

Collecting Patient-Specific Data to Improve Health Care Outcomes

A.S.P.E.N.'s Sustain™ Home Parenteral Nutrition Registry

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Nutrition support clinicians in the U.S. care for thousands of patients receiving home parenteral nutrition (HPN) each year, yet national data on the numbers of patients treated, safety of HPN therapy, and patient outcomes, remain undefined. In a health care climate characterized by rising costs and fragmented patient care, data is an essential element in demonstrating the value of care being provided. Understanding the critical role data plays in evidence-based practice, as well as in shaping emerging health care delivery models, the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) launched an initiative in February of 2011 to collect comprehensive, multi-year patient data. Dedicated to improving patient care by advancing the science and practice of clinical nutrition and metabolism, A.S.P.E.N.'s Sustain™ Home Parenteral Nutrition Registry is a national patient registry for nutrition care that seeks to define this important patient population with data, and is open to participation from many sites of care.

Registries, repositories, or databases are terms used to describe a collection of clinical data associated with a specific disease state, condition, or procedure. Data collected in a registry can be used to evaluate the epidemiology of disease states, treatment outcomes, and to guide patient care.¹⁵ The Agency for Healthcare Research and Quality (AHRQ) defines a patient registry as an organized system that uses observational study methods to collect uniform data to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purpose(s).⁶ Data collected can help promote quality and improve health care by identifying patient needs and values, promoting evidence-based decision making, and anticipating future health care trends and needs.⁷ While a registry is not needed for every disease, condition, or procedure, those that are high-risk, high-volume, and/or high-expenditure, such as HPN, are ideal for capture in a registry in order to improve quality and efficacy of care provided.⁶

A Brief History of Home Parenteral Nutrition and Data

HPN has offered patients with intestinal failure a life-saving option. Some individuals have not only survived, but thrived for over 30 years on this therapy. Yet



despite the relatively long history of parenteral nutrition in U.S. health care, comparatively little is known about the utilization and efficacy of HPN. In 1984, a patient registry was developed to track the longitudinal outcomes of a cohort of home patients in the U.S. and Canada.⁸ The registry, called OASIS (Oley-A.S.P.E.N. Information System), was a joint effort of the Oley Foundation and A.S.P.E.N. and existed from 1985 to 1992. The prevalence of HPN during that time was 238 patients per million people in the U.S.⁹ The most recent published prevalence data from 2002 estimated that 39,000 people received HPN, and was based on a single, national home infusion provider's database.¹⁰ Given the paucity of data reflecting current prevalence of HPN use—across a full spectrum of providers and disease states—as well as patient outcomes, it was critical that A.S.P.E.N. develop a registry to track HPN demographics and care. It's believed that the ability to better characterize this population will allow practitioners to

improve clinical practice through evidence-based care. In addition, the field will be better positioned to support reimbursement and policy development on behalf of patients and their families. The technological advances afforded us since the last Registry—key-strokes on a secure website compared with filling out and mailing paper forms—should increase overall participation, in addition to facilitating more regular review, analysis and communication of registry data.

Sustain™, which means “to give support or relief to, or to supply with sustenance,” was developed with the mission of maintaining a prospective, longitudinal nutrition therapy patient registry that focused on patient outcomes of care over time. From the nutritional formula provided, to the evaluation of its impact on patients’ health and well-being, this data will ultimately be published, utilized for organizational bench-marking, and contribute to evidence-based decision-making.^{11,12} The first phase of this Registry is to study HPN patients. Future populations may include home enteral nutrition, parenteral or enteral nutrition in acute and long-term care settings, and/or hospitalized malnourished patients (see the box below for Sustain™ Registry goals).

Sustain Registry Goals

1. Collect information regarding the patients who require HPN in the U.S.
2. Measure outcomes associated with HPN.
3. Allow institutional benchmarking against the aggregate data.
4. Publish the findings in order to improve the quality of care for patients receiving HPN.

Sustain™ aims to answer several research questions that could further shape clinical best practices, as well as educate referral sources, payers, and patients themselves regarding certain details of their care (see Exhibit 1).

Participating in the Registry What’s Involved?

Sustain™ utilizes a prospective, longitudinal cohort design to collect data over time for adult and pediatric patients initially discharged from the hospital, and existing patients already on HPN, with follow-up on a periodic basis. Clinicians from hospitals and home infusion providers are designated as either Site Investigators or Participants.

Federal regulations and institutional policies require that research or research procedures involving the use of patient-specific medical record information must allow for full patient protection. As a result, before sites can formally enroll in Sustain™ and prospectively enter data on HPN patients, they must obtain institutional review board (IRB) approval. Certain organizations may require written informed consent of the patients unless the IRB waives

Exhibit 1 Examples of Clinical Research Questions

- What is the length of HPN dependency stratified by diagnosis and age?
- What is the rate of hospital readmission for catheter-related bloodstream infections (CRBSI) in adults versus children?
- What is the rate of CRBSI stratified by type of catheter and catheter care protocol?
- Are catheter-related complications different for patients who have peripherally inserted central catheters (PICCs), versus tunneled catheters versus subcutaneous infusion ports?
- Is there a relationship between doses of IV fat emulsion and liver failure in patients with short bowel syndrome?
- What is the rate of growth of children who are HPN dependent?
- Is there a link between nutritional intake and functional status?

the need for signed informed consent. Sustain™ has also received an independent IRB approval for those organizations that may not have ready access to an IRB. **Several home infusion provider organizations are already participating in Sustain™—see the sidebar on p.30 for the experiences of two NHIA member companies.**

All costs associated with the implementation and maintenance of the Registry are supported by Sustain™ through its funding sources. Unlike many registries, contributing sites will not be charged to participate. Health care clinicians will need to recruit patients and enter data, so there are some labor costs associated with participation in the Registry.

Data is obtained at baseline, which is defined in new HPN patients as “at time of hospital discharge and/or home care admission” and with existing patients, as “the time when clinician enrolls the patient.” While there are a substantial number of data elements that can be entered for each patient, only 23 are critical in the baseline form. Each patient is followed longitudinally, with periodic follow-up data entered into the Registry at regular intervals (see Exhibit 2). Sustain™ is actively working with software vendors to determine if an electronic data bridge between their software and the Sustain™ Registry is feasible—this would simplify the extraction of data, alleviating the need for re-entry.

Each site receives quarterly aggregate reports of its own patients, and a benchmark comparison to the total pooled data. Patients receiving PN in long-term care, other institutional settings, or those receiving intradialytic parenteral nutrition (IDPN) are currently excluded from the Registry—but may be added in future phases of Registry work.

Exhibit 2 Sustain Data Elements

Baseline:

- Demographics
- Diagnoses and Reason for PN
- Current PN formula
- Nutrition status
- Psychosocial status
- Functional status
- Patient teaching

Follow-up:

- Demographics
- Diagnoses and ongoing reason for continuing PN
- Current PN formula
- Nutrition status
- Morbidity data (including complications)
- Rehospitalization data
- Mortality data
- Community resources

What We're Learning

As of August 2012, the Registry includes data for 500 HPN patients from 14 active participating sites in geographically diverse areas of the U.S. (see Exhibit 3). An additional 38 sites are in the process of obtaining IRB approval. Existing HPN patients comprise 44% of the Registry sample. Adults and pediatrics represent 88% and 22% of the current patients respectively (see Exhibit 4). Short bowel syndrome (SBS), Crohn's disease, and gastrointestinal motility disorder are the top three diagnoses of adult patients, while SBS, gastroschisis, and necrotizing enterocolitis are the top three diagnoses of pediatric patients in Sustain™. The majority of patients receive HPN six times per week via a tunneled central venous catheter. Most patients have private insurance, followed next by Medicare and Medicaid.

In addition to the demographic data, the Sustain™ Registry will provide morbidity and mortality data—such as the frequency, rate, and reason for hospital readmissions; rate of catheter-related bloodstream infection (CRBSI); incidence of liver disease and metabolic bone disease; and number of deaths related and unrelated to HPN.

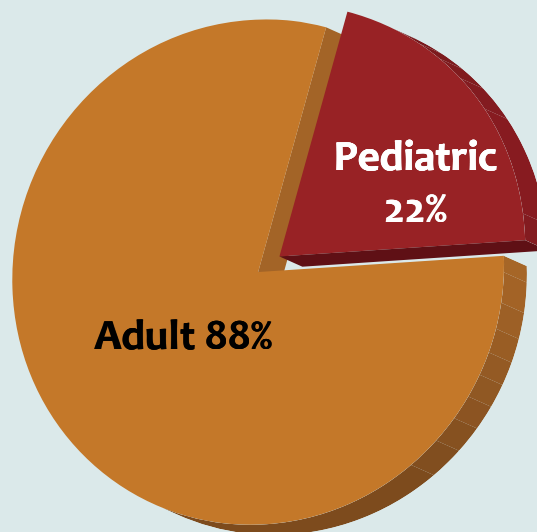
Although this patient Registry is in its infancy, provider participation is encouraging and the initial data available for analysis has been informative. We hope that as demographic and patient outcomes are revealed, the Sustain™ findings will be used to inform public policy makers, as well as to benchmark best practices. For more information about the Sustain™ Home Parenteral Nutrition Registry, visit: www.nutrition-care.org/Sustain. ▀

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Exhibit 3 Current Active Sustain Participating Sites

- Children's Hospital Boston
- Children's Hospital of Michigan
- Cleveland Clinic
- Equinox Healthcare, Inc.
- Mayo Clinic - Jacksonville
- Pediatric Home Service
- Rhode Island Hospital
- Sharp HealthCare
- Spectrum Health
- SwedishAmerican Hospital
- Texas Children's, Baylor College of Medicine
- Thrive-Rx
- University of Michigan, Mott Children's Hospital
- University of Pennsylvania

Exhibit 4 Percent of Adult and Pediatric Patients



M.S., Pharm.D., is the association's Secretary/Treasurer. Rose Ann DiMaria-Ghalili, Ph.D., R.N., CNSC, is an Associate Professor for the Doctoral Nursing and Nutritional Sciences Departments at Drexel University; Beth Lyman, R.N., M.S.N., CNSC, is the Senior Program Coordinator for the Nutrition Support Team at Children's Mercy Hospital in Kansas City, Missouri; Ezra Steiger, M.D., is a Professor of Surgery at the Cleveland Clinic Lerner College of Medicine and a member of the Nutrition Support Team for its Digestive Disease Institute Intestinal Rehab and Transplant Program; and Marion F. Winkler, Ph.D., R.D., L.D.N., CNSC, is an Associate Professor of Surgery and a Surgical Nutrition Specialist at the Alpert Medical School of Brown University. Comments about this article or questions about Sustain™ may be directed to: Peggi Guenter at peggi@aspn.org.

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Home Infusion Providers Patient Registry

By Jeannie Counce



Patient-specific knowledge is powerful, and never more so than when it is purposefully shared. For home infusion providers participating in the Sustain™ Home Parenteral Nutrition Registry, the prospect of gaining critical knowledge about the patients they serve and effectiveness of their interventions is empowering.

“We hope to use this information to design better services that meet the needs of our patients in different disease states, foster better outcomes, and lead to more cost-effective health care,” says Karen Ackerman, M.S., R.D., L.D.N., CNSC, Clinical Dietitian at Thrive Rx in Cincinnati, Ohio. Although there are not yet enough patients entered in the Registry to begin benchmarking, Ackerman says her company is eager to learn more. “That information will allow us to tailor our programs to the needs of the patient community and to modify and improve our processes.”

Simply being able to document some of the most fundamental information is a step in the right direction for providers and the field, Ackerman adds. “Currently we don’t even have reliable basic information, like how many home parenteral nutrition (HPN) consumers there are or the most prominent disease states. It’s good for the patient community and its helpful for us as a field to know what’s out there.”

The idea of a national database was equally as exciting to the clinical team at Pediatric Home Service (PHS) in Minneapolis, Minnesota. “It allows us to collect data that can be used to build evidence-based practices,” observes Judy Giel, RRT, CRTT, Senior Vice President of Clinical Services. Giel points out that caring for medically complex pediatric patients is a specialty, and providing them with parenteral nutrition is an incredibly nuanced clinical service given that their needs change along with their rapid development. “There are others doing HPN for peds, so we anticipate being able to compare ourselves with practices across the country—draw

Empowered by Participating in National

from the experience of others or provide them with information,” she says.

Giel explains that PHS’ primary concern is improvement, and data from a registry would allow her team to compare and contrast successful outcomes with clinical interventions. “For example, we’ve had great success preventing line infections, so we want to look at what we put into place and see if the data supports good outcomes. Are our interventions as successful as they can be? If not, we’ll go back to the drawing board.”

Building evidence-based practices is important to referral sources, as well. “I can envision going back to referral sources with things we’ve learned,” says Ackerman, who notes she’s received positive feedback from physicians on Thrive Rx’s participation in Sustain™. “Any information we can offer about what works with this patient population is helpful.”

“Our outcomes reflect on them as a prescriber,” adds Giel, explaining that PHS has been publishing its clinical and operational outcomes online for some time and recently expanded their postings. “We feel we have an obligation to put our results out for public review so we can learn and improve. They are also a resource for families and prescribers looking to make decisions.”

Both providers agree that participating in Sustain™ is easy and fairly quick. Since neither was a hospital affiliate, they didn’t have an established internal review board (IRB). Instead, they took advantage of the sample and educational tools provided by A.S.P.E.N. “Using the existing IRB made it easy, saved time, and removed barriers,” explains Rebecca Long, RRT-NPS, LRT, PHS’ Director of Ancillary Service.

The secure, web-based data entry system is straightforward as well, according to the providers. “At first, the thought was daunting,” recalls Ackerman, “but once you do

a couple it’s easy. Now I know what I need to have on hand and get everything ready ahead of time.” The data entry process is very intuitive, adds Teresa Rink, R.D., L.D., CNSC, Clinical Dietitian at PHS. “We enter baseline demographics, nutrition information, psychosocial and family data and functional status; then do follow-ups on a regular basis or in the case of an event, such as hospitalization, change in formula, discontinuation of therapy, or morbidity.”

“Sustain™ is very easy,” adds PHS’ Giel. “We’re thankful that they’ve done a lot of the work for us.”

All that work should make it easy for more providers to participate. “We want others on board because the benchmarking will be more of an apples-to-apples comparison,” says Giel. “Everyone is so busy delivering care, but I see how easy it is to participate and I realize the more data we have, the more useful it will be,” echoes Ackerman, who is looking forward to seeing data on central line infections among other areas.

“Hopefully the data we collect will show that patients have the potential to do well on HPN and experience a high quality of life with few complications, like being admitted to the hospital.”

Historically, the hospital has been the only alternative for patients like those served by PHS. “Our entire health care system is under pressure to reduce costs, and being able to show that our services are cost-effective compared to hospital care is crucial,” concludes Giel. “We want to be at the intersection of safety, effectiveness, and quality of care—and collecting data provides opportunity in this new paradigm.” ■

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