

Highlights

- Over 5,000 patients enrolled
- Facilities from 40 states
- Representative National Sample

Inside this Issue

- The ANNA DOPPS workshop
- World-wide DOPPS
- Dialysis Facility Staffing
- Questions and Answers

The DOPPS Report

Newsletter of the Dialysis Outcomes and Practice Patterns Study

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The DOPPS Workshop at ANNA

On June 1, 1998 a workshop for DOPPS Study Coordinators was held in San Antonio, Texas during the ANNA conference. This turned out to be a hard-working meeting, involving a mutual sharing of viewpoints and experiences among DOPPS unit Study Coordinators and DOPPS Coordinating Center staff. Over thirty DOPPS Study Coordinators attended the three-hour meeting. Dr. Donna Mapes and Dr. Marcia Keen of Amgen also attended, as well as several members from the DOPPS Coordinating Center. Dr. Mapes presented some of the preliminary findings of the DOPPS data. The meeting was an enjoyable and valuable experience for all who attended. Several issues pertaining to data collection were discussed, and several suggestions were proposed.

This first section of the newsletter is devoted to a discussion of these issues and some of the ideas and proposed solutions from the attending Study Coordinators. We hope that these suggestions will lead to more efficient data collection and increased data quality. The DOPPS Coordinating Center would like to thank all of the unit Study Coordinators for

their input and suggestions, and also for their hard work and continued participation. DOPPS would not be possible without their support.

Major Issues Discussed

Two major issues formed the basis of the meeting:

1. The importance of collecting accurate data:

DOPPS is a study of the association between practice patterns and patient outcomes. It is important to have practice pattern data supplied by the unit Medical Director (via the Medical Director Survey) and Nurse Manager (via the Unit Practices Survey).

Complete, accurate, and unbiased outcomes data are also needed in four major areas: mortality, vascular access, hospitalizations, and quality of life.

2. Procedures for improving the ease and feasibility of data collection:

How can DOPPS data collection procedures be improved? What improvements can be made in terms of instructions and training, communication, and simplifying data collection?

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What's new for DOPPS Study Coordinators?

1. Monthly Reports

We are in the process of creating feedback reports that we will send to each unit once per month, letting the Study Coordinator know their status in the study, including such things as:

- Date of last CHC received by the DOPPS Coordinating Center (DOPPS CC)
- Date next updated CHC is due
- Date of last batch of questionnaires received by the DOPPS CC
- Approximate next date questionnaires will be sent to the facility
- Date questionnaires are due
- List of outstanding questionnaires not yet received by DOPPS CC
- Status of Medical Director Survey and Unit Practices Survey

2. Educational Phone Calls

In an effort to ensure quality data collection, phone calls will be made to Study Coordinators to discuss general problem areas of data collection found with the particular unit. These calls will serve to educate Study Coordinators in data collection procedures for specific areas, such as properly documenting vascular access procedures or inpatient and outpatient events. These calls will be made shortly before the next round of questionnaires is sent to the unit.

3. Discrepancy Reports

Patient-specific discrepancy reports are being developed that can be sent to units. These reports will indicate problems in a specific area of data collection for a specific patient.

Discussion and Results of the DOPPS Workshop

Feedback

The suggestion made most frequently to the Coordinating Center by the Study Coordinators was that more feedback is needed. Study Coordinators indicated that they want to provide quality data in a timely matter, but are often unsure how to complete questions. Without feedback, they can only assume that they are doing data collection properly. It was suggested to use faxing as the preferred method of communicating. In response to these suggestions, we have begun to develop new and improved ways of communicating on a more regular basis with Study Coordinators. These ideas are outlined in the blue box to the left entitled "What's new for DOPPS Study Coordinators?". We hope that these changes will make DOPPS data collection easier and more efficient for Study Coordinators.

Common Problems

Common problems with DOPPS data collection were discussed and several explanations and solutions were offered by Study Coordinators. These problems are outlined below, along with the possible explanations provided by the Study Coordinators, and proposed solutions.

Vascular Access Questions and Proposed Solutions

Table 1 illustrates how several commonly encountered problems in vascular access documentation should be reported on the Quarterly Interval Summary (QIS).

• Problems with data abstraction:

1. Incorrect sequential numbering of vascular accesses on the QIS;
2. Incomplete reporting of vascular access status or procedures (particularly access failures) on the QIS. For example, when a new access is created, Study Coordinators often omit an entry regarding the failure of the old access.

Table 1. Correct documentation of commonly encountered problems in vascular access reporting.

Date	Access #	Type	Side	Location	Status	Procedure	Comments	EXPLANATION
8/25/97	101	G	L	UA	F			101 is assigned since the exact number of vascular accesses prior to DOPPS enrollment was not known.
12/15/97	101	G	L	UA	X		Clot	In this next reporting interval, access 101 is clotted.
12/15/97	102	T	R	IJ	P	1		A temporary catheter was inserted. This is given an access # of 102 to follow 101.
12/15/97	102	T	R	IJ	F			It is documented that the temporary catheter is functioning after being inserted.
12/17/97	101	G	L	UA	P	2		A thrombectomy was performed in an attempt to salvage access 101.
12/18/97	101	G	L	UA	P	11		Access 101 was still not functioning after the thrombectomy, so the access was removed.
12/25/97	102	T	R	IJ	F			At the end of this reporting interval, access 102 is the functioning access.

The example above (combining 2 intervals) illustrates correct procedures for completing the vascular access section: (1) Notice the proper documentation of the failure and procedures on access #101, and the creation and status of access #102; (2) Notice that the first entry indicates at the end of the previous reporting interval (8/25/97), access #101 was functioning; (3) Notice at the end of the current reporting interval (12/25/97), the functioning status of the access being used (#102) is documented; (4) Finally, notice that an access # was provided with each entry.

Vascular Access, con'd:

- When the functioning access stays the same (“carries over”) from one QIS reporting interval to the next, Study Coordinators write nothing in the QIS vascular access section.
- When there is more than one entry regarding the same access, the Study Coordinator omits the access number after the first entry.

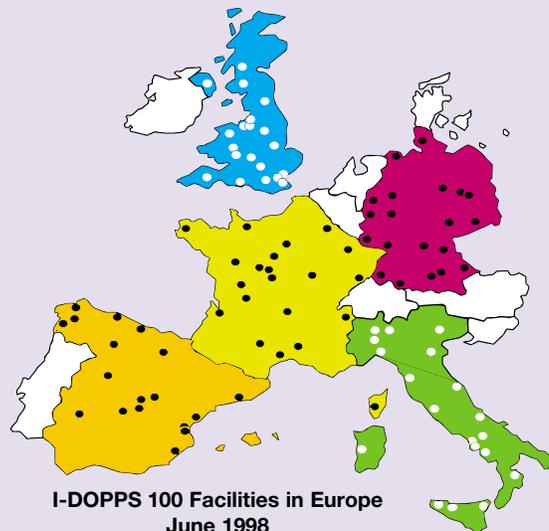
- **Possible explanation:** Instructions are unclear.
- **Correct Procedures (illustrated in Table 1):**

Sequential numbering: If the patient is known to have had previous access placements, but the exact number is not known, then the number of the current access is set at “101” and subsequent accesses are numbered 102, 103, etc.

Incomplete reporting: (1) Proper care should be taken to document any new procedures, and to document *when and why an access failed*; (2) For the last day of each QIS reporting interval (i.e. on every QIS form), indicate the status of the current vascular access, even if the status has not changed since the previous reporting interval; (3) An access number should be indicated for *every* QIS entry.

World-Wide DOPPS...

The DOPPS has been expanded to two continents beyond the US. This is probably the first prospective international representative study of a single disease entity with a common modality of treatment, i.e. hemodialysis for ESRD. DOPPS in Europe (I-DOPPS) involves 5 countries with 20 dialysis units in each country and 3000 patients. In Japan-DOPPS, recruitment of 60 units is underway. All of these studies follow to a common design, protocol and analysis. Questionnaires have been translated into 6 languages. The goal is not to compare countries, but like the US DOPPS, to compare practice patterns and their effects on patient outcomes. The international design will enhance the number of variances in practice patterns as well as outcomes.



Vascular Access, con'd:

• Suggested Solutions:

1. Improve instructions to clearly indicate that a vascular access entry should be made on *every* QIS form for every patient, even if nothing has changed.
2. Improve instructions to clearly indicate proper sequential numbering procedures and documentation of vascular access procedures and failures.
3. Assist Study Coordinators each mailing by providing a one-page simplified code sheet, listing procedure codes and examples for completing the vascular access section.
4. The DOPPS CC plans to provide patient-specific discrepancy reports to Study Coordinators, indicating problems with the vascular access history of a specific patient.
5. The DOPPS CC plans to phone Study Coordinators to discuss general problems found in their vascular access reporting, and to educate Study Coordinators as to the correct procedures for completing the vascular access section.

Mortality Questions and Proposed Solutions

- **Problem 1:** Medical Questionnaires and Quarterly Interval Summaries are often not completed for departed patients (death, transplant, transfer, etc.).

• Possible explanations:

1. It is unclear to Study Coordinators that obtaining medical data on departed patients is necessary.
2. The time lag between the batches of questionnaires sent to units leads to problems in retrieving medical records on departed patients, as these records are put into storage.

- **Correct Procedure:** It is important to collect data on all patients selected for DOPPS. This includes patients who die, transfer, or undergo transplant.

• Suggested Solutions:

1. Keep records on all patients in the unit for at least 9 months. This will help ensure

easier availability of patient records for data abstraction.

2. The DOPPS CC could provide each unit with blank Quarterly Interval Summary (QIS) forms, which the Study Coordinator can complete immediately after the patient departs the unit, before the records are put into storage. The forms will be accompanied by specific instructions as to what dates should be used as the beginning and end dates of the QIS reporting interval.

Why should medical records be saved at the unit for 9 months?

Typically, there is at least a 4 month interval between episodes of data collection. A patient entered on the CHC may not be selected for participation until 4 months after s/he was entered on the CHC. By the time the facility receives the MQ and QIS for completion on a specific patient, that patient may have died or departed the unit. For this reason, please retain all records for patients who die or depart your facility for at least 9 months after the date of death or departure.

- **Problem 2:** Study Coordinators often do not complete Termination Forms for departed patients, and often do not mark their departures on the Cumulative Hemodialysis Census (CHC).

- **Correct Procedure:** Termination Forms should be completed for all selected DOPPS patients who die or leave the unit. Columns 8-10 on the CHC (date of last dialysis, date of death) should be completed for *all* patients in the unit (DOPPS and non-DOPPS).

• Suggested Solutions:

1. The DOPPS CC will provide the Study Coordinator with more blank Termination Forms to use as needed.
2. The DOPPS CC will make phone calls to Study Coordinators as needed to discuss this problem.

The Medical Director Survey (MDS) and Unit Practices Survey (UPS)

- **Problem:** We absolutely need an MDS and UPS from every unit once each year. There are still several units that have never sent us one or both of these surveys.
- **Possible explanation:** The Study Coordinator is not aware that the Medical Director was given an MDS or Nurse Manager was given a UPS.
- **Suggested Solutions:**
 1. Send the MDS and UPS to the Study Coordinator to distribute to the appropriate individuals.
 2. Provide the status of these surveys (i.e. date surveys sent to unit, date surveys due to DOPPS CC) on the monthly report being developed for Study Coordinators.

Inpatient (Hospitalization) & Outpatient Data Questions & Proposed Solutions

- **Problem with data abstraction:** Missing and incomplete hospitalization and outpatient events reported on the Quarterly Interval Summary (QIS); Overlapping hospitalizations incompletely or incorrectly recorded.
- **Possible explanation:** Study Coordinators often do not know the reason for hospital and outpatient visits.
- **Suggested Solutions:**
 1. Study Coordinators may be able to use hospital billing records to complete the inpatient and outpatient sections of the QIS.
 2. The DOPPS CC plans to provide patient-specific discrepancy reports to Study Coordinators, indicating problems with the hospitalization and/or outpatient event history of a specific patient.
 3. The DOPPS CC plans to phone Study Coordinators to discuss general problems found in their hospitalization and/or outpatient reporting, and to educate Study Coordinators as to the

correct procedures for completing the hospitalization and outpatient events sections.

Post-dialysis BUN Measurements Questions and Proposed Solutions

- **Problem with data abstraction:** Missing and incomplete post-dialysis BUN measurements on the Quarterly Interval Summary (QIS).
- **Possible explanation:** Instructions are unclear. Study Coordinators mistake the most recent measurement in the unit with the most recent measurement *in the reporting interval*.
- **Correct Procedure:** Indicate the most recent post-BUN measurement taken in the unit during the QIS reporting interval. For example, let's say a reporting interval is 1/1/98 - 4/30/98, and post-BUN measurements were taken for a patient 3/3/98, 4/3/98, and 5/3/98. The measurement taken on 4/3/98 is the most recent in the reporting interval and should be reported on the QIS.
- **Suggested Solutions:** Clarify the instructions to indicate that the Study Coordinator should report the most recent post-BUN measurement taken in the unit during the reporting interval.

Completing the Patient Questionnaire

- **Problem:** Many patients refuse to complete the Patient Questionnaire (PQ).
- **Possible explanation:** The PQ is too long.
- **Suggested Solutions:**
 1. The PQ is administered once each year. We have shortened the PQ administered in the second and subsequent years.
 2. Another proposal was to break the PQ into two separate parts to be completed at separate times. The DOPPS CC is examining this issue.

Dialysis Facility Staffing

One of the most important areas of DOPPS investigation is dialysis facility staffing. Data collected from the Medical Director Survey, the Unit Practices Survey, and the Patient Questionnaire provide relevant information about staffing practice patterns. Ultimately, we are interested in the relationship between specific staffing patterns and patient outcomes. For example, we will be investigating whether hospitalization rates are related to the number of direct patient care staff.

DOPPS is investigating facility staffing in three types of facilities: hospital facilities (28.2% of DOPPS units); free standing non-profit facilities (10% of DOPPS units); and free standing for-profit facilities (61.8% of DOPPS facilities). Due to differences in sample size, caution should be taken in interpreting differences among types of facilities.

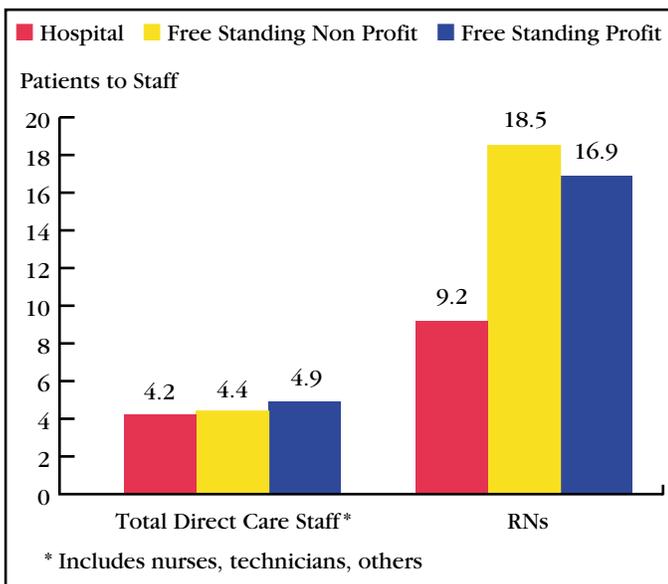


Figure 1. Hemodialysis Patients/Direct Care Staff, 1997-98

Figure 1 provides a comparison of the number of hemodialysis patients per direct patient care staff in hospital facilities, free standing non-profit facilities and free standing for-profit facilities. Two types of comparisons are described: one comparison of patients per direct patient care staff has all direct patient care staff grouped together (left-hand side

of graphic), while another comparison includes only RNs as direct care patient staff (right-hand side of graphic).

While the difference in the number of hemodialysis patients per direct care staff (grouping all direct care staff together) for hospital versus free standing non-profit versus free standing for-profit was small, the difference in the number of hemodialysis patients per RN for the three types of facilities was substantial. The most statistically significant difference was found in the number of hemodialysis patients per RN in hospital facilities versus free standing non-profit facilities, with 9.2 patients per RN in hospital facilities and 16.9 patients in free standing for-profit facilities ($p < 0.01$).

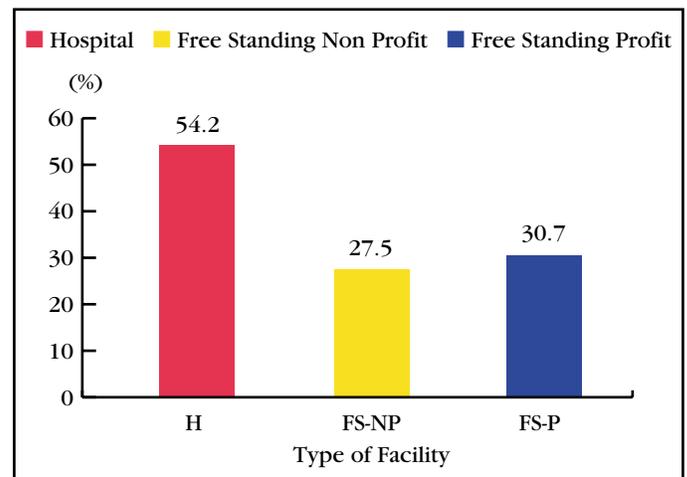


Figure 2. RNS as Percent of Total Direct Care Staff, 1997-98

Figure 2 reports RNs as a percent of total direct care staff at hospital, free standing non-profit facilities and free standing for-profit facilities. Hospitals report a statistically significant higher proportion of RNs as direct care staff (54.2%) than free standing for-profit facilities (30.7%), at $p < 0.01$.

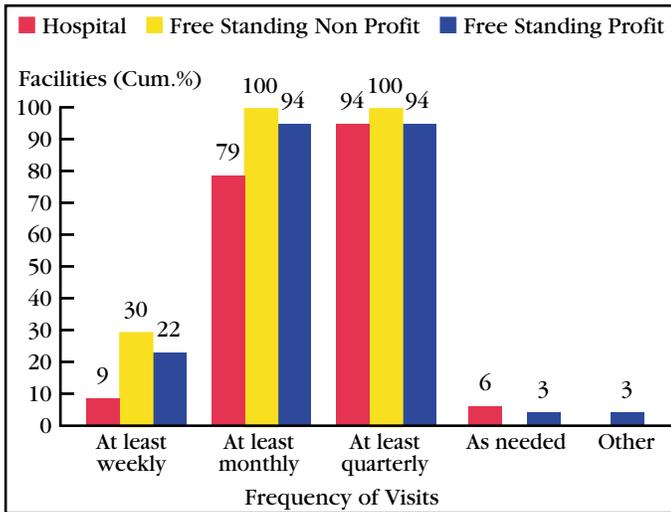


Figure 3. Frequency of Dietitian Visits

Figures 3 and 4 show the frequency of dietitian and social worker visits. These data illustrate that monthly contact with patients by the dietitian and social worker are less common in hospital facilities (79% and 41%, respectively) than they are in either free standing non-profit facilities (100% and 64%, respectively), or free standing for-profit facilities (94% and 71%, respectively). There appears to be more emphasis on regular contact with a dietitian than with a social worker.

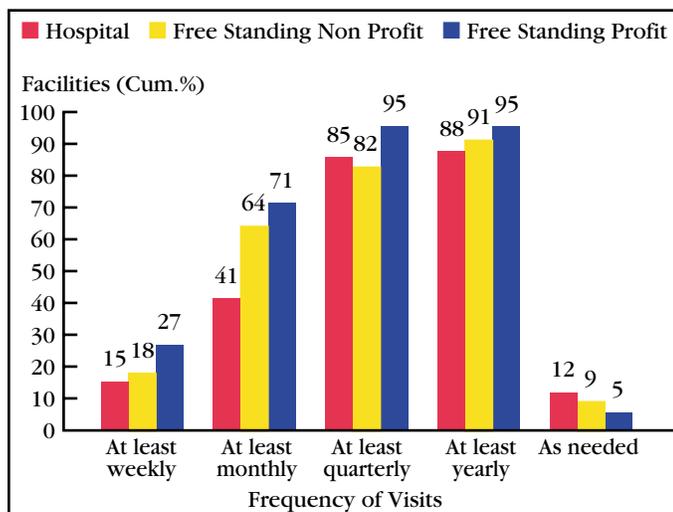


Figure 4. Frequency of Social Worker Visits

Figure 5 provides a comparison of the time devoted by physicians to patient interaction. These comparisons are based on data collected from two different sources: the Medical Director Survey (MDS), which is completed by the medical director, and the Unit Practices Survey (UPS), which is typi-

cally completed by the facility's nurse manager. As reported by medical directors, physician interaction time with patients per month is highest for hospital facilities (34.7 minutes per month), followed by free standing for-profit facilities (27.3 minutes per month), and lowest at free standing non-profit facilities (19.2 minutes per month).

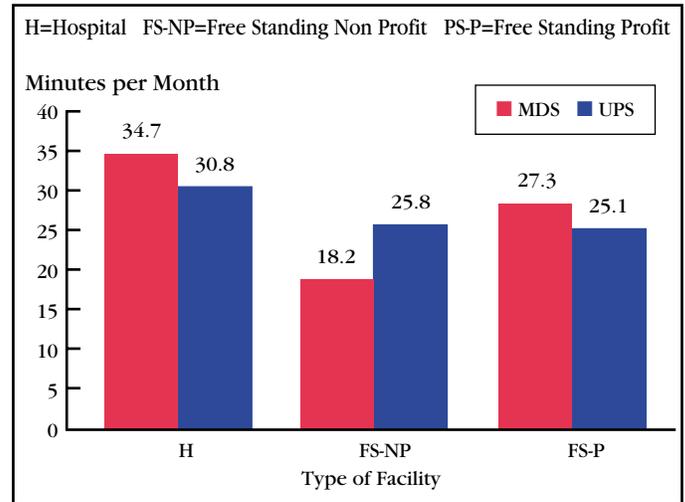


Figure 5. Physician Patient Interaction Time per Month During Dialysis

Nurse managers report that physician interaction time with patients is 30.8 minutes per month at hospital facilities, 25.8 minutes per month at free standing non-profit facilities, and 25.1 minutes per month at free standing for-profit facilities. Note that what is reported by nurse managers is higher than what is reported by medical directors for physician interaction time at free standing non-profit facilities, whereas nurse managers report lower physician interaction time than medical directors at hospital facilities and free standing for-profit facilities.

Summary

DOPPS data related to staffing practices continue to be collected. One of the important goals of DOPPS is to answer questions about the relationship between staffing and patient outcomes. For example, does the amount of physician interaction time with patients have an impact on rates of hospitalization? DOPPS-related analyses will soon start to focus on the relationships between staffing patterns and patient outcomes, including mortality, hospitalization, and vascular access survival.

Questions and Answers

Frequently Asked Questions from Participating Units

Q Do I need to complete Medical Questionnaires and Quarterly Interval Summaries for patients that have died or left the unit?

A Yes! It is important for us to have medical data on all patients who were selected to be in DOPPS. This includes patients who have left the unit due to death, transfer, transplant, etc. We strongly suggest keeping the medical records for at least 9 months for all patients who die or depart the facility.

Q Why are patients who completed the Patient Questionnaire (PQ) getting another one?

A DOPPS collects quality of life data on patients annually to investigate how the patient's quality of life changes from one year to the next. You will find that the second year PQ is shorter than the first year PQ.

Q When will I be getting my next batch of questionnaires?

A We are developing a new monthly report that we will send to all Study Coordinators, indicating approximately when they can expect to receive their next set of questionnaires, as well as the date that they are due back to the DOPPS Coordinating Center.

Q Do I need to make an entry on the QIS vascular access section if there is no change since the last QIS?

A Yes! We ask that you always make a QIS vascular access entry, even if the functioning access is still the same as the last QIS, and the information you write is the same ("carries over") as what you wrote before. Be careful to note any procedures done to the vascular access since the last reporting interval.

Q What if I leave the unit and can no longer act as Study Coordinator?

A Call or fax the DOPPS Coordinating Center and let us know the name of the new Study Coordinator at your unit. Pass the DOPPS materials along to the new Study Coordinator. We will contact this new individual and answer any questions s/he has. If you are having trouble finding a replacement Study Coordinator, the DOPPS CC will help you.

Q When will we get some specific results about our unit?

A We are in the process of developing report that will be specific to each unit. We plan to send 2-3 such reports per year, discussing such topics as vascular access and hospitalizations. We welcome your input about topics of interest to you. Please feel free to call the DOPPS CC with your suggestions.