Clinical Research

Establishing a Comprehensive Database for Home Parenteral Nutrition: Six Years of Data

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ABSTRACT: Documenting the outcomes of therapy is mandatory in today's health care environment. Such information is required by external agencies and desired by internal users. This article describes the development of a comprehensive database by one home infusion service that allows benchmarking of the results of care with other services over time. It also can be used to identify problems that are suitable for quality improvement initiatives. The database additionally allows analyses of the relationship between changing patient demographics and treatment processes over time and selected outcomes. Given the high cost and growing number of patients receiving home infusion services, the ability to address these kinds of questions is imperative for individual providers and for the entire health system.

Documenting the outcomes of therapies and interventions has become mandatory in today's health care environment. Regulatory agencies, purchasers of services, and potential or actual customers are all demanding information about the results achieved by the providers of care. At the University of Michigan Health System, a database has been created that allows the measurement of demographic, treatment process, and outcome variables associated with the delivery of selected home infusion services. Such a database allows the benchmarking of processes and outcomes of care with other providers, and the trending of outcomes, processes, and patient characteristics over time.

Home parenteral nutrition (HPN) represents a complex treatment modality. Patients are referred for therapy when they are unable to maintain adequate nutrition. Patients present with a variety of primary and secondary diagnoses, are usually chronically ill, and span the age range. They may experience complications during the period of infusion therapy as a result of their underlying disease process, the therapeutic process, or both. Duration of therapy may last from a few days to a few years. The majority of patients receiving HPN could be classified as high cost patients.

This paper describes the development and utilization of a comprehensive database for HPN patients that can serve as a standard for benchmarking our processes and outcomes of care. The results of 6 years of HPN patient care services are presented, and examples of the kinds of additional analyses that can be conducted using such a database.

Background

Many issues have been identified in connection with the delivery of parenteral nutrition in the home. Psycho-social concerns have included frustration over the inability to eat,[1] altered body image,[2] social stigma,[3] social barriers to work,[4] chronic dependence on a caregiver,[4] and financial burden.[5] Physiologic complications in HPN therapy include fluid and electrolyte imbalances, glucose imbalances, catheter sepsis and catheter-related mechanical problems,[6] and fatigue.[7] System-related issues have involved inadequate discharge planning, insufficiently trained homecare staff, and lack of clinical guidelines.[7,8] Resource utilization issues include repeated hospital admissions and visits to the emergency department.

In spite of these issues, the delivery of home parenteral nutrition and other infusion services has grown at a rapid pace. An estimated 18,000 patients received HPN in 1986 and 39,000 in 1992.[9] It has been estimated that the number of HPN patients is growing at a rate of 25% per year.[10] HPN is being used in the management of new diseases, such as AIDS, and for the more typical metabolic and neo-

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plastic conditions. When assessing the success of home infusion services, the outcomes measured are usually mortality and longevity, complications of therapy, extent of rehabilitation as judged by the provider, and hospitalization.[11] Less frequently studied are outcomes such as quality of life and caregiver distress.

In 1995, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) introduced specific nutrition care standards for hospitalized patients, which included mandatory interdisciplinary care planning and effectiveness monitoring of nutrition care support.[12] These were followed by ORYX, which required the systematic collection of data on a limited number of outcome variables using standardized methods. These requirements, along with other Report Card initiatives and quality improvement activities taking place within health care organizations, have convinced providers that they must invest in database development to enable them to respond to inquiries about care processes and outcomes.

Materials and Methods

The database is drawn from patients receiving home infusion services from a university hospital–affiliated home infusion company in the Midwest. Patients are usually referred for home infusion services from the inpatient setting, with the referral process arranged by discharge coordinators. A team of hospital-based nurses performs an initial assessment of the patient and the designated primary caregiver, and begins the training process. Patients may receive all, some, or none of their training in the inpatient setting. If training is incomplete before discharge, it is continued by home health nurses.

Data were abstracted from the medical records of most HPN patients completing therapy between January 1993 and December 1998. The database does not include patients who chose or who were directed to receive their home infusion services from a different infusion care provider. It also excludes patients who began their therapy before the establishment of the current home infusion company or whose medical records were missing large amounts of data. Data abstraction forms were developed by the first two authors (K.J., D.K.), tested, and refined. Face and content validity were established by an expert panel, which consisted of two nurses from the HPN team; a dietitian from the home enteral nutrition therapy team; a pharmacist from the home medical infusion team; a home health nurse experienced with home infusion therapy; the medical director; a service manager; and a nurse researcher. Written guidelines were developed to ensure data abstraction reliability and to help train new data collectors. A code book was developed to guide the coding and computer entry of the abstracted data. Because of the complexity and length of many of the medical records, all were abstracted twice, and the

results compared by the principal investigator. All data inconsistencies were resolved by the HPN nurse manager.

Data categories include patient demographics; primary and secondary diagnoses; reason for home infusion therapy; nutritional status; treatment processes including type of infusion pump and IV catheter; and outcomes including catheter sepsis, hospitalizations, system problems, and final disposition. Data were entered into a Microsoft ACCESS database program, and analyses were done using SAS for the personal computer. Simple descriptive statistics were used for the analyses in this paper.

Results

Demographics

Figure 1 shows the demographic characteristics of the patients cared for by the service and discharged over the past six years. The number of individuals discharged annually from the service nearly doubled over the time period, reflecting the increasing popularity of home-based therapies. The mean age of the patients was 33.6 years (±22.9), with an age range extending from one month to 78 years. There were slightly more females (53%) than males (47%) in the predominantly white (90%) population. The majority of patients were either married (46%) or under the age of 18 (34%). The most frequent source of payment was Blue Cross/Blue Shield (41%), reflecting the service's Midwest location. Most patients lived with their spouses (49%) or their parents (42%). The usual primary caregiver was a family member (76%), although 23% of the charts identified the patient as the primary caregiver.

Figure 2 shows the distribution of primary diagnoses among patients in our sample. The primary diagnoses were distributed primarily across solid (26%) and blood (14%) neoplasms and various gastrointestinal conditions, although there was a fairly large number of other diagnoses, including AIDS, hyperemesis associated with pregnancy, and end-stage renal disease. Figure 3 shows that the two most common final dispositions from therapy were resumption of oral intake (52%) and death (21%). Some patients (6%) transferred to other infusion providers, primarily because of insurance company decisions. A few patients were removed from therapy due to non-compliance (5%) or other issues, whereas a few other patients withdrew from therapy (3%), due primarily to quality of life concerns. The majority of patients who died while on therapy had cancer listed as the primary cause of death. Only four patients died from sepsis, which can be a complication of the treatment process.

Treatment Characteristics

Table 1 shows the primary treatment process variables abstracted for the database. The typical

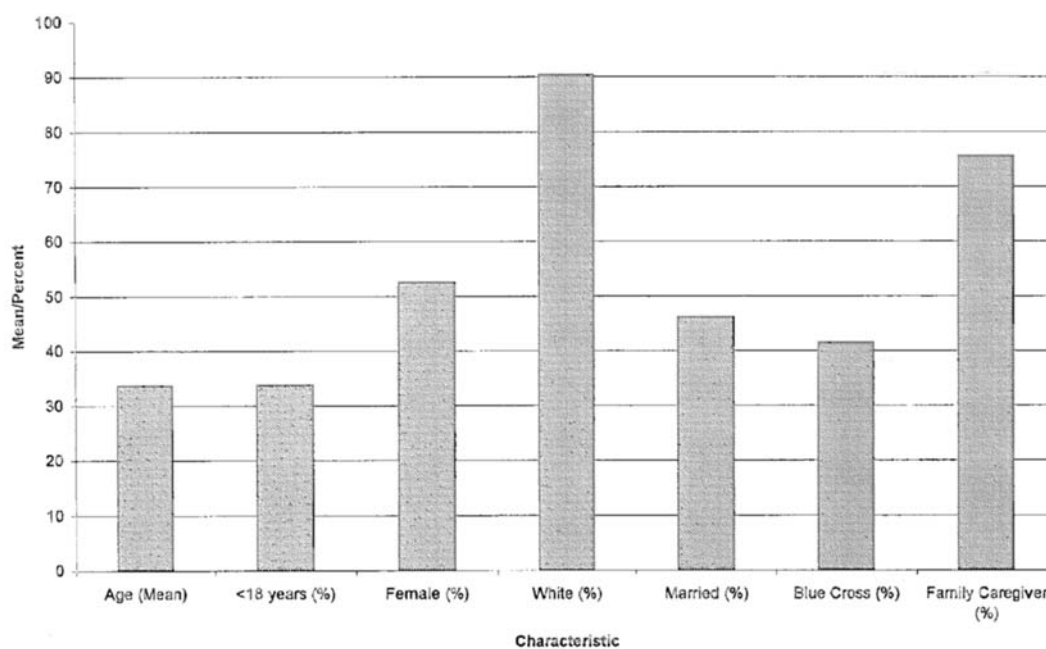**Figure 1. Patient Demographic Characteristics**

Figure 1. Patient demographic characteristics.

patient underwent one course of home parenteral nutrition therapy, although almost 10% of the patients received more than one course of therapy. Patients missed on average more than two weeks of home therapy due to hospital admissions. Thus the average patient was on HPN for just over 100 days, receiving about 87 days of therapy in the home and the rest in the hospital. There was one, predomi-nant, ambulatory electronic infusion pump (CADD-total parenteral nutrition [TPN]) used in the early years and a different pump (AIM) brought into use in the later years. The most commonly used infusion catheters were peripherally inserted central cathe-ters (PICCs; 50%) and tunneled catheters (Hick-mans and Broviacs; 44%). Initial catheters were removed most often because therapy was completed
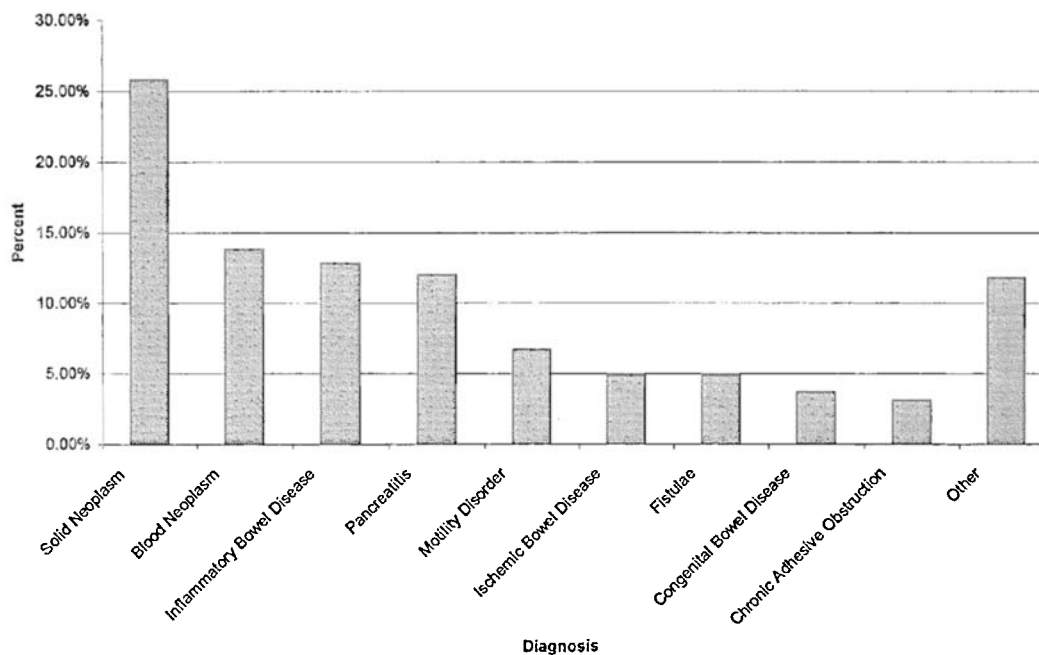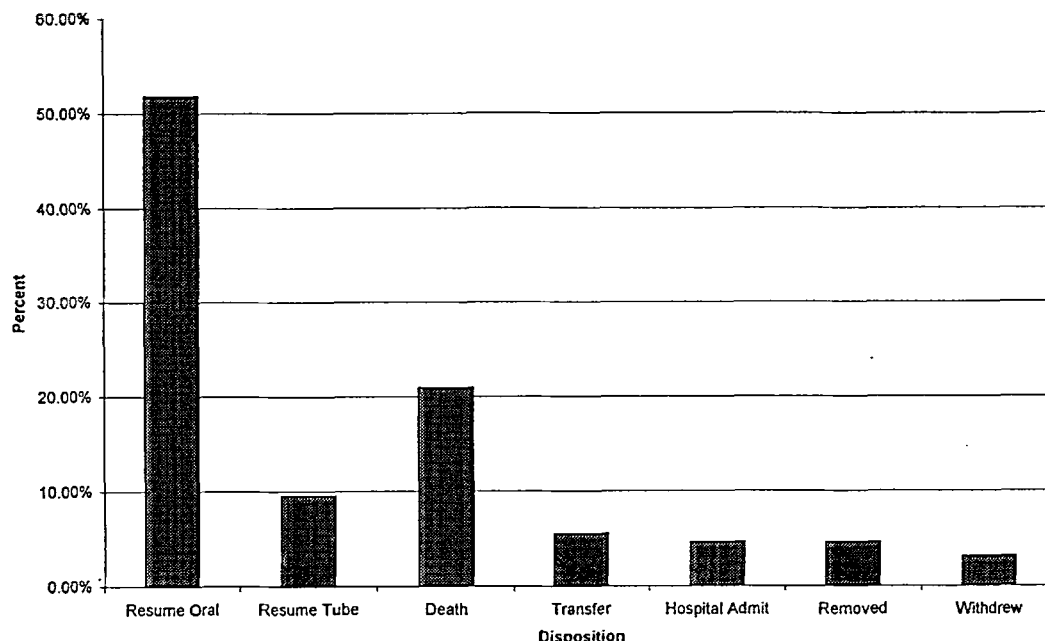

Figure 2. Primary diagnoses.

Figure 3. Final disposition from therapy.

(27%), the patient died (15%), or the patient developed a catheter sepsis (11%). Catheters were also removed for a myriad of other reasons, including leaking, occlusion, being pulled or falling out, exit site infection, line migration, and ruling out sepsis. About two-thirds of the patients needed one infusion catheter for their course of therapy. The mean number of days for all IV catheters was 164 (±187) days per patient. Most of the patients had either a gauze and tape (43%) or transparent (53%) dressing over their catheters. The frequency of catheter dressing changes varied substantially across patients, ranging from once a day (19%) to once a week (4%). The most common schedules were two (35%) or three (19%) days a week. The individual doing the catheter dressing change also varied across patients. Home health nurses (53%) were most frequently responsible for the dressing change, but family caregivers also changed a large percentage (40%) of the dressings.

Patients received an average of 5.1 (±3.4) hours of home infusion training by the nurse before discharge from the hospital. The range in training hours was 0 to 28, although this latter figure represented an outlier, and the next highest number of training hours was 14. Some patients required no hospital training because they had received home infusion therapy previously, or were to receive all training from the home health nurse after discharge. Spouses (32%) and parents (38%) of patients were most often involved with the training, although a broad range of individuals and pairs of relatives were also involved. About one-third of the caregivers experienced problems during their training, most often feeling overwhelmed by the process and the amount of information to be learned. Many caregivers required reinforcement of specific aspects of the instruction.

Outcomes

Table 2 and Figure 4 display the patient outcomes monitored within the database. Clinical outcomes of interest included the incidence of catheter sepsis, non-catheter infections, and symptomatology. Catheter sepsis episodes had to be confirmed by a positive culture that identified a specific microorganism. A new catheter sepsis was identified only if more than three weeks had elapsed from a previous diagnosis, or if there was a new line in place or a new organism cultured. Non-catheter-related infections included documented urinary tract infections and wound infections. Symptoms were recorded whenever patients or their caregivers reported problems such as nausea, diarrhea, itching, pain, and fever. Utilization outcomes included number of hospital admissions, number of hospital days, number of emergency room visits, and the reasons for hospital admission and emergency care. Treatment-related outcomes include catheter problems (mechanical problems with the catheter), tubing problems (problems with the tubing such as air or blood backups), pump, delivery and supply problems, satisfaction with care and services, and education/training needs postdischarge. Psychosocial and economic problems that were identified by the patient, caregiver, or home health nurse were also recorded. These included reported difficulty coping with the disease or treatment process, depression, anger, family conflicts, and loss of electricity or telephone service.

Outcome Summary

Twenty-seven percent of the entire sample experienced at least one episode of catheter sepsis, with a range of one to nine sepsis episodes per infected

Table 1
Treatment process characteristics

Variable	N	% (Mean)
Courses of therapy-mean	326	1.12 (±0.5)
Total days at home-mean	326	86.5 (±130.4)
Total days on service-mean	326	104.1 (±146.7)
Infusion pump		
CADD/TPN	117	36.1%
AIM	206	63.6%
Other	1	0.3%
Catheter dressing		
Gauze/tape	137	43.1%
Transparent	168	52.8%
Other	8	2.5%
Dressing change frequency		
Daily	62	19.4%
Every 3 days	62	19.4%
2/week	111	34.7%
3/week	60	18.8%
1/week	12	3.8%
Other	13	4.1%
Dressing changed by:		
Agency	171	53.4%
Family caregiver	128	40.0%
Patient	18	5.6%
Other	3	0.9%
Pre-discharge training hours-mean		
Nurse	249	5.1 hrs (±3.4)
Pharmacist	249	0.8 hrs (±1.8)
Caregiver involvement in training		
None	37	14.5%
Spouse	81	31.6%
Parent	96	37.5%
Son/Daughter	13	5.1%
Other	29	11.6%
Learning difficulties documented		
None	171	67.3%
Overwhelmed	37	14.6%
Needed reinforcement	18	7.1%
Other	25	10.0%
Type of catheter—initial		
PICC	163	50.0%
Tunneled	142	43.5%
Other	21	6.5%
Reason for initial catheter removal		
Completed therapy	83	25.6%
Patient death	48	14.8%
Catheter sepsis	37	11.4%
Leaking	23	7.1%
Occlusion	7	2.2%
Pulled/fell out	8	2.5%
Thrombosis	5	1.5%
Phlebitis	5	1.5%
Discontinued treatment	9	2.8%
R/O sepsis	14	4.3%
Line migration	8	2.5%
Exit site infection	8	2.5%
Catheter tear, rip	6	1.9%
Catheter malfunction	3	0.9%
Cellulitis	3	0.9%
Other	6	1.9%
Total catheters—mean	315	1.6 (±.93)
Total catheter days—mean	257	164.2 (±186.9)

PICC = Peripherally Inserted Central Catheter.
Number in parentheses is standard deviation.
n = number of subjects.

Table 2
Patient outcome variables

Variable	Number	Mean*
Catheter sepsis	326	0.51 (±1.1)
Hospital admissions	326	2.02 (±3.2)
Hospital days	326	18.1 (±28.3)
Emergency room visits	326	0.70 (±1.4)
Non-catheter infections	326	0.54 (±1.3)
Catheter problems	326	1.33 (±2.2)
Tubing problems	326	0.67 (±1.2)
Pump, delivery, and supply problems	326	2.76 (±2.7)
Education/training/reinforcement	326	2.82 (±3.4)
Psychological/social issues	326	1.43 (±2.2)

*Number in parenthesis is standard deviation.

patient. Sixty-five percent of the patients were hospitalized at least once, for a wide variety of problems ranging from catheter sepsis to scheduled chemotherapy. The range of hospital admissions per hospitalized patient extended from 1 to 21. The mean number of days per hospital episode was 18.1 (±28), with a range extending from 1 to 164. Thirty-four percent of the patients had at least one emergency room visit. The number of visits per patient ranged from 1 to 10, with a mean of 0.70 (±1). Twenty-seven percent (n = 88) of the patients experienced a non-catheter infection, with some patients experiencing repeated infections (up to 13 per patient). Very few of the patients had an adverse drug reaction (4.9%), which usually was associated with concomitant antibiotic therapy. In contrast, 50% of the patients (n = 163) had reported catheter problems, such as exit site infection or resistance/sluggishness. Thirty-six percent (n = 117) of the subjects had reported tubing problems, primarily air in the tube or blood backup.

Non-clinical problems were also reported by patients or their caregivers. Most patients receiving services from the home infusion provider were very satisfied with their care. Only 9% (n = 29) expressed any dissatisfaction, and the complaints were often directed at non-home infusion services, such as home health or laboratory services. A small percentage (7%, 23 patients) expressed concerns about the costs of care or billing practices. In contrast, fully 80% of the patients (n = 261) had at least one reported difficulty with their infusion pump, deliveries, or supplies. The mean number of reported problems with the pump, deliveries, or supplies was 2.8 (±3) per patient. In addition, 68% (n = 222) had knowledge deficits and received some type of additional training or education via the telephone after discharge. The mean number of teaching interventions per patient was 2.8 (±3). Fifty-three percent (n = 173) of the patients had psychosocial or economic issues that were associated with the treatment or their underlying disease process. Psychosocial problems were frequently related to caregiver stress, and patient stress, depression, or non-com-
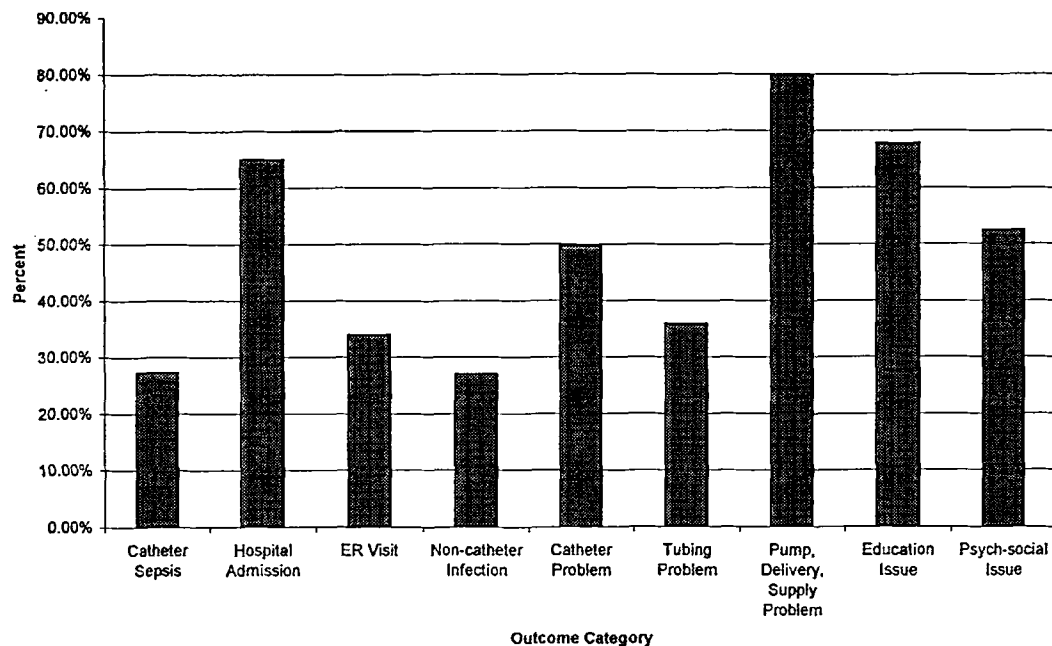
Figure 4. Patient outcomes.

pliance with therapy. Finally, symptoms were frequently experienced and reported by these patients or their caregivers, averaging 7.1 (±9) symptoms per patient.

Discussion

The data contained in this database have multiple uses. These include benchmarking treatment processes and outcomes, identifying issues for quality improvement projects, monitoring the effect of treatment process changes on patient outcomes, and monitoring changes in the demographics of the patients receiving services to identify emerging or changing needs.

Benchmarking

The database allows us to compare our outcomes with those reported in the literature by other centers. In the past, the OLEY Foundation collected data from multiple centers and reported these on an annual basis. When comparing our overall hospitalization rate with previous OLEY reports, it appeared that our rate was higher than that achieved by other centers. Further analyses revealed, however, that our database included a much higher percentage of patients with neoplasms, who frequently experienced scheduled admissions for chemotherapy. Once these hospital episodes were excluded from the analysis, our hospitalization rate fell into line with the other centers. The source of hospital data, however, does not allow easy separation of hospital admissions into the OLEY categories of primary diagnosis, new diagnosis, and treat-

ment-related diagnosis. Additional comparisons can be made regarding longevity and mortality rates for selected populations. Identified differences could lead to further explorations of possible related factors, including differences in severity of illness, selection criteria, or therapeutic approaches.

Quality Improvement Projects

Another useful application of the database is the ability to detect and then correct problems in service delivery. These are problems that interfere with the smooth delivery of clinical services and which do much to influence overall patient satisfaction and the cost of the provided services. Our data collection highlighted several areas where improvements were needed. One major area for improvement was getting the right supplies in the right quantity to the patients' homes in a timely manner. A second focus had to be placed on the infusion pumps themselves, which had recurring problems with programming, power pack failure, alarms, rate control, and so on. Such an experience can be used to influence manufacturers to improve their products, or face potential loss of a high-volume customer. The data can also be used to develop patient education programs for areas in which patients reported problems.

Treatment Process Changes

Having a database that now extends over a six-year period allows us to link changing practice patterns to the outcomes experienced by patients. Some of these changes have been driven by the reimbursement environment, and others by chang-

ing clinical practice patterns. Many changes in therapeutic approach have occurred during this time period. The electronic infusion devices were changed due to continued patient reports of problems. PICC lines became more popular than central venous catheters, as they were believed to be more cost-effective than traditional tunneled catheters. Dressing changes went from 3 or more days a week to once or twice a week. Training went from 12 hours on average in the inpatient setting before discharge, to 4 to 6 hours, with training continued by the home health nurse. In rare instances, there was complete reliance on the home health nurses for training. At the same time, the average number of educational interventions postdischarge increased from 0.40 per patient in 1993 to 2.8 in 1995, and reached 5.1 in 1997. The quicker discharges and reduced training hours before discharge were evident across all the payer groups.

Having a comprehensive database allows us to analyze what impact, if any, these changes have had on selected patient outcomes. For example, we documented a steady increase in the number of patient/caregiver phone calls related to educational needs over the same time period as the decline in predischarge training hours. We are currently examining whether one type of IV infusion catheter has fewer catheter-related problems compared with other types, and whether the occurrence of catheter problems is related to changed catheter care routines or to other factors.

Patient Demographic Changes

The characteristics of the patients being offered home infusion services has also been changing over time. A broader array of primary diagnoses is apparent, with HPN now being offered to patients with acute conditions (hyperemesis associated with pregnancy) and to patients with non-traditional chronic conditions, such as cerebral palsy and Sickle Cell disease. Fewer patients are dying while actively receiving HPN, suggesting initiation of nutrition support earlier in the course of the disease or chemotherapy regimen. There also appears to be an expansion of the criteria used to select caregivers, moving from spouses and parents to more distant relatives and even non-relatives. Such changes have implications for the support that will be required to assure a successful home infusion therapy experience.

Special Projects

The computerized database can also be used as a supplement to more focused studies. For example, a study comparing PICC line outcomes by source of insertion (IV team versus radiology) was conducted using preliminary data from the database, then supplemented by additional record review. Another study examined catheter sepsis rates in pediatric

patients, again supplementing information contained in the database with additional data collection. The availability of a comprehensive database makes such studies much more feasible, as it reduces the time required for data collection considerably.

Conclusions

The creation of a retrospective database for measuring the outcomes of home infusion therapy has enabled us to compare our outcomes with other providers, monitor the impact of changes over time, and implement specific strategies to improve the quality of care delivery. It is a resource for questions that are raised from participants involved with the care of these patients. It also raises questions that can be the focus of more controlled studies. The retrospective database also demonstrates the impact this therapy has on patient and family quality of life. Repeated hospitalizations, continuing symptomatology, coping with delivery, supply and pump problems, and experiencing complications of the underlying disease and treatment process, all contribute to a lower quality of life for these individuals. Interventions to avoid complications and subsequent hospitalizations, better manage symptoms, and reduce system-related problems would contribute to an improved quality of life for these patients.

The retrospective database also has many limitations. First, it is constrained by the type of data that are routinely collected and recorded in medical records. The quality of the data is only as good as the quality of the documentation. There may be errors of omission and commission. Further, there is no information collected directly from the patient. Patient-based assessments (PBAs) would provide valuable outcome information from the patient's perspective, including measures of functional status and well-being, patient/family satisfaction with care and caregivers, caregiver preparation and support, and symptom management. A prospective data collection process would allow collection of specific desired data elements from a wider variety of sources, including billing records and patient surveys. However, such data collection is difficult because of the long-term nature of this type of therapy—requiring repeated measures, and because the probability of missing data are greater with the use of patient surveys.

Outcomes studies have the potential to answer very important questions regarding the impact of medical, nursing, drug, and nutrition therapies on the costs of care, the quality of care, and the quality of life.[13] This article has described one approach to outcomes analysis and some preliminary findings regarding the quality of care being delivered to home parenteral nutrition therapy patients in one setting. The data also offer a standard against which other

infusion groups can benchmark their clinical outcomes.

Acknowledgment

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