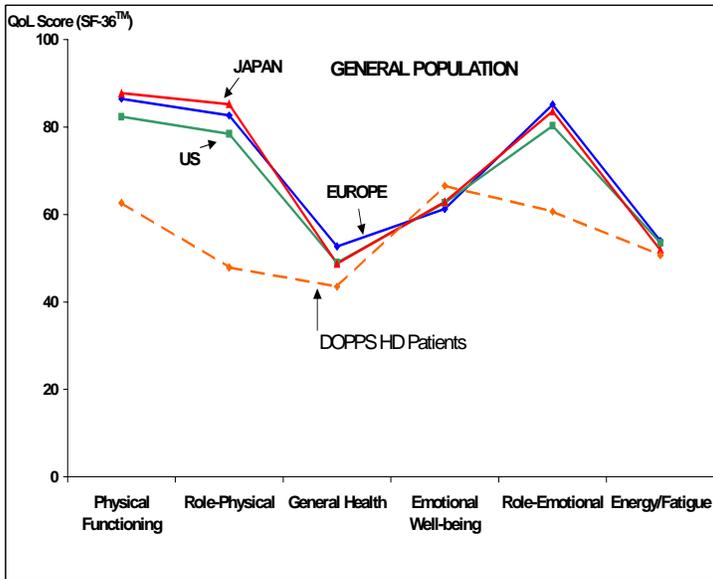


Figure 5. Selected SF-36™ Summary Scale Scores for General Populations of Europe, Japan, and U.S. Compared with DOPPS HD Patients, 1997-1999.

year he or she continues to dialyze. This longitudinal study design measures variations in quality of life over time.

The Kidney Disease Quality of Life-SF™ (KDQoL) instrument constitutes the first 38 questions of the Patient Questionnaire. (In Japan, the PQ consists only of the KDQoL.) The “core” of the KDQoL-SF™ is based on the Short Form 36 (SF-36™), an instrument that is widely used for the

assessment of health-related quality of life. The SF-36™ has been tested extensively for reliability and validity. Reliability is the precision or consistency with which an instrument measures what it is designed to measure when repeated from person to person. Validity is the extent to which an instrument truly measures what it is supposed to measure. For example, if an instrument is supposed to measure “happiness,” then we need to know that 1) the instrument is consistently measuring “happiness” when administered repeatedly, and that 2) the instrument is measuring “happiness,” not another related concept such as overall life satisfaction. Both the SF-36™ and the KDQoL™ have been shown to be reliable and valid instruments for the measurement of health-related patient well-being.

Table 1 provides a list, along with a brief description, of each of the SF-36™ summary scales. Each of these is scored on a scale of 0-100; higher scores indicate better quality of life. The summary scales combine to make up two composite measures of general health: **the Physical Component Summary (PCS)** and the **Mental Component Summary (MCS)**. The Physical Functioning Scale, Role-Physical Scale, Pain Scale, and General Health Scale are the primary subscales combined to provide the PCS. The Emotional Well-Being Scale, Role-Emotional Scale, Social Function Scale, and Energy/Fatigue Scale are the primary subscales aggregated to form the MCS. The PCS and MCS are useful summaries that measure two broad areas of self-

Table 1. Description of SF-36 Summary Scales.		
SF-36 General Health Areas	Questions on PQ	Description
Physical Health Summary Scales		
Physical Functioning	3a-3j	Extent to which physical activities such as housework, lifting, and climbing stairs are limited
Role – Physical	4a-4d	Impact of health on work, difficulty of work and amount of time spent on work or other activities
Pain	7,8	Extent of pain and its impact on work
General Health	1, 11a-11d	Perception of general health status
Emotional Health Summary Scales		
Emotional Well-Being	9b, 9c, 9d, 9f, 9h	Impact of health on emotional well-being
Role – Emotional	5a-5c	Impact of emotional problems on work and other activities
Social Function	6, 10	Impact of physical and emotional health on social activities
Energy/Fatigue	9a, 9e, 9g, 9i	Measures impact of health on energy level

} Primary Subscales of Physical Component Summary (PCS)

} Primary Subscales of Mental Component Summary (MCS)

reported health, one physical and one emotional.

Let us look at a fictitious patient and how this patient's real life activities influence the measurement of his quality of life. Mr. Smith is a 38 year-old man who is married, has two children, and receives hemodialysis treatments three times a week. His health restricts some of his physical activities such as carrying in the groceries and playing golf. This is information about how Mr. Smith's health affects his daily activities, and contributes to the score of the Physical Functioning Scale. Mr. Smith works as a computer programmer and is able to adjust his work hours to make time for his hemodialysis treatments. His kidney disease does not directly affect his professional work. This is information about how Mr. Smith's chronic illness affects his ability to work and contributes to the score of the Role-Physical Scale. These scales, along with the other six, combine to determine the PCS. Mr. Smith is depressed about his health and this affects his sense of emotional well-being. Even spending time with his wife and children does not relieve his depression and he avoids social activities with friends. This information is relevant to measures of the Emotional Well-Being, Role-Emotional and Social Function Scales. Along with the other scales, these scales combine to determine the MCS.

Figure 5 provides six different SF-36™ Physical Health and Emotional Health Summary Scales for the general populations of Europe, Japan, and the U.S. These statistics provide evidence that these general populations report very similar levels of health-related quality of life. From these data, we know that if we

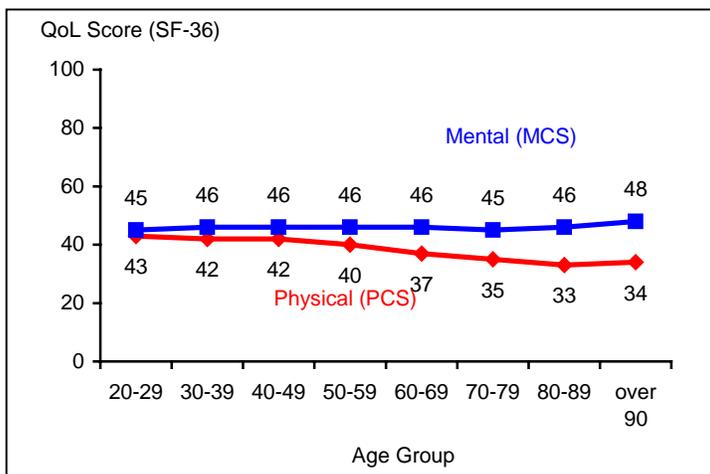


Figure 6. SF-36™ MCS and PCS Scores by Age for DOPPS HD Patients 1997-1999. DOPPS HD Patients, SF-36™ Component Summary Scales.

want to examine differences between the general population and DOPPS patients in Europe, Japan, or the U.S., the baseline for comparison is almost the same in each case. **Figure 5** also provides the average measure for each of these same six summary scales, in aggregate, for

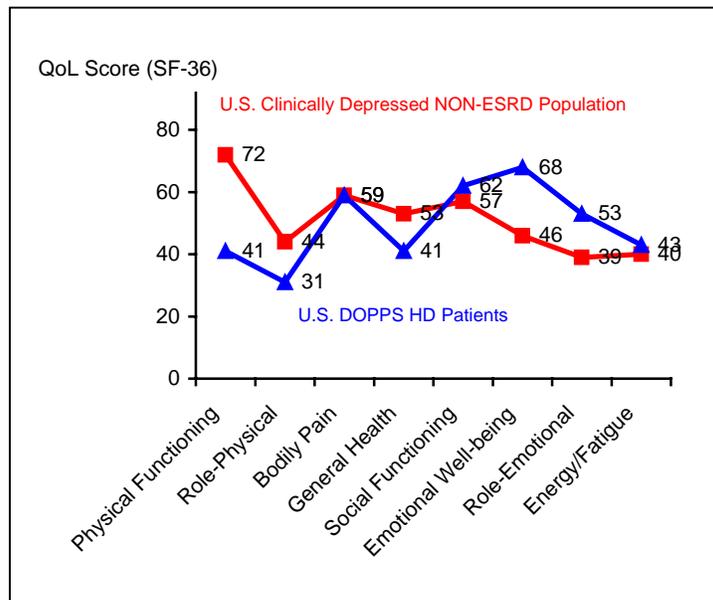


Figure 7. All SF-36™ Summary Scales for U.S. Clinically Depressed Non-ESRD Population vs. U.S.-DOPPS HD Population, 1997-1999. U.S.-DOPPS HD patients age adjusted to 60 years.

all DOPPS patients. (Since the data for the general populations of Europe, Japan, and the U.S. represent a population with an average age of 45, the average measures of quality of life for dialysis patients are adjusted to represent an average age of 45 as well.) These statistics demonstrate that there are, in some cases, substantial differences between the scores of the general population and the scores of the DOPPS hemodialysis population. On average, hemodialysis patients have lower quality of life than the general population, with more marked differences in physical health summary scores than mental health summary scores. Future DOPPS research will seek to understand more about these differences.

Figure 6 displays the PCS and MCS by age group for the average DOPPS (Europe, Japan, and the U.S.) hemodialysis patient. These statistics demonstrate that PCS decreases markedly with increasing age while the MCS remains fairly stable with increasing age.

How do hemodialysis patients compare to other chronically ill patient groups in terms of their quality of life? **Figure 7** compares the U.S. DOPPS hemodialysis sample to a U.S. sample of clinically depressed patients.

Table 2. KDQoL SF-36™ Targeted Areas		
ESRD Targeted	Questions	Description
Symptoms/problem list	14a-k, l	Extent of being bothered by physical symptoms
Effects of kidney disease	15a-h	Extent of interference with life
Burden of kidney disease	12a-d	Extent to which disease takes time, creates feeling of burden
Work status	20, 21	Measures whether patient is working and if health status affects ability to work
Cognitive function	13b, 13d, 13f	Extent of impaired thinking
Quality of social interaction	13a, 13c, 13e	Feelings of isolation, irritability, and confusion
Sexual function	16a-b	Impact of disease on sexual activity
Sleep	17, 18a-c	Impact on sleep
Social support	19a, 19b	Extent of satisfaction with social supports
Dialysis staff encouragement	24a, 24b	Extent of satisfaction with dialysis staff support
Patient satisfaction	23	Extent of satisfaction as a patient

The hemodialysis patients display substantially better mental health-related quality of life, while the clinically depressed patients exhibit substantially better physical health-related quality of life for all categories except bodily pain. Data about differences between hemodialysis patients and other patient groups provide important information about the relative well-being of hemodialysis patients.

In addition to the “core” SF-36™, the Kidney Disease Quality of Life-SF™ also contains 11 multi-item scales that measure the specific impact of kidney disease on patients receiving dialysis treatment. These scales are called “ESRD Targeted Areas.” Disease-specific instruments demonstrate increasing sensitivity in measuring small changes in chronic diseases. As with the SF-36™, each of these is scored on a scale of

0-100; higher scores indicate better quality of life.

Table 2 provides a list and a brief description of each ESRD Targeted Area.

DOPPS research studies will focus both on general health-related quality of life and the unique issues and problems of hemodialysis patients. Both areas are important as we pursue knowledge and strategies for improving the lives of hemodialysis patients.

Special Note to All Study Coordinators

Thank you for your dedication and hard work. DOPPS would not be a reality without your professional efforts and support. We would like to take this opportunity to remind you that ALL chronic hemodialysis patients must be listed on your facility’s Cumulative Hemodialysis Census. Please be careful to include all chronic hemodialysis patients, even if a patient dialyzes at your facility for only a very short period of time. If you ever have any questions about whether or not to include a chronic patient on your CHC, it is best to take a conservative approach and list that patient on the CHC.

Technical Notes:

- To protect confidentiality, one dot from a non-participating unit is added to each country on each map. Three facilities in Alaska and Hawaii are not shown on the U.S. map.
- Weighting is employed in graphics representing the total DOPPS sample (all seven countries). This is done to ensure the correct representation for the ESRD populations in the corresponding countries.
- In Figure 5, general population data comes from Gandek, et al. (1998). The average age of the populations is 41.1 years to 47.6 years, therefore the DOPPS sample is age adjusted to 45 years-old. Higher scores indicate better quality of life.
- In Figure 7, U.S. Clinically Depressed General Population data from Ware, et. al. (1997). Higher scores indicate better quality of life.
- All DOPPS data are based on Patient Questionnaires and Medical Questionnaires collected from 1996-1999.

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Questions & Answers

Frequently Asked Questions from Participating DOPPS Facilities

Q: I just received my next round of questionnaires. Which ones should I work on first?

A: When you receive your questionnaires (U.S.-DOPPS) or PAF (Euro- and Japan-DOPPS), try to hand out your Patient Questionnaires immediately. This increases the chance that your selected patients will be able to fill out this questionnaire before any of them depart the unit. Remember that this information is perishable; you want to give your selected patients as much opportunity as possible to complete these important questionnaires.

Q: I finished completing the vascular access section on the Interval Summary for a patient, and I realized that I forgot to mention a procedure. What should I do?

A: If you forget to document a procedure or an event in the vascular access, hospitalization, or outpatient events sections, write the missing procedure or event on any available line, along with the date on which the procedure or event occurred. Events and procedures do not need to be listed in chronological order, as long as you correctly report the date.

Q: Every now and then we have an “acute” patient in our unit for dialysis. Should we include them on the CHC?

A: No, these patients should NOT be included on your CHC. “Acute” means that the patient is receiving hemodialysis, but not for chronic, irreversible kidney disease. Only list chronic in-center hemodialysis patients on your CHC. Sometimes an acute dialysis patient fails to recover renal function and becomes a chronic patient. Such a patient should be entered on your CHC when his or her status changes to chronic. In the U.S., this might correspond to when you complete the HCFA Medical Evidence Form (Form 2728).

Q: I am a DOPPS Study Coordinator in California, and I am curious about why DOPPS has become a worldwide study.

A: U.S.-DOPPS, Euro-DOPPS, and Japan-DOPPS follow a common design, protocol, and analysis. The goal of the DOPPS project is not to compare countries, but rather to compare practice patterns and their effects on patient outcomes. By including seven countries (France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States) we are able to study a wider variety of practice patterns. This will increase what we learn about the associations among practice patterns and patient outcomes.

Q: A patient in my unit died right after I received my last round of questionnaires, and there were forms to be completed for this patient. Do I need to fill out questionnaires for this patient, even though he died?

A: Please complete questionnaires for ALL selected patients, regardless of whether they are still dialyzing at the facility. It is from patients like this that we can learn the most about why some patients die soon after beginning dialysis or switching modality.

Questions? Contact:

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