



A.S.P.E.N.'s National Patient
Registry for Nutrition Care

FINAL REPORT SUSTAIN HOME PARENTERAL NUTRITION PROJECT April 2015

Table of Contents

Introduction

Project Background

Growth of Sustain

Sustain Participants

Sustain Governance

Scientific Considerations

1. *Institutional Review Board Approval*
2. *Benchmarking Reports*
3. *Publications*
4. *Invited Presentations*
5. *Scientific Query and Public Data Sets*
6. *List of Approved Analyses*

Operational Considerations:

1. *Modification in Data Collection 2013-2014*
2. *Conclusion of Data Collection*
3. *Dataset Analytic Considerations*
4. *Site Recruitment and Promotion*
5. *Patient Confidentiality and Data Integrity*
6. *Considerations for Future Data Collection Projects*
7. *Project Support*

Introduction

Sustain™, LLC: A.S.P.E.N.'s National Patient Registry for Nutrition Care is a comprehensive, web-based tool that allows clinicians to enter patient data, measure and analyze results, benchmark outcomes with aggregate data, and disseminate findings. The purpose of Sustain is to maintain a prospective nutrition therapy registry in order to improve patient outcomes. The registry is designed to address multiple aspects of nutrition care.

Sustain's initial phase focused on Home Parenteral Nutrition (HPN). Home parenteral nutrition provides a life-saving option for patients with intestinal failure and other serious GI conditions. Sustain's subsequent phases will enable expanded data collection to



examine other patient populations, therapies, and issues in nutrition care.

The goal of the Sustain HPN Project was to enroll and capture data and outcomes of 100% of HPN patients in the US by:

1. Collecting information on patients and populations who require home parenteral nutrition in the U.S.
2. Measuring outcomes associated with home parenteral nutrition.
3. Allowing institutional benchmarking against aggregate data.
4. Publishing findings to improve the quality of care for patients receiving home parenteral nutrition.

The purpose of this report is to summarize the initiatives of the Sustain HPN Project since its launch in 2011.

Project Background

Currently in the U.S., there are few large data sets of characteristics of HPN patients or clinical outcomes. Historical data are available from the Oley-A.S.P.E.N. Information System (OASIS) for 1985-1992 and the North American Home Parenteral and Enteral Patient Registry for 1992-1994.¹⁻³ In 2005, one home nutrition support provider published outcomes from a 5-year retrospective evaluation of 4540 HPN patients per year.⁴ While some large medical centers do have databases to track HPN patients, the Sustain Registry HPN Project was a national effort to look at outcomes from many sites, as the use of HPN in the U.S. is considered to be much higher than other countries. In 2011, the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) launched a national patient registry for nutrition care (Sustain™) to prospectively collect outcomes on adult and pediatric HPN patients.⁵ Specific areas of interest included: Length of HPN therapy according to patient diagnosis, nutrition and functional status, pediatric growth and development, PN formula patterns, selected complications, catheter infection rates, hospital readmission rates, and mortality.

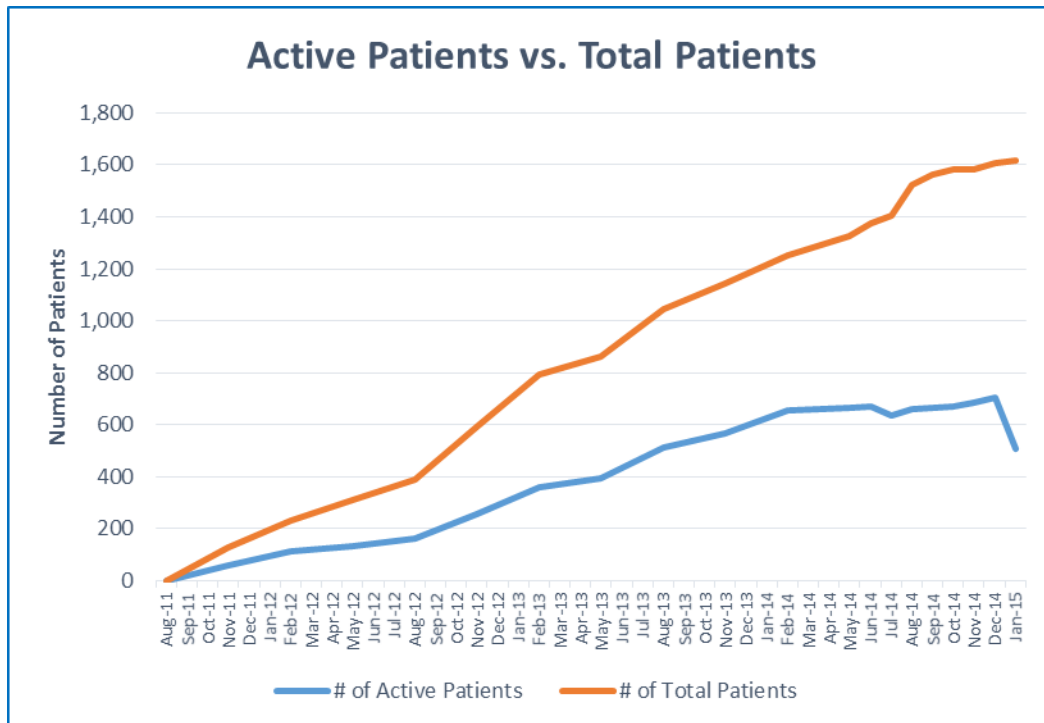
The Sustain HPN Project data represents the largest current repository of HPN research data collected in the United States, and it is expected that this resource will make meaningful strides towards improving the clinical care and policies that are relevant to this patient population.

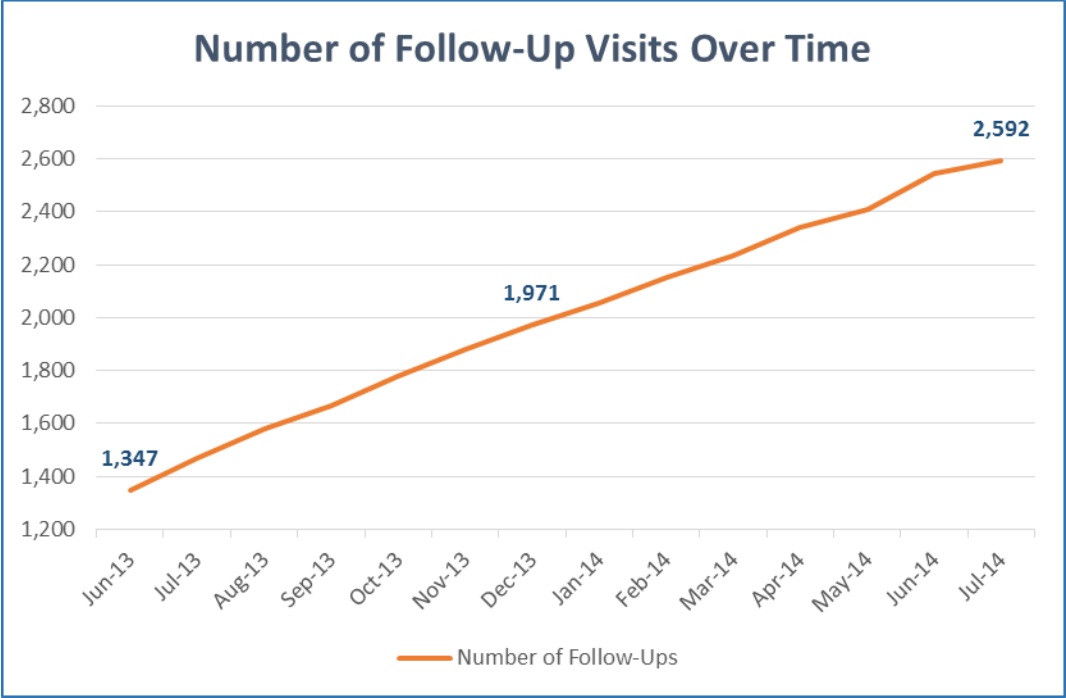
1. Howard L. Home parenteral nutrition: survival, cost, and quality of life. *Gastroenterol.* 2006;130 Supplement, S52-S59.
2. North American Home Parenteral and Enteral Nutrition Registry. Annual reports 1992. The Oley Foundation, 1994. www.oley.org, accessed June 30, 2014.
3. Howard L, Ament M, Fleming CR, Shike M, Steiger E. Current use and clinical outcome of home parenteral and enteral nutrition therapies in the United States. *Gastroenterol.* 1995;109:355-365.
4. Ireton-Jones C, DeLegge M. Home parenteral nutrition registry: A five-year retrospective evaluation of outcomes of patients receiving home parenteral nutrition support. *Nutrition.* 2005;21:156-160.
5. Guenter P, Robinson L, DiMaria-Ghalili RA, Lyman B, Steiger E, Winkler MF. Development of Sustain™: A.S.P.E.N.'s National Patient Registry for Nutrition Care. *JPEN J Parenter Enteral Nutr.* 2012;36:399-406.

Growth of Sustain

The Sustain Home Parenteral Nutrition (HPN) project was launched in January 2011 with the first patient entered into the Registry in August 2011. When data collection concluded at the end of January 2015, the Registry had accrued 3.5 years of patient data. The graphs below show the growth in the number of total patients and active patients during the project period, and number of follow-ups over time. In total, 38 medical centers, hospitals, and home infusion providers completed the IRB and approval process (defined as “active sites”) and of these, 32 sites entered 1,642 patients (86% adult patients, and 14% pediatric patients). Among active sites, 39.5% are academic medical centers, 26.3% are home infusion providers, and 34.2% are children’s hospitals. During the open enrollment period, data on 1463 patients with at least one follow-up visit was collected.

Growth of Sustain 2011-2015





Sustain Participants

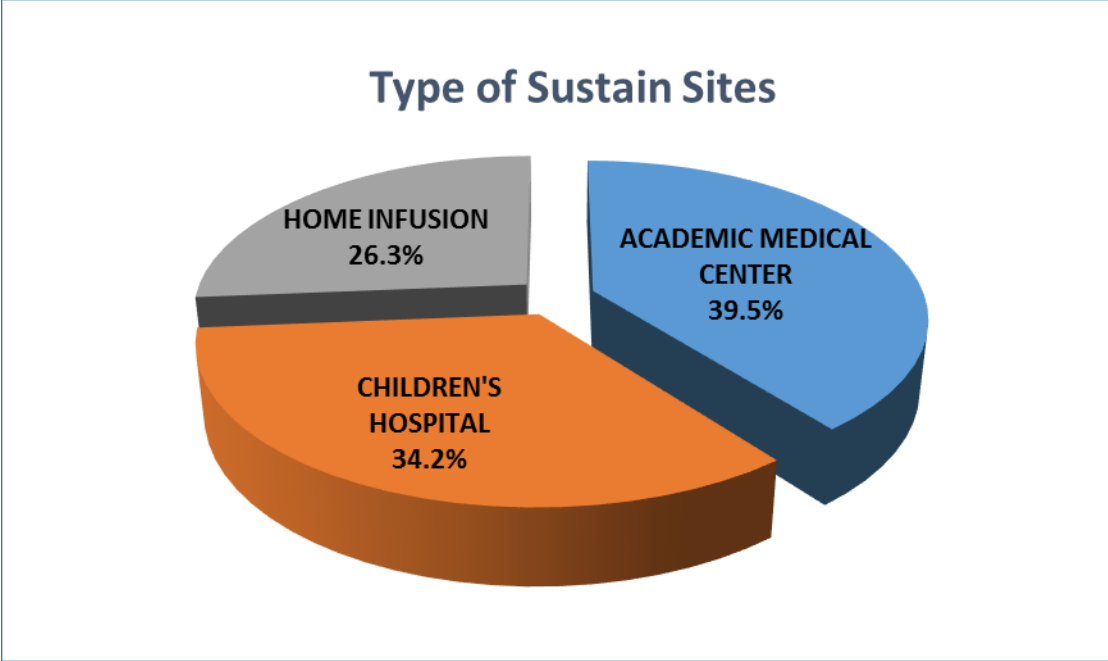
One of the benefits of Sustain HPN Project was the building of a multi-center data collection consortium. The relationships built and the contributions made by the volunteer site participants, principle investigators, and council members was the main driver for the success of Sustain. A.S.P.E.N. leadership is very grateful to all of the efforts made by our members and supporters towards this project.



Mandy Corrigan, featured in photo with Dr. Larry Robinson, was awarded the 2012 Sustain Distinguished Service Award for her overwhelming dedication and efforts with Sustain.

Below find the list of Approved Data Entry Sites during the project. Not all approved sites were able to contribute data but they did complete the approval process.

Sustain Approved Data Entry Sites During HPN Project
Arnold Palmer Hospital for Children
CarePoint Partners - Dallas
CarePoint Partners - Providence
CarePoint Partners - Tampa
Children's Hospital Boston
Children's Hospital of Michigan
Children's Mercy Hospital
CHOC Children's Orange County
Cleveland Clinic
Clinical Nutrition Support Service University of Pennsylvania Health System
Columbia University Medical Center
Connecticut Children's Medical Center
Cook Children's Medical Center
Equinox Healthcare Inc
Fairview Home Infusion
Geisinger Medical Center
Indiana University Health Home Care
Intermountain Medical Center
Le Bonheur Children's Hospital
Mayo Clinic
Nation's Home Infusion, LLC
Nationwide Children's Hospital
Pediatric Home Service
Rady Children's Hospital
Rhode Island Hospital and Hasbro Children's
Riley Hospital for Children at IU Health
Sharp Home Infusion and Central Pharmacy Services
Spectrum Health—Butterworth
SwedishAmerican Healthsystem
Texas Children's, Baylor College of Medicine
The Children's Hospital of Philadelphia
The George Washington University Hospital
ThriveRx
Truman Medical Center
University of Chicago
University of Michigan
University of Virginia Health System
Vanderbilt Center for Human Nutrition



Sustain Governance

The Sustain Registry HPN Project was overseen by the Executive, Scientific, and Operations Advisory Councils, each of which had distinct responsibilities. The Executive Council was responsible for providing high level strategy and direction to the Registry. Responsibilities of the Scientific Advisory Council included reviewing data collection tools, annual reports, IRB templates, quality improvement/benchmarking reports, scientific queries, research proposal reviews, and publications. The Operations Advisory Council was responsible for ongoing site recruitment, ensuring data quality and integrity, statistical infrastructure, and user satisfaction.

Current Sustain Advisory Council Members for 2014-2015

Executive Council	Scientific Council	Operations Council
Larry Robinson, BS, MS, PharmD	Marion Winkler, PhD, RD, FASPEN	Lillian Harvey-Banchik, MD
Lillian Harvey-Banchik, MD	Ezra Steiger, MD, FASPEN	Carol Ireton-Jones, PhD, RD, FASPEN
Carol Ireton-Jones, PhD, RD, FASPEN	Janet P. Baxter, MPhil, SRD, RN	Karen Ackerman, MS, RD, LDN, CNSD
Ezra Steiger, MD, FASPEN	Beth Carter, MD	Stephen Adams, MS, RPh, BCNSP
Marion Winkler, PhD, RD, FASPEN	Rose Ann DiMaria-Ghalili, PhD, RN, FASPEN	Mandy Corrigan, MPH, RD, CNSC
Mary Hise, PhD, RD, CNSC	Jessica Monczka, RD	Sharon Durfee, RPh, BCNSP
Michael Medwar	Marianne Opilla, RN, CNSC	Theresa Han-Markey, MS, RD

Alan Parver, JD	Vicki Ross, PhD, RN	Debra Kovacevich, RN, MPH
		Katherine Bennett, RD, MPH, CLE
		Ross Taylor, MD, CNSC

Scientific Considerations

Sustain™ HPN Project is listed in the Agency for Healthcare Research and Quality's (AHRQ) ClinicalTrials.gov under the program *AHRQ's Registry of Patient Registries*. The study was listed as the Sustain Home Parenteral Nutrition Registry and can be accessed through the [Registry of Patient Registries website](#).

Institutional Review Board Approval

Sites were required to submit a research protocol and receive approval from their Institutional Review Board (IRB) in order to participate in the Sustain Registry. The New England Institutional Review Board (NEIRB) first granted approval to Sustain in 2011 and the most recent re-approval occurred in March 2014. Sites without local IRBs could be covered by the NEIRB. Six sites used IRB coverage under this central mechanism. Of the 38 active sites, 53% were granted a waiver of consent from their IRB, while 47% are required to obtain written informed consent. Some sites require both written informed consent and child assent. Sustain users provided feedback suggesting that gaining IRB approval and re-approval was challenging and in some cases had delayed their participation in the registry. In response to this concern, an IRB template was developed and Frequently Asked Questions (FAQs) were posted on the Sustain website to provide additional support to sites as they navigated the IRB approval process. The NEIRB approval letter was also posted on the website for easy access.

Benchmarking Reports

In April 2012, the first cross-sectional benchmarking report was prepared and distributed to active sites with patients entered into Registry. This report compared individual sites' data with aggregate data across all sites in the Sustain Registry. After that time, all active sites received quarterly cross-sectional and longitudinal benchmarking reports. These reports provided sites with valuable information about their patient populations and how their patient demographics and outcomes compared to the aggregate population. Sites were encouraged to share these reports with their team and administrators, and they were also asked to provide feedback regarding improvements in the reporting process. In March 2015, a final benchmarking report was provided to all sites.

Publications

The following abstracts and manuscripts have been published:

Winkler MF, et al. Characteristics of a Cohort of Home Parenteral Nutrition Patients at the Time of Enrollment in the Sustain Registry *JPEN J Parenter Enteral Nutr* 2015 (accepted for publication)

Ross V, Guenter P. Comparison of Central Line–Related Thrombosis and Infection Rates Among New and Existing Home Parenteral Nutrition Patients: Two Years of Sustain™ Data *JPEN J Parenter Enteral Nutr* January 2014 online data supplement: Abstract # 1834251 page 14-15. (Scientific abstract presentation, Clinical Nutrition Week, Savannah, GA Jan 2014)

Winkler MF, Guenter P, Robinson L, DiMaria-Ghalili RA, Lyman B, Ireton-Jones C, Steiger E. Sustain™ Home Parenteral Nutrition Patient Care Registry: Year 1 Data *JPEN J Parenter Enteral Nutr* January 2013 37 online data supplement: 26-27. (Scientific abstract presentation, Clinical Nutrition Week, Phoenix AZ Feb 2013)

Guenter P, Robinson L, DiMaria-Ghalili RA, Lyman B, Steiger E, and Winkler MF. Development of Sustain™: A.S.P.E.N.'s National Patient Registry for Nutrition Care *JPEN J Parenter Enteral Nutr*, July 2012; vol. 36, 4: pp. 399-406.

Guenter P, Robinson L, DiMaria-Ghalili RA, Lyman B, Steiger E, Winkler MF. Collecting Patient Specific Data to Improve Health Care Outcomes: A.S.P.E.N.'s Sustain Home Parenteral Nutrition Registry. *Infusion*, the National Home Infusion Association journal. September-October 2012; 27-31.

Lifeline – the Oley Foundation Newsletter On HPN? Get Your Provider Involved with a Valuable Database! February 2011 www.oley.org

Invited Presentations

To date, the following presentations have been made:

April 2013 National Home Infusion Association National Meeting. *Sustain™ Home Parenteral Nutrition Registry* Carol Ireton-Jones, PhD, RD, LDN, FASPEN. Dallas, TX.

February 2013 Clinical Nutrition Week. *Home Parenteral Nutrition Patient Registries: An International Perspective*. Ezra Steiger. Phoenix, AZ. [Sustain educational session at CNW13](#).

September 22, 2012 *Sustain™ A.S.P.E.N.'s HPN Patient Registry* Marion Winkler, PhD, RD, LDN, CNSC Florida Chapter Annual Meeting FASPEN Fort Lauderdale, FL

September 1-3, 2012 Pediatric SBS Registry and Sustain Daniel Teitelbaum Pediatric Intestinal Failure Consortium Meeting Pittsburgh, PA.

August 7, 2012 HPN Awareness Week Program ASPEN HPN Patient Registry Sustain™ Baxter Healthcare, Deerfield, IL.

June 26, 2012 *ASPEN HPN Patient Registry Sustain™* Marion Winkler, PhD, RD, LDN, CNSC Oley Foundation Annual Conference Redondo Beach, CA.

April 4, 2012 *Sustain™ A.S.P.E.N.'s HPN Patient Registry* Peggi Guenter, PhD, RN
Children's Hospital of Philadelphia Clinical Nutrition Lecture Series Philadelphia, PA.

January 24, 2012 *Sustain™, LLC: The Why, the How and the Data. HPN and Public Policy* Alan Parver, Shareholder, Posinelli Shughart, Washington, DC *Sustain: Development and Operations* Peggi Guenter, PhD, RN, A.S.P.E.N., Silver Spring, MD
Sustain: HPN Data Marion Winkler, PhD, RD, LDN, CNSD, Clinical Nutrition Week 2012 Orlando, FL

January 23, 2012 *Sustain™, LLC Users and Prospective Users Interactive Session* at Clinical Nutrition Week 2012 Orlando, FL Mandy Corrigan RD.- Cleveland Clinic and Beth Carter, MD- Texas Children's Hospital

November 17, 2011 *Sustain™ A.S.P.E.N.'s HPN Patient Registry* Larry Robinson, Peggi Guenter, Marion Winkler, Ezra Steiger, Beth Lyman A.S.P.E.N. Webinar

October 19, 2011 *Sustain™ A.S.P.E.N.'s HPN Patient Registry* Peggi Guenter, PhD, RN Philadelphia Chapter A.S.P.E.N. Fall Meeting King of Prussia, PA

July 5, 2011 *ASPEN HPN Patient Registry Sustain™* Ezra Steiger, MD Oley Foundation Annual Conference Bloomington, MN.

April 2011 *Sustain™ Patient Registry Informational Webinar* Larry Robinson, Peggi Guenter, Ezra Steiger, Marion Winkler via A.S.P.E.N. Webinar Platform.

January 31, 2011 *Sustain™ Patient Registry Informational Session* Larry Robinson, Peggi Guenter, Ezra Steiger, Marion Winkler, Beth Lyman CNW 11 Vancouver, BC.

Scientific Query and Public Data Sets

Sustain encourages widespread use of its data resources to address policy-related issues and to improve the care of patients on home parenteral nutrition. A [Sustain Publication Guideline](#) was developed and released in December, 2012, which explained how active sites can utilize their own and aggregate data for benchmarking and research purposes. Policies, procedures, and project guidelines were published in January 2013, ([Sustain Registry Scientific Query Protocol](#)) so sites and investigators who are interested in Sustain Registry data have clear instructions and guidelines on how to access the data. In late 2014, a protocol was developed to provide guidelines to Sustain's Scientific Advisory Council for reviewing submitted proposals. All site users were advised on what is included in the Sustain public-use data sets, what other documentation is available to support the use of the data sets, and what the data sets could be used for. This information was also made available to non-participating sites and individuals through emails, the Sustain website, A.S.P.E.N.'s *Insight Weekly*, question and answer sessions at Clinical Nutrition Week 2015. .

List of Approved Scientific Analyses

Plans for future research articles from Sustain data include:

1. Characteristics of Home Parenteral Nutrition Patients from the Sustain Registry: August 2011-February 2014. Marion F. Winkler, PhD, RD, LDN, CNSC, FASPEN, et al. (submitted to *Journal of Parenteral and Enteral Nutrition*)
2. Intravenous catheter outcomes in over 1000 home PN patients. Vicki M. Ross, RN, PhD, CNSC, et al. (under development)
3. Characteristics and outcomes of HPN patients with short bowel syndrome. Marion Winkler, PhD, RD, LDN, CNSC, FASPEN, et al. (under development)
4. Characteristics and outcomes of HPN patients with obesity and/or s/p bariatric surgery (proposal under consideration)
5. Characteristics and outcomes of pediatric HPN patients. Sustain Pediatric Site Investigators. (under development)

Operational Considerations

Modification in Data Collection 2013-2014

As a result of surveys, direct communication with users and council members, the need to modify data entry to improve the data collection process and analysis was identified. In 2013, the original data fields were reviewed by the Scientific Advisory Council to determine if modifications would improve the quality of the data collection. In addition to this review, a detailed analysis of missing data elements was undertaken to determine if there were meaningful patterns of missing data. As a result of these evaluations, critical elements were identified, data collection was streamlined, and a new data collection system went online on February 15, 2014. Improvements included a reduction in the number of fields, various clarifications, auto-population, more detail on the follow-up form, and built-in pop-ups to answer common questions. Additional quality controls features were added to reduce user error at the point of data entry.

In preparation for the system change, Sustain users had the opportunity to attend an on-line training session and they were provided with information on what to expect during the training session. These training sessions received positive feedback including comments that users found it easier to complete follow-up data entry activities. During Clinical Nutrition Week in January 2014—one month before the new data system went online—a Sustain users meeting was held to convey information about the new changes and to provide a platform for discussion and questions. As part of ongoing efforts to improve data quality, user tips and updates were communicated through email, website postings, and the *Sustain Newslines*, Sustain's bi-annual newsletter.

Conclusion of Data Collection

The data collection phase of the HPN project concluded on January 31, 2015, with nearly 3.5 years of active data collection. Prior to close-out, sites were asked to update their patients with a focus on their current patients. This request aimed to provide the Registry with a detailed picture of patients' status at the end of follow-up.

Data Set Analytic Considerations

Creating a complete data set with the greatest number of patients possible was a challenging task for melding the Sustain data from the original data collection forms with

the new February 15, 2014 data collection forms. As a result of the upgrade to the data collection process on February 15, 2014, not all the data elements are directly merged together. Therefore, several data sets were created to include baseline and longitudinal data for data elements for the following period: 1) August 2011 to February 14, 2014, and 2) February 14, 2014 – January 31, 2015. We hope to produce a data set that covers August 2011 – January 31, 2015 that will include only data elements that were the same in both the original and new data collection forms. This is challenging because there are several variables that don't "map" directly. For example, Diagnosis in the original system was ascertained in a "check all apply" section where multiple diagnoses could be selected. However, in the new system, diagnosis was ascertained as Primary Reason for Home PN, so only one diagnosis could be selected. Also, some variables do not exist in the same form in the two systems. Cystic fibrosis is one such example. In the new system, Cystic Fibrosis is not a check all that apply choice like in the old system, but is listed as a choice which can only be selected if a higher level choice like malabsorption is selected first. Addressing these data management considerations is currently underway.

Site Recruitment and Promotion

Efforts to raise awareness of the Sustain HPN Registry and to recruit new sites occurred throughout the project period. These activities included: advertising in *JPEN J Parenter Enteral Nutr*, and the Preliminary Program Guides and Onsite book for CNW, building and maintaining a registry website (www.nutritioncare.org/sustain), email blasts to A.S.P.E.N. physicians, updates in A.S.P.E.N. email blasts, exhibiting at meetings (CNW, the Oley Foundation, Academy of Nutrition and Dietetics, Society of Hospital Medicine), and distributing press releases.

Patient Confidentiality and Data Integrity

An important feature of the Sustain Registry HPN project was its focus on patient confidentiality and data integrity. We were proud that during the 4 years of Registry operation, there were no reported concerns or data breaches from the site users, Sustain administrators, or the hosting vendor. The final Sustain data sets will be stored by A.S.P.E.N. on a secure server with password safeguards applied to individual files.

Considerations for Future Data Collection Projects

The experience gained through the Sustain HPN Project has identified several important tenets that may lead to improvements in future data collection projects:

- Keep cost in mind when considering future projects. Data collection projects are costly in terms of time and money.
- Identify the questions you want to answer before developing the data collection fields. Make sure that the data being collected will potentially answer important questions and enhance the body of knowledge.
- Have a bio-statistician involved from the beginning, and if a longitudinal study, an epidemiologist should be involved. Insure that the data collected can be analyzed. Generate interest for research before the data collection phase begins. Identifying potential research projects will enhance the construction of the data collection tool.

- Consider use of REDCap for future projects to reduce expense of outside database vendor. REDCap was not available when Sustain HPN project began.
- Consider the time necessary for involved sites to initiate participation in a data collection project, including completing the IRB approval process, and identification and training of data collection personnel. These are time consuming processes that must be accomplished before data collection begins.

Project Support

The Sustain Registry was supported by research grants from the Baxter Healthcare Corporation, C.R. Bard Foundation, Inc, and the A.S.P.E.N. Rhoads Research Foundation. The Sustain leadership sincerely thanks the supporters of this project and their commitment to patients receiving home parenteral nutrition.

