



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

SUSTAIN ANNUAL REPORT July 2013

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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, longitudinal nutrition therapy registry in order to improve patient outcomes. In its initial phase, Sustain will store data for patients receiving Home Parenteral Nutrition (HPN). Home parenteral nutrition (HPN) provides a life-saving option for patients with intestinal failure who need vital nutrients that they would otherwise not absorb. Subsequent phases of this registry will enable expanded data collection for other patient populations and therapies. The goal of this registry is to enroll and capture data and outcomes of 100% of HPN patients in the US. Specifically, this HPN registry will:

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



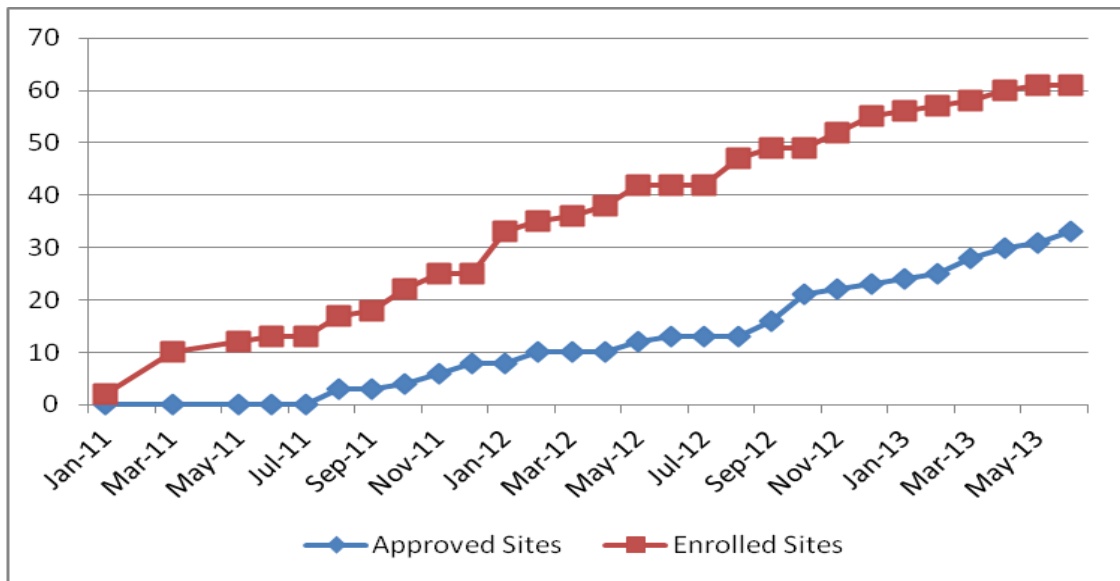
parenteral nutrition.

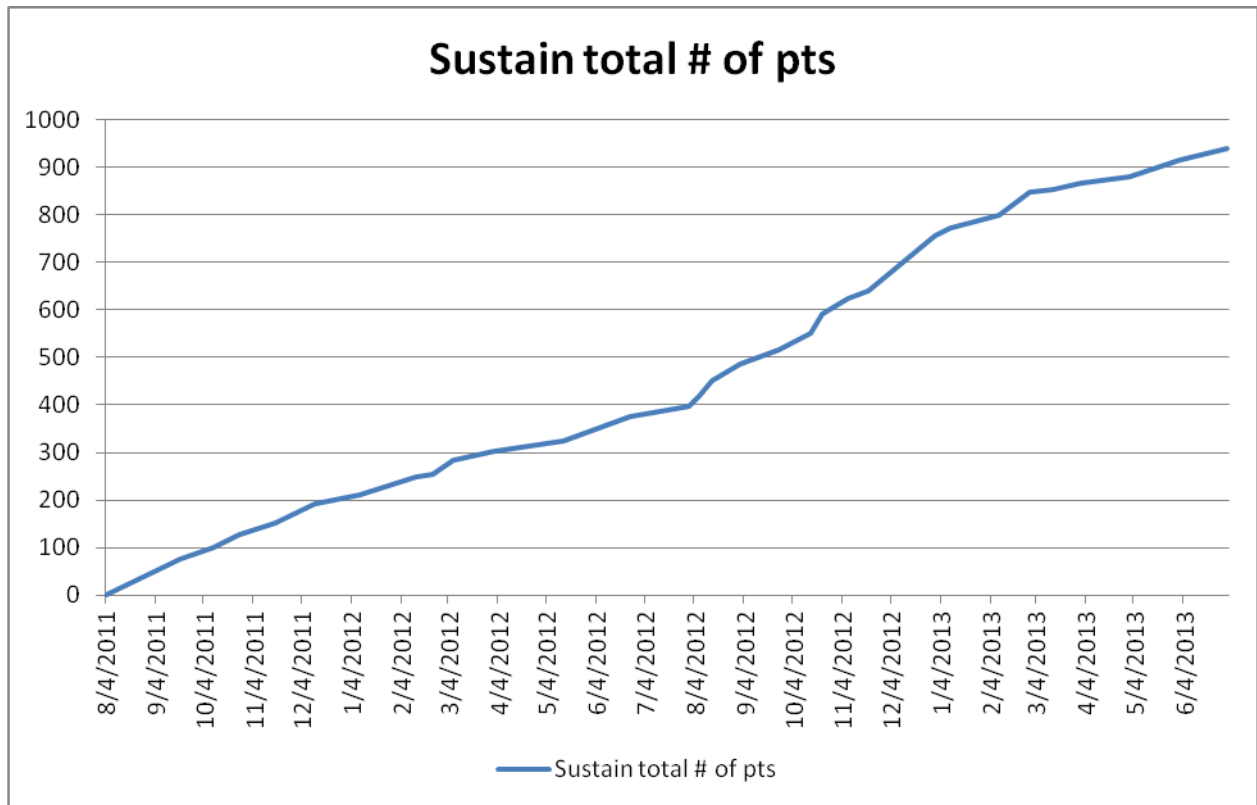
The purpose of this report is to brief all Sustain stakeholders on the progress of the registry since its launch. It is also to raise awareness about Sustain and the HPN registry in general in order to help assist the Sustain Council leadership plan next steps for the program. We would appreciate any feedback and suggestions for improvement of this program.

Growth of Sustain

The Sustain Registry for Home Parenteral Nutrition (HPN) was launched in January 2011 and in August of this year, two years of patient data will have been collected. Growth in both the total number of patients enrolled, and the total number of active data entry sites has almost tripled in the past year. (See graphs below) Thus far, 61 medical centers, hospitals, and home infusion providers have enrolled, 33 sites have completed the IRB and approval process and are considered active, with more than 952 patients entered. At least half of the enrolled sites are pediatric programs. Many home infusion companies are now active and have already enrolled patients. More than 20 other interested sites including two national home infusion companies who have a large number of branches have expressed interest in Sustain and several are very close to becoming active sites.

Growth of Sustain 2011-2013





Approved Data Entry Sites

Sustain Sites as of 7/1/2013
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
Geisinger Medical Center
Indiana University Health Home Care
Intermountain Medical Center
Le Bonheur Children's Hospital

Mayo Clinic
Nationwide Children's Hospital
Pediatric Home Service
Rady Children's Hospital
Rhode Island Hospital and Hasbro Childrens
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 George Washington University Hospital
ThriveRx
University of Chicago
University of Michigan
University of Virginia Health System

Sustain Governance

The Sustain Registry is overseen by the Executive, Scientific and Operations Advisory Councils. The Executive Council is mainly responsible for high level strategy and direction of the Sustain Registry. Responsibilities of the Scientific Advisory Council include reviewing the data collection tools, annual reports, IRB templates, quality improvement/benchmarking reports, scientific queries, research proposal reviews, and publications. The Operations Advisory Council has responsibility for ongoing site recruitment, ensuring data quality and integrity, statistical infrastructure, and user satisfaction.

Current Sustain Advisory Council Members for 2013-2014

Executive Council	Scientific Council	Operations Council
Larry Robinson, BS, MS, PharmD	Marion Winkler, PhD, RD	Lillian Harvey-Banchik, MD
Lillian Harvey-Banchik, MD	Ezra Steiger, MD	Carol Ireton-Jones, PhD, RD
Carol Ireton-Jones, PhD, RD	Janet P. Baxter, MPhil, SRD, RN	Karen Ackerman, MS, RD, LDN, CNSD
Ezra Steiger, MD	Beth Carter, MD	Stephen Adams, MS, RPh, BCNSP
Marion Winkler, PhD, RD	Rose Ann DiMaria, PhD, RN	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
	Rex Speerhas, RPh	Katherine Phillips, RD, MPH, CLE
		Ross Taylor, MD, CNSP

Scientific Issues

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

Institutional Review Board Approval

In order to meet the requirements to participate in a research registry, sites must submit a research protocol and receive approval from their Institutional Review Board (IRB). The New England Institutional Review Board (NEIRB) granted reapproval of Sustain in March 2013. Sites that do not have local IRBs are covered by the NEIRB. Only 6 of sites have required IRB coverage under this central IRB mechanism.

Of the 33 active sites, 52% have been granted a waiver of consent from their IRB, while 48% are required to obtain written informed consent. Some sites require both written informed consent and child assent.

Sustain users providing feedback suggested that gaining IRB approval and re-approval can be challenging and has delayed their participation in the registry. In response to this concern, an IRB template is being developed and Frequently Asked Questions (FAQs) on the Sustain website will provide additional support. The NEIRB approval letter is also posted on the website for easy access.

Sustain Data and Benchmarking Reports

In April 2012, the first cross-sectional benchmarking report was prepared and distributed to active sites. This report compares individual site data with aggregate data from the entire Sustain population. Currently, all active enrolling sites receive quarterly cross-sectional and longitudinal reports. These sites gain valuable information about their patient population and how they compare to the aggregate population on such elements as patient demographics, catheter infection rates, and re-hospitalization rates. Sites are encouraged to provide feedback and suggestions to improve the reporting process.

Publications

To date, the following abstracts and manuscripts have been published:

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

Sept. 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

Sept. 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.

Jan. 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, CNSC, Clinical Nutrition Week 2012 Orlando, FL

Jan. 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.

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

Scientific Query and Publications

Scientific research and analysis using Sustain registry data is encouraged. Policies, procedures, and project guidelines were published in January 2013, ([Sustain Registry Scientific Query Protocol](#)) so participating sites and investigators who are interested in answering scientific questions using Sustain registry data have clear instructions and guidelines.

A [Sustain Publication Guidelines](#) was also developed and released in December 2012. This document explains how sites can utilize their own and aggregate data for benchmarking and research purposes.

Operational Issues

Site Recruitment and Promotional Activities

Promotional efforts to raise awareness of the Sustain registry and to recruit new sites continue. These activities include: 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 tenet for the Sustain registry is patient confidentiality and data integrity. Since the launch of Sustain and throughout the first 2 years of operation there have been no reported concerns or data breaches from the site users, Sustain administrators, or vendor.

Fundraising and Supporters

The Sustain Registry is supported by grants from the C.R. Bard Foundation, Inc; Baxter Healthcare Corporation; and the A.S.P.E.N. Rhoads Research Foundation. Additional funding and support is actively being sought.



Future Plans

Data Collection Elements

Open communication between site users and Sustain Council leadership and staff has been established and maintained. During the 2012 and 2013 Clinical Nutrition Week meetings, a users' group was held to provide a forum for discussion and feedback. As a result of surveys, direct communication with users and council members, the need to modify data entry to improve the data collection and analysis was identified.

All current data collection elements are being reviewed by the Scientific Advisory Council to determine if modifications would help improve data entry and therefore, the quality of the data collection. In addition, a detailed analysis of missing data elements was undertaken. As a result of this evaluation, critical elements have been identified and data collection will be streamlined. An additional goal is to clarify data elements and reduce time spent on data entry.

Recruitment and Marketing Efforts

A revised marketing and promotion plan is being developed to continue to raise awareness of the Sustain HPN registry and to encourage participation.

The Sustain leadership is exploring the possibility of creating some means to extract data from proprietary computer operating systems used by some major sites in order to facilitate the entry of data. Termed a "data bridge," such a device could take on the form as simple as a program that would extract data from one operating system's database into a spreadsheet format to facilitate entry of data in batch form into the Sustain Registry database. If such a project were targeted to collect critical data elements from a system to input into Sustain, it is felt that data entry for some potential participating programs could be simplified and encourage participation.

Questions and Comments

Any questions on this report or about Sustain can be directed to Katy Hanley, Sustain Registry Coordinator, by email, katyh@aspen.nutr.org, or phone, 301-920-9133.