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The I-DOPPS Report

Newsletter of the International Dialysis Outcomes and Practice Patterns Study *Volume 1, Issue 1* *February, 1999*

I-DOPPS is Underway in Five European Countries

The International Dialysis Outcomes and Practice Patterns Study (I-DOPPS) was initiated in July of 1998. I-DOPPS is a two-year prospective observational study of the associations between hemodialysis practice patterns and patient outcomes of mortality, hospitalization, vascular access and quality of life. I-DOPPS is based on a parallel study, the Dialysis Outcomes and Practice Patterns Study (DOPPS), that is currently being conducted in the United States. The **University Renal Research and Education Association (URREA)**, located in Ann Arbor, Michigan, U.S.A., is coordinating the DOPPS and I-DOPPS projects.

One hundred dialysis facilities in five European countries (France, Germany, Italy, Spain and the United Kingdom) have been randomly selected for participation in I-DOPPS. To date, 95 facilities have completed a Cumulative Hemodialysis Census (CHC). The CHC provides a complete list of all hemodialysis patients in the facility throughout the study and is used for selecting a random sample of patients. By the end of January 1999, all 100 facilities will be participating and starting to collect patient-specific data. As of year-end 1998, patient-specific clinical data for over 1,700 patients have been collected.The questionnaires for I-DOPPS data collection are being completed by a "study coordinator" (usually either a nurse or physician) at each participating dialysis facility. The patient-specific and facility-specific data collected as part of the I-DOPPS project will constitute a unique and powerful database of information about hemodialysis patients and their treatment. These data will be used for research for improving the well being of patients with End Stage Renal Disease.

I-DOPPS Country Investigators: *France:* • Bernard Canaud, MD • Christian Combe, MD; *Germany:* • Jürgen Bommer, MD • Erwin Hecking, MD; *Italy:* • Vittorio Andreucci, MD • Francesco Locatelli, MD; *Spain:* • Luis Piera, MD • Fernando Valderrabano, MD; *United Kingdom:* • Colin Aldridge, PhD • Roger Greenwood, MSc, MD, FRCP • Hugh C. Rayner, MD; *Members at Large:* • Nathan W. Levin, MD • Severin Ringoir, MD, PhD

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

I-DOPPS is an international hemodialysis study coordinated by the University Renal Research and Education Association (URREA).
I-DOPPS is supported by a grant from Amgen.

An internationally recognized group of nephrologists serve as Country Investigators for the I-DOPPS.

The I-DOPPS Country Investigators are:

France

Bernard Canaud, MD
Christian Combe, MD

Germany

Jürgen Bommer, MD
Erwin Hecking, MD

Italy

Vittorio Andreucci, MD
Francesco Locatelli, MD

Spain

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Members at Large

Severin Ringoir, MD, PhD
Nathan W. Levin, MD

Quintiles, an international Contract Research Organization, in close collaboration with URREA, is coordinating data collection for I-DOPPS in all five countries. This project could not have proceeded without the professional contributions of the personnel from Quintiles and the participating dialysis facilities. We are very grateful to the study coordinators at each facility, medical directors and all other dialysis facility personnel who have made this project possible.

Study Implementation

The implementation of the I-DOPPS project was a long and complex process. The development of the study design started in the summer of 1996 and continued for a full year. Following are some of the activities that occured during that year.

"On-Site" Meetings in Each Country

The purpose of each of these meetings was to gather information about issues of hemodialysis specific to each country. Along with the Country Investigators, four to five leading nephrologists from each country were invited to attend and contribute their expertise and knowledge of local hemodialysis practice.

Questionnaire Development & Translation

The questionnaires for the I-DOPPS project are based on the questionnaires used for DOPPS in the United States. However, substantial modifications were required to adapt the questionnaires for use in each of the participating countries. Once modified, the questionnaires were translated into French, German, Italian, Spanish, and Queen's English. The translated questionnaires were reviewed by the I-DOPPS Country Investigators to ensure that the translations were appropriate, consistent across countries, and easily understood.

As part of the process of translation, a glossary (dictionary) of nephrology terms was developed for each of the five languages. Our plans include compiling these glossaries into documents, both hard copy and electronic, that can be used as a reference for the international renal community. For example, this glossary would enable a researcher or other professional to find the translation of a term such as "vascular access" in the other languages. We are excited about the potential utility of this glossary.

Pilot Testing

The Unit Practice Survey, Medical Questionnaire and Cumulative Hemodialysis Census were pilot tested in each participating country. The feedback we received from the nurses and physicians who participated in the pilot test was extremely valuable and was used to modify and improve the questionnaires. We are very grateful to the nurses and physicians who helped us with this important task.

Development and Implementation of Data Collection Procedures

URREA and Quintiles worked collaboratively to develop and implement the procedures for distributing and returning completed questionnaires to the Quintiles Data Management Center. Data collection procedures were carefully designed. The ease and feasibility for the data collector was given the highest consideration.

Site Visits

The Clinical Research Associates, employed by Quintiles, each visited all 20 facilities in each country to meet with the study coordinator and review data collection procedures for the I-DOPPS.

Summary

After substantial effort dedicated to a complete set of tasks, I-DOPPS was officially "launched" in July of 1998 with some initial CHCs sent to participating facilities. Our sincere thanks go to all who have contributed to the implementation of I-DOPPS and to the personnel of the participating dialysis facilities whose support and cooperation have made this important project possible.

Figure 1. Geographic distribution of I-DOPPS facilities enrolled as of October 1998 (*n* = 100).

World-Wide DOPPS

The DOPPS is a worldwide project that is being conducted on three continents: North America (U.S. DOPPS), Europe (I-DOPPS), and Asia (Japan DOPPS) (See Figures 1, 2 and 3). This is probably the first prospective international representative study of a single disease entity with a common modality of treatment, i.e. hemodialysis for End Stage Renal Disease.

In the United States, a national representative sample of 160 dialysis facilities and 4,800 hemodialysis patients are participating. In Japan DOPPS, recruitment of a national representative sample of 60 dialysis facilities is underway. The locations of 58 of these facilities are shown in Figure 2.

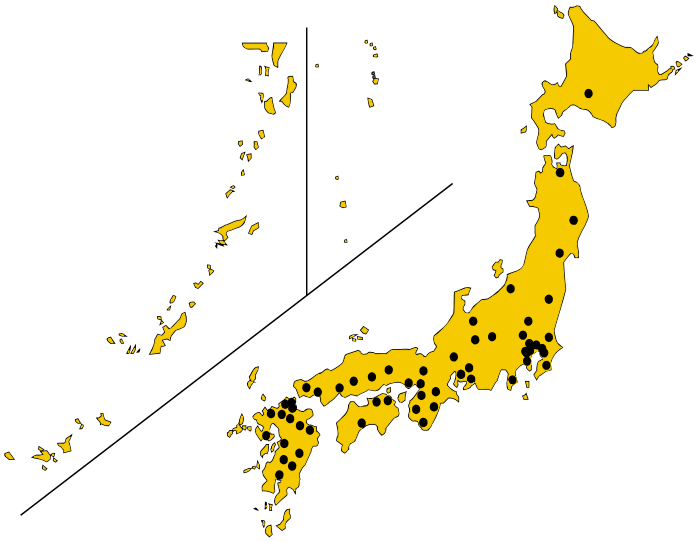

Figure 2. Geographic distribution of Japan-DOPPS facilities enrolled as of October 1998 (*n* = 60).

These three studies follow a common design, protocol and analysis and constitute the World-Wide DOPPS. The goal of the World-Wide DOPPS projects is not to compare countries, but rather to compare practice patterns and their effects on patient outcomes. The inclusion of seven countries (France, Germany, Italy, Japan, Spain, the United Kingdom, and the United States) will enhance the variability of practice patterns. This will increase what we learn about the associations among practice patterns and patient outcomes.

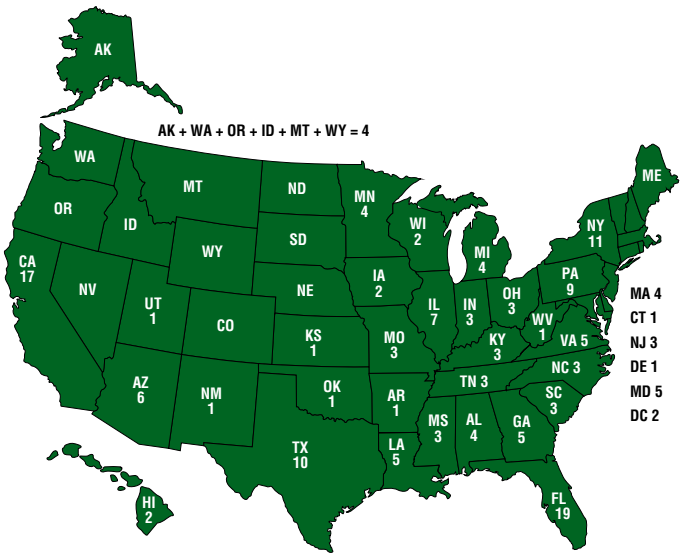

Figure 3. Geographic distribution of DOPPS facilities enrolled in the U.S. October 1998 (*n* = 161).

Preliminary Hemodialysis Patient Statistics from I-DOPPS

Each facility participating in I-DOPPS completes a Cumulative Hemodialysis Census (CHC). The CHC is a list of patients at the facility that provides a sampling frame from which to randomly select prevalent patients within a facility for participation in the study. The CHC also provides some demographic information for every hemodialysis patient at that facility. In the United States, comparable data have been collected as part of the DOPPS project.

One of the objectives of the World-Wide DOPPS is to describe patient characteristics. The preliminary statistics presented in this section are from the I-DOPPS CHC and the U.S. DOPPS CHC. The I-DOPPS statistics are based on a sample of 95 CHCs (from France, Germany, Italy, Spain and the United Kingdom) completed in late 1998. The DOPPS statistics are based on a sample of 144 CHCs completed at the start of the DOPPS study (1997).

Figure 4 provides the mean patient age for prevalent hemodialysis patients in the five European countries participating in the I-DOPPS and in the United States. There appears to be modest variation in mean age

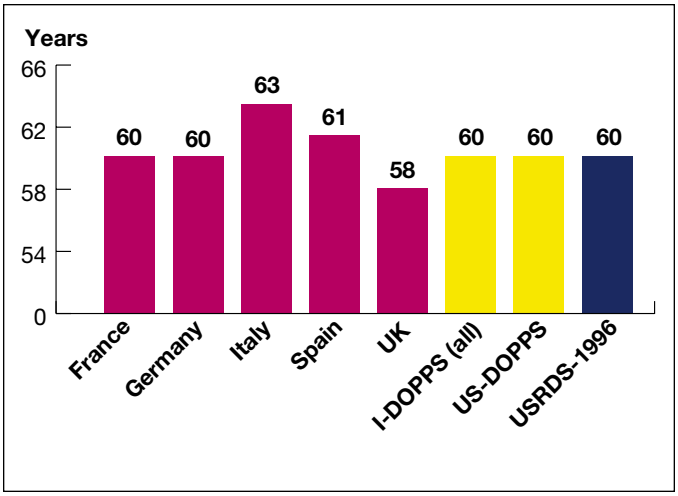

Figure 4. Mean Patient Age on 1998 I-DOPPS CHC by Country and Study.

across countries, with the United Kingdom having the lowest mean age of 58 years and Italy having the highest mean age of 63 years.

Figure 5 reports the percentage of hemodialysis patients that are female in the five European countries and in the United States.

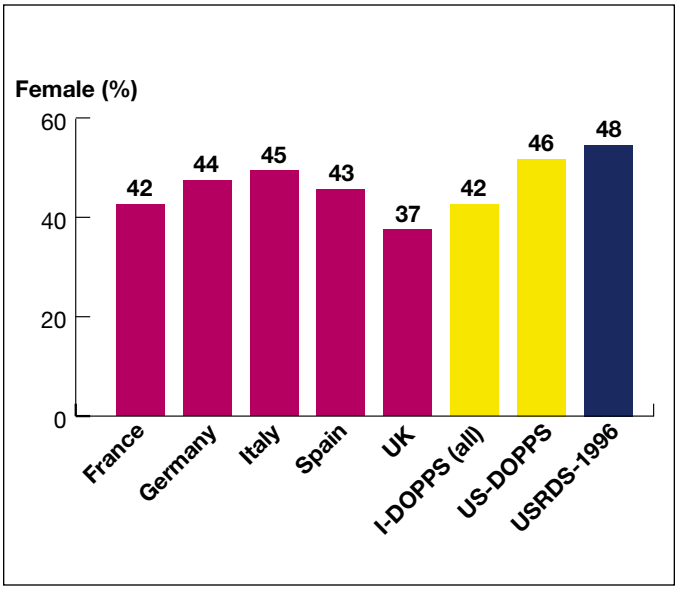

Figure 5. Percentage Female from I-DOPPS CHC, by Country and Study, 1998.

Figure 6 illustrates the percentage of prevalent hemodialysis patients for whom the primary cause of ESRD is diabetes in five European countries and the United States. These statistics provide evidence for wide variation in this patient characteristic, both among the European countries as well as between Europe and the United States. In Europe, France and Italy report the lowest percentage of diabetes as the primary cause of ESRD with approximately 10-11%, while Germany has the highest percentage with 24%. In the United States, the percentage is substantially higher than any of the European countries at 41%.

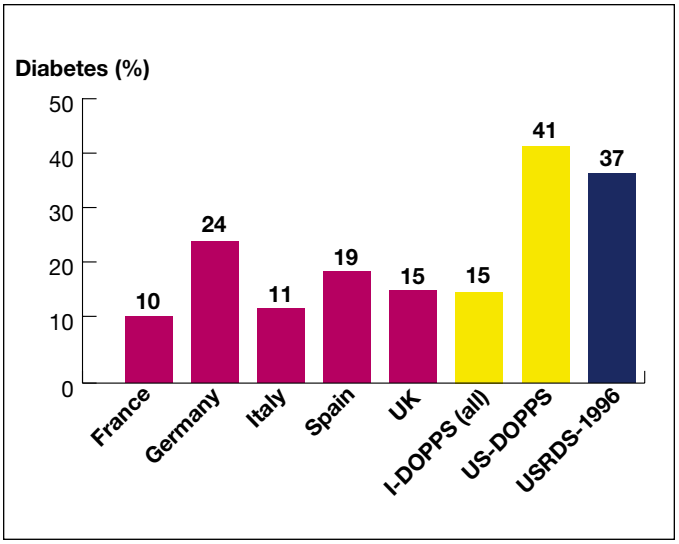

Figure 6. Diabetes as the Cause of ESRD, Percent of CHC Patients by Country, 1998.

Based on data from a sample of CHCs in the I-DOPPS, average dialysis facility size is reported in Figure 7. All facilities with less than 25 patients have been excluded from I-DOPPS and facilities with less that 20 patients have been excluded from U.S. DOPPS. There appears to be some variation in average facility size across the five European countries and substantially more variation in facility size between Europe and the United States.

In Europe, Spain has the smallest average facility size with 53 hemodialysis patients, while Italy has the largest average facility size with 65 hemodialysis patients. In the U.S. DOPPS, average facility size appears to be substantially higher at 84 hemodialysis patients.

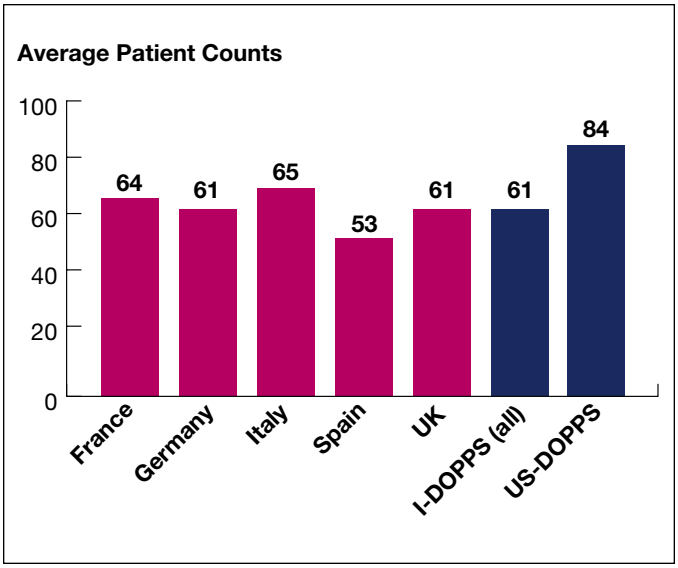

Figure 7. Average facility size of I-DOPPS and DOPPS facilities, 1998.

Figure 8 illustrates that there is large variation in the distribution of race among hemodialysis patients in the United States compared to Europe. Within Europe, all participating countries except the United Kingdom report that over 93% of hemodialysis patients are white. In contrast, the United Kingdom reports that blacks and other non-whites make up 16% of the hemodialysis population. The U.S. DOPPS data indicate that 54% of hemodialysis patients are white, 37% are black, 4% are Southeast Asian, and 4% are reported as "other."

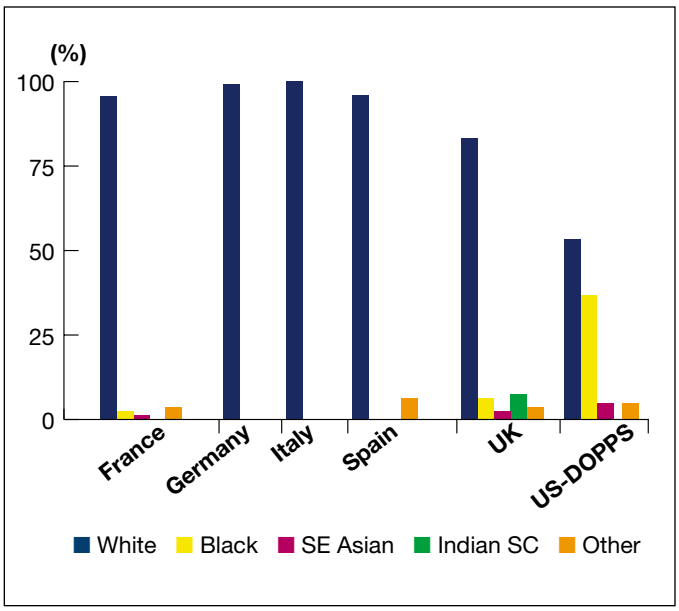

Figure 8. Distribution of Race in I-DOPPS, by Country, 1998.

Summary

These preliminary statistics on patient demographics demonstrate that differences in patient characteristics merit further investigation. Having nationally representative data from the United States and from five European countries will make it possible to investigate practice patterns and patient outcomes as well. The main purpose of the I-DOPPS and DOPPS is not to make comparisons by country. Rather, the objective is to study the associations between practice patterns and patient outcomes. In the long run, this pursuit should lead to improvements in the well being of hemodialysis patients throughout the world.

Spring I-DOPPS Meetings, 1999

There will be an I-DOPPS Meeting held in each country (France, Germany, Italy, Spain and the UK) during the Spring of 1999. The Medical Director and Study Coordinator from each of the participating facilities have been invited to attend the I-DOPPS Meeting for their country. The purpose of these meetings is to examine and resolve issues related to data collection and data quality. Preliminary data will be presented and discussed and difficult areas of data collection will be explored. The focus of discussions will be on collecting accurate and timely data in order to ensure a very high level of data quality for I-DOPPS.

The following is a schedule for the I-DOPPS Spring Meetings:

Country	Location	Date
Germany	Heidelberg	March 13
United Kingdom	Dublin	April 21
Italy	Rome	April 24
France	Paris	June 14
Spain	Madrid	June 16

We sincerely hope that each and every participating facility will be represented at their country's I-DOPPS meeting. We are looking forward to meeting with the Medical Directors and Study Coordinators who have made this project possible.

For More Information Contact URREA:

Philip J. Held, PhD
philiph@urrea.org

Liz Holzman, MBA
eholzman@urrea.org

Eric Young, MD, MS†
eyoung@umich.edu

Ronald Pisoni, PhD
rlpisoni@urrea.org

URREA
315 West Huron, Suite 260
Ann Arbor, MI 48103 USA
Tel U.S.: (734) 665-4108
Fax U.S.: (734) 665-2103

QUINTILES CLINICAL RESEARCH ASSOCIATES

Project Manager
Hanneke Schreurs, MSc, MBA

France
Fabienne Hemme

Germany
Leonhard Purmann, MSc
Christine Bode, PhD

Italy
Simona Ré, MSc

Spain
Immaculada Muñoz, BA

United Kingdom
Neil Leslie, BA

Technical Notes:

I-DOPPS data are based on preliminary 1998 analyses from 95 Cumulative Hemodialysis Censuses (CHCs).

1996 USRDS data are from the 1998 Annual Data Report, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Division of Kidney, Urologic, and Hematologic Diseases, Bethesda, MD.

Questions & Answers for Study Coordinators

Frequently Asked Questions from Participating Facilities

Q As a "Study Coordinator," which questionnaires should I focus on getting completed first?

A Since a patient selected for the study may actually depart the facility before you receive the questionnaires for the Quintiles Data Management Center, please get a patient consent form completed for all patients new to the facility. This applies to patients new to the facility after Facility Round 1. Once you have received questionnaires from the Quintiles Data Management Center, first focus on distributing and obtaining completed Patient Questionnaires. Remember that once a patient dies or departs the facility, a PQ can no longer be completed. By contrast, a MQ or IS can, if necessary, be completed after a patient dies or departs.

Q If a patient leaves the dialysis facility, is hospitalized for 10 weeks and then returns (to the same dialysis facility), do I fill in Columns 10-13 on the CHC when the patient goes to the hospital and re-enter the patient with a new census number on the CHC when the patient returns?

A **NO**. In I-DOPPS, a hospitalization, for any length of time, is **never** considered to be a departure from the facility. However, if the patient does not return to the same facility after the hospitalization and either dies or transfers to another facility, Columns 10-13 on the CHC should be completed at the time of the death or transfer to another facility.

Q If a patient listed on the PAF (Patient and Assignment Form) has died or departed the dialysis facility, do I still complete the questionnaires (Medical Questionnaire, Patient Questionnaire, and Interval Summary) for this patient?

A **YES!** It is still very important that the MQ and IS are completed for a selected patient who dies or departs the facility. However, it will not be possible for the patient to complete the PQ if the patient has died or departed the facility.

Q If a patient has an enrollment date of September 25, 1998 and is diagnosed with cerebrovascular disease on October 15, 1998, should the answer to C.32 and C.33 on the Medical Questionnaire (diagnosis of cerebrovascular disease) be yes?

A **NO.** Since the patient did not have a diagnosis of cerebrovascular disease on or before the enrollment date, the answer to C.32 and C. 33 on the Medical Questionnaire should be either NO or Suspected (if it was suspected before the date of Enrollment). Depending on whether the diagnosis of cerebrovascular disease was made when the patient was an inpatient or outpatient, this information should be entered on the Interval Summary, Section J (Summary of Hospital Admissions) or Section K (Outpatient Events Summary).

Questions & Answers for Study Coordinators

Frequently Asked Questions from Participating Facilities

Q On the CHC, should I enter code 1 (Yes) in Column 5 (Diabetic Status) if the patient is diabetic, but diabetes is NOT the primary cause of End Stage Renal Disease?

A **NO.** Code 1 (Yes) should be entered in Column 5 ONLY if diabetes is the reported primary cause of End Stage Renal Disease.

Q For patients who are new to the study, do I need to immediately obtain consent for their participation in I-DOPPS?

A Patient consent is a very important issue in I-DOPPS. Our goal in I-DOPPS is to achieve a patient consent rate (95%. If patient consent rates are too low, the study has the potential of becoming biased and not reflecting the outcomes of all types of hemodialysis patients. Therefore, it is very important to achieve the highest patient consent rate possible to assure that I-DOPPS will be a scientifically valid and representative sample. Although it is important to encourage patients to complete a Patient Questionnaire, if a patient refuses to complete a Patient Questionnaire, it is still very important to convince patients to allow access to medical records so that a Medical Questionnaire and Interval Summaries can be completed for the patient. Therefore, we recommend that whenever a new patient enters a dialysis unit, immediately explain the benefits of I-DOPPS to the patient and try to obtain patient consent at that time. Patients who are considered to be transient are not eligible for selection into I-DOPPS. If your dialysis unit has a large number of transient patients, it is not necessary to obtain patient consent for these transient patients. However, if a person who you expected to be a transient patient is treated at your unit for more than six continuous weeks, then that patient is no longer considered transient for the I-DOPPS and patient consent should be obtained.

Q When can we expect to receive the Medical Director Survey that the Medical Director completes and the Unit Practice Survey that the Study Coordinator or other nurse completes?

A We understand that many of you may have been expecting to receive the Medical Director Survey and Unit Practice Survey by now; however, it was necessary to make important modifications to these questionnaires so that the translations into French, German, Italian, Spanish and Queen's English would be professional and appropriate. It is our current expectation that the Medical Directors Surveys and the Unit Practice Surveys will be mailed to all participating facilities in March 1999.

Q For the Outpatient Events Section (Section K) of the Interval Summary Part 2, do I enter information about a patient's visits to other physicians besides his or her nephrologist?

A **YES!** Please record in Section K of the Interval Summary all information about any visits on an outpatient basis to a physician or clinic for medical care. This includes visits to physicians or physician consultants and outpatient procedures such as an x-ray, colonoscopy, chemotherapy treatment, mammogram, etc. Please remember to include, on the Interval Summary, any new diagnoses that may have resulted from one of these visits or procedures.

† Indicates investigators subcontracted with the University of Michigan