

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

Sustain Newsline

Volume 1, Issue 3 December 2012

Update on Sustain

Sustain[™] continues to offer an unprecedented opportunity for organizations to help collect valuable data about consumers who are on HPN. The information entered into the registry will ultimately improve patient outcomes. Thus far, **52** medical centers, hospitals, and home infusion agencies have enrolled; **22** are approved, trained and entering data, with more than **653** patients entered. We have dozens of other sites including national home infusion companies with a large number of branches that are interested in participating.

In September 2012, participating sites received a crosssectional report along with the first longitudinal report. The Sustain reports were distributed to all sites actively entering patient information. These sites gained valuable information about their patient population compared to the aggregate patient group.

To learn more or to get your organization involved, please visit the <u>Sustain website</u>.

Peggi Guenter, PhD, RN Senior Director, Clinical Practice, Advocacy, and Research Affairs, A.S.P.E.N., peggig@aspen.nutr.org



Sustain at CNW 2013

Join us at Clinical Nutrition Week 2013 (CNW13) in Phoenix and participate in the following events to learn more about Sustain!

Sustain Users and Prospective Users Interactive Session

Monday, February 11th, 9:30 – 10:30 am

Come walk through the Sustain data collection site with experienced users, view data reports and get your questions answered about how you can get your HPN patients into this registry.

Home Parenteral Nutrition Patient Registries: an International Perspective (M31)

Monday, February 11th, 2:00 - 3:30 pm

- Sustain: A.S.P.E.N.'s National Patient Registry for Nutrition Care: The First Year Data Analysis presented by Dr. Ezra Steiger.
- The Canadian Home TPN Registry: 5 Year Nutritional Outcomes, Complications and Mean Survival presented by Dr. Johane Allard
- Home Parenteral Nutrition: An International Benchmarking Exercise presented by Dr.Janet Baxter.
- Moderated by Dr. Marion Winkler.

Live Demo Sessions:

There will be a demonstration area near registration where you will have a hands-on opportunity to try out the Sustain database system. Dates and times:

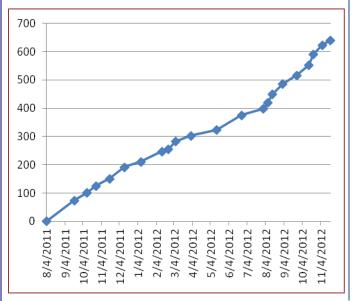
Sunday, February 10 9:45 - 10:45 am 3:30 - 4:30 pm Monday, February 11 10:45 - 11:45 am 3:30 - 4:30 pm Tuesday, February 12 9:45 - 10:45 am

Sites Participating in Sustain

Sustain is proud to announce that the following institutions have completed the approval process are now official sites!

- Arnold Palmer Medical Center for Children
- CarePoint Partners Dallas
- CarePoint Partners Providence
- CarePoint Partners Tampa
- Children's Hospital Boston
- Children's Hospital of Michigan
- Children's Hospital of Orange County (CHOC)
- Children's Mercy Hospital
- Cleveland Clinic
- Connecticut Children's Medical Center
- Equinox Healthcare, Inc.
- Mayo Clinic Jacksonville
- Nationwide Children's Hospital
- Pediatric Home Service
- Rhode Island Hospital & Hasbro Children's
- 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

Number of Enrolled Patients



CNW13 in Phoenix, Arizona



Plan on attending Clinical Nutrition Week 2013, held February 9 – 12, 2013, in Phoenix, Arizona. There will be a session on HPN registries.

CNW13 is the premier conference on clinical nutrition and metabolism! Gain vast insight into evidence-based research and practical applications that will impact how you care for your patients every day. Register today!

No Time To Enter Patient Info?



We know that your time is precious....Here are some creative ways to deal with entering patient information when staff time is limited.

Some sites have printed out the data collection forms, completed the paper forms and then enlist the help of clerical

staff to do the data entry.

Some sites have tapped into other resources to help enter the patient data, such as:

- Medical Students
- Fellows
- Pharmacy Students
- Dietetic Interns

Another Time Saver - Critical Elements

Now Only 22 Questions to Answer for Each Patient

Look for the orange dots on the data collection forms which represent critical fields. These critical fields are the questions that we have identified as most important. The number the critical elements have been reduced; now just 22 questions that should be completed for each patient.

So if time is limited, and you are unable answer all questions on the patient forms, just complete the questions with the orange dot!

Not an Official Sustain Site?



User's Corner

In an effort to assist users and to have patient data entered more consistently, **Help Screens in the Registry** have been updated to provide additional clarification and information. Below is the list of updates for the patient forms.

Baseline Patient Information

Attending Physician's Name

If there are multiple providers caring for a patient, list whoever is signing the orders and following the patient for their GI issues and PN as the Attending Physician.

Discharging Institutions Name

For Discharging Institutions name, if an infant was born at Hospital X on PN, and now is being followed by Institution Y, the Discharging Institution is the patient's birth hospital, unless the patient is readmitted and discharged from Institution Y prior to entry into the Sustain Registry.

Date Home PN Began

- If patient is new to the registry and has been off and then back on HPN, the Date Home PN Began = most recent start date of HPN.
- If newborn is immediately put on PN, prior to discharge from the hospital, the Date Home PN Began = date of newborn's discharge.

Baseline Nutritional Status

Growth Charts

- · For children up to 2 years of age,
 - use the <u>2006 WHO charts</u> with supine length measurement, as population standard against which individual growth and nutritional characteristics should be described
- For children aged 2 20 years,

..... use the <u>CDC 2000 charts</u> with a standing height measurement used for plotting.

Healthcare centers may utilize their electronic health records (EHR) systems to develop an efficient system of documenting and plotting serial measurements against the reference or standard curves

Baseline PN Formula/Medication/Nutrient Intake

Medications Put the drugs below into these catagories

ANTICOAGULANTS in CARDIOVASCULAR DRUGS

ENOXAPARIN, HEPARIN, WARFARIN

SYMPATHOMIMETIC (ADRENERGIC) AGENTS in

ANTICHOLINERGIC AGENTS

ALBUTEROL, ALBUTEROL/IPRATROPIUM, EPINEPHRINE, FLUTICASONE/SALMETEROL, PSEUDOEPHEDRINE HCL

TNF Alpha Inhibitors in Anti-Inflammatory Classification Adalimumab, Etanercept

Catheter Information

Who is changing dressings? – Choices are patient, caregiver, both or visiting nurse.
 Visiting Nurse = person who has received medical training; not a lay person. Dressing change can be made at home or at the clinic.

 Date of Insertion = date of most recent line that is currently in the patient, not the date of insertion for the original line.

Follow-up General Information

Date of Form

After selecting the type of follow-up, enter the Date of Form. Date of Form = Date of Visit

Follow-up Current Nutritional Status

All New Diagnoses

Check only new diagnoses on this form. Previous diagnoses that are already indicated by ***, do not need to be checked again.

Follow-up Patient Hospitalized

Morbity Section Date of hospitalization = date of admission

Follow-up Patient Discontinues Therapy

Current PN Formula

If a patient discontinues therapy for more than a few days, please select the follow up form type – **Patient Discontinues PN Therapy**. Enter date of discontinuation and reason for the discontinuation. Also, add information in the Food and Diet Section; such as type of diet, and percent of calories. Please also add patient's height and current weight in the Current Nutritional Status Section.

Then if the patient is put back on HPN at a later date, a follow up visit – Follow Up **Patient Restart** needs to be entered. Please go into the Patient Information Form within the Follow Up Patient Restart and update the date HPN began with the restart date.

Follow-up Morbidity Form

Catheter Infection Definition

If the patient has a catheter infection- please be sure you are using the following CDC definitions:

Catheter-related bloodstream infection (CRBSI) and central line-associated bloodstream infection (CLABSI) are often used interchangeably even though the meanings differ. CRBSI is a clinical definition, used when diagnosing and treating patients, that requires specific laboratory testing that more thoroughly identifies the catheter as the source of the BSI. It is not typically used for surveillance purposes. It is often problematic to precisely establish if a BSI is a CRBSI due to the clinical needs of the patient (the catheter is not always pulled), limited availability of microbiologic methods (many labs do not use quantitative blood cultures or differential time to positivity), and procedural compliance by direct care personnel (labeling must be accurate). Simpler definitions are often used for surveillance purposes. For example, CLABSI is a term used by CDC's National Healthcare Safety Network (NHSN) (visit NHSN CLABSI information) [206]. A CLABSI is a primary BSI in a patient that had a central line within the 48-hour period before the development of the BSI and is not bloodstream related to an infection at another site. However, since some BSIs are secondary to other sources other than the central line (e.g., pancreatitis, mucositis) that may not be easily recognized, the CLABSI surveillance definition may overestimate the true incidence of CRBSI.

CDC 2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections

Follow-up Patient Expires

Mortality Section

When one of your patients dies, make sure that you enter a date of death, or select date unknown, if you do not have this information, in the Mortality form, along with the reason the patient expired.

Infusion Features Sustain

Infusion Article:

Check out the feature article about Sustain published in the September-October 2012 issue of Infusion. the National Home Association Infusion journal. Collecting Patient Specific Data to Improve Health Care Outcomes Sustain A.S.P.E.N.'s Home Parenteral Nutrition Registry by Guenter, Ph.D., R.N.; Lawrence Robinson, B.S., M.S.,



Pharm.D.; Rose Ann DiMaria-Ghalili, Ph.D., R.N., CNSC; Beth Lyman, R.N., M.S.N., CNSC: Ezra Steiger, M.D.; and Marion F. Winkler, Ph.D., R.D., L.D.N., CNSC.

Infusion Magazine (Article access available to NHIA members and Infusion subscribers.)

New HPN Research

In order to keep you current on HPN research, this newsletter section will provide citations on the latest selected research in A.S.P.E.N. journals. Also look for the new information in oral presentation and posters coming out of CNW13.

HPN:

- Vitamin Serum Level Variations Between Cycles of Intermittent Parenteral Nutrition in Adult Patients With Short Bowel Syndrome. +lahel Manon de Lima Ferreira, Camila Bitu Moreno Braga, Nathalie de Lourdes Souza Dewulf, Julio Sérgio Marchini, and Selma Freire de Carvalho da Cunha JPEN J Parenter Enteral Nutr 0148607112441800. first published on March 27, 2012 as doi:10.1177/0148607112441800.
- Prevalence of Vitamin D Deficiency and Response to Oral Vtamin D Supplementation in Patients Receiving Home Parenteral Nutrition Puja R. Kumar, Tanis R. Fenton, Abdel A. Shaheen, and Maitrevi Raman JPEN J Parenter Enteral Nutr. 2012;36: 463-469.
- Anemia and Leukopenia in a Long-Term Parenteral Nutrition Patient During a Shortage of Parenteral Trace Element Products in the United States. Pornpoj Pramyothin, Dong Wook Kim, Lorraine S. Young, Sanit Wichansawakun, Caroline M. Apovian JPEN J Parenter Enteral Nutr 0148607112463942, first published on October 15, 2012 as doi:10.1177/0148607112463942 Full Text Full Text (PDF)
- Reversal of Parenteral Nutrition-Associated Liver Disease With a Fish Oil-Based Lipid Emulsion (Omegaven) in an Adult Dependent on Home Parenteral Nutrition David L. Burns and Brian M. Gill JPEN J Parenter Enteral Nutr 0148607112450301, first published on June 8, 2012 as doi:10.1177/0148607112450301 Full Text (PDF)

HPN Registries:

- Prescription of Trace Elements in Adults on Home Parenteral Nutrition: Current Practice Based on the Canadian Home Parenteral Nutrition Registry R. Abdalian, G. Fernandes, D. Duerksen, K. N. Jeejeebhoy, S. Whittaker, L. Gramlich, and J. P. Allard JPEN J Parenter Enteral Nutr 0148607112463074, first published on October 12, 2012 as
 - doi:10.1177/0148607112463074 Full Text Full Text (PDF)



- Canadian Home Parenteral Nutrition (HPN) Registry: Validation and Patient Outcomes G. Fernandes, B. Kaila, K. N. Jeejeebhoy, L. Gramlich, D. Armstrong, and J. P. Allard JPEN J Parenter Enteral Nutr 2012;36: 407-414.
- Development of Sustain™: A.S.P.E.N.' s National Patient Registry for Nutrition Care Peggi Guenter, Lawrence Robinson, Rose Ann DiMaria-Ghalili, Beth Lyman, Ezra Steiger, and Marion F. Winkler JPEN J Parenter Enteral Nutr 2012:36 399-406.
- The Canadian Home Total Parenteral Nutrition (HTPN) Registry: Vitamin K Supplementation and Bone Mineral Density Badr Aljarallah, Gail Fernandes, Khursheed N. Jeejeebhoy, Leah M. Gramlich, J. S. Whittaker, David Armstrong, Don R. Duerksen, and Johane P. Allard JPEN J Parenter Enteral Nutr 2012;36: 415-420.

Catheter Related Research:

- Hospital Readmissions for Catheter-Related Bloodstream Infection and Use of Ethanol Lock Therapy: Comparison of Patients Receiving Parenteral Nutrition or Intravenous Fluids in the Home vs a Skilled Nursing Facility Mandy L. Corrigan, Cassandra Pogatschnik, Denise Konrad, and Donald F. Kirby JPEN J Parenter Enteral Nutr 0148607112448400. first published on May 29, 2012 as
 - doi:10.1177/0148607112448400 Full Text (PDF)



- Role of Peripherally Inserted Central Catheters in Home Parenteral Nutrition: A 5-Year Prospective Study Jose I. Botella-Carretero, Carmen Carrero, Eva Guerra, Beatriz Valbuena, Francisco Arrieta, Alfonso Calañas, Isabel Zamarrón, Jose A. Balsa, and Clotilde Vázguez JPEN J Parenter Enteral Nutr 0148607112457422, first published on August 16, 2012 as doi:10.1177/0148607112457422 Full Text (PDF)
- Catheter-Related Complications in Cancer Patients on Home Parenteral Nutrition: A Prospective Study of Over 51,000 Catheter Days. Paolo Cotogni, Mauro Pittiruti, Cristina Barbero, Taira Monge, Augusta Palmo, and Daniela Boggio Bertinet JPEN J Parenter Enteral Nutr 0148607112460552, first published on September 20, 2012 as doi:10.1177/0148607112460552 Full Text Full Text (PDF)
- Central Venous Catheter Thrombosis Associated With 70% Ethanol Locks in Pediatric Intestinal Failure Patients on Home Parenteral Nutrition: A Case Series Theodoric Wong, Vanessa Clifford, Zoë McCallum, et al. JPEN J Parenter Enteral Nutr. May 2012:36: 358-360.
- Prophylactic Anticoagulation Decreases Catheter-Related Thrombosis and Occlusion in Children With Home Parenteral Nutrition I. L. Vegting, M. M. Tabbers, M. A. Benninga, J. C. Wilde, M. J. Serlie, T. A. Tas, C. F. Jonkers, and C. H. van Ommen JPEN J Parenter Enteral Nutr 2012;36:456-462.

- Impact of a National Shortage of Sterile Ethanol on a Home Parenteral Nutrition Practice: A Case Series Mandy Corrigan and Donald F. Kirby JPEN J Parenter Enteral Nutr 2012;36: 476-480.
- Ethanol Lock Therapy in Reducing Catheter-Related Bloodstream Infections in Adult Home Parenteral Nutrition Patients: Results of a Retrospective Study. Bijo K. John, Magsood A. Khan, Rex Speerhas, Kristen Rhoda, Cindy Hamilton, Robert DeChicco, Rocio Lopez, Ezra Steiger, and Donald F. Kirby JPEN J Parenter Enteral

Nutr.2012;36:603-610. Full Text Full Text (PDF)



Home Parenteral Nutrition Tutorial

Home Parenteral Nutrition Tutorial Donald F. Kirby, Mandy L. Corrigan, Rex A. Speerhas, Dorothy M. Emery. JPEN J Parenter Enteral Nutr.2012;36:632-644. Full Text Full Text (PDF)

ENROLLMENT AND APPROVAL TIPS:

Participation in Sustain is easy! Follow these simple steps:

Steps to Become an Official Site:

- 1. Enroll: Complete and submit the enrollment form.
- Obtain approval to participate from your IRB. Submit the IRB protocol, informed consent and/or waiver of informed consent to your IRB. Once you receive IRB approval, please send us a copy of your approval letter.
 - Participation Agreement (pdf) (word)
 - IRB Protocol (pdf) (word)
 - Patient Informed Consent (pdf) (word)
 - Waiver of Informed Consent (pdf) (word)

Blank Data Collection Forms can be used in conjunction with the IRB submission.

- Baseline (adult-.pdf) (pediatric-.pdf)
- Follow-up (adult-.pdf) (pediatric-.pdf)
- Complete and submit your Participation Agreement
 - Participation Agreement (pdf) (word)
- 4. Send all forms to: Katy Hanley, Sustain Registry Coordinator, A.S.P.E.N., 8630 Fenton St., Suite 412, Silver Spring, MD 20910 katyh@aspen.nutr.org

Watch the Sustain Demonstration



Just 4 minutes long. See how user-friendly the system is!

Sustain Councils

Sustain Advisory Councils as of December 1, 2012. Thank you to the councils for their continued support, expertise and guidance.

Executive Council

Lawrence Robinson, Chair Mary Hise Carol Ireton-Jones Beth Lyman Michael Medwar Alan Parver Ezra Steiger Marion Winkler

Scientific Advisory Council

Ezra Steiger, Co-Chair Marion Winkler, Co-Chair Janet P. Baxter **Beth Carter** Rose Ann DiMaria-Ghalili Darlene Kelly Jessica Monczka Marianne Opilla Rex Speerhas

Operations Advisory Council

Carol Ireton-Jones, Co-Chair Beth Lyman, Co-Chair Stephen Adams Mandy Corrigan **Sharon Durfee** Lillian Harvey Banchik Ross Taylor

Funding Sustain

A.S.P.E.N. would like to express our sincere thanks to the following organizations for their support of Sustain.





We are continually seeking additional sponsorship for this important project, so please contact Cheretta Clerkley at A.S.P.E.N. cherettac@aspen.nutr.org, if your organization would like to support Sustain.

ASPEN Publications Guidelines

BASED ON THE FOLLOWING SECTION OF THE SUSTAIN PARTICIPATION AND DATA USE AGREEMENT, THE SUSTAIN SCIENTIFIC COUNCIL HAS DEVELOPED GUIDELINES REGARDING THE USE OF THE DATA FROM THE BENCHMARKING REPORTS.

<u>Use of Benchmarking Reports</u>. Participant agrees to comply with all publishing or use guidelines established by Sustain from time to time regarding permitted uses and disclosures of Benchmarking Reports. In general, Participant shall only use reports for appropriate internal and external purposes in a manner that is accurate and not misleading.

Guidelines on Use of Sustain Data

Sustain Participants and Participating Sites engage in the process of collecting Sustain data and utilization of registry-derived information for the purpose of local and national improvement in the quality of Home PN care. This Guideline provides information on the specific and accepted professional use of this data and registry-derived information from Sustain.

1. Participant use of their own site's data

The participating site will be able use your own site's data in any way that your site wants including publication of such data.

2. Participant use of the Sustain benchmarking data

The benchmarking data is the site's data as compared to the aggregate Sustain data. Any information from the benchmarking report can be used internally for quality assurance and educational purposes. Such internal utilization may satisfy institution quality assurance requirements such as mortality and morbidity review and confidential service conference discussions. Process improvement within an institution may be monitored for continuous quality improvement impact, using the data and outcomes as reported for and by the Sustain Registry. The benchmarking reports and any data contained therein cannot be disclosed outside of the Participant for any reason, including but not limited to, for marketing or to promote the site's program as compared to others. Participant is prohibited from publishing the benchmarking reports. Data contained within the benchmarking reports cannot be used for publication or research unless all requirements set forth in #3 below in this document are met.

3. Use of Sustain benchmarking and aggregate data for research purposes

Individual Participant-specific site data and aggregate data may be used for clinical research by that Participant if reviewed and approved by the Sustain Scientific Council for scientific merit and ethical propriety. Clinical research on aggregated national data may be used to produce one or more of the following forms for reporting and dissemination of information: abstract, scientific meeting presentation, or manuscript for publication in the medical literature under the following conditions:

- 1. Participants can only publish aggregate data after permission is received by the Sustain Scientific Council.
- 2. Any abstract, scientific meeting presentation, or manuscript for publication in the literature must have the "Sustain" name in the title or text or presentation materials.
- 3. Any scientific meeting presentation, or manuscript for publication in the literature must acknowledge the "Sustain" funding support using the following language:

Sustain is supported, in part, by unrestricted scientific grants from Baxter Healthcare Corporation and the A.S.P.E.N. Rhoads Research Foundation.

Note: Check the Sustain website periodically for additional supporters and include those as well.

Process for Obtaining Permission to Publish

Participants may submit requests to Sustain for scientific queries using either the benchmarking reports provided or requiring access to raw **de-identified** patient data from the Sustain Registry. Request for permission should include a full research proposal. All such requests for data queries and publication permissions shall be subject to prior approval by the Sustain Scientific Council who shall give due consideration to scientific merit, the funds and other resources available to address queries and other pertinent factors. As a part of its efforts to promote the use of the Sustain Registry as a tool for the development of beneficial scientific information, Sustain will provide reasonable assistance to the Participant in refining Participant's requests for queries so as to enhance their potential for approval. Participant may be required to enter into an agreement regarding the use of the data.

The Sustain Scientific Advisory Committee retains the right to update this document on a periodic basis. Check the SUSTAIN website (www.nutritioncare.org/sustain) for the latest publication guidelines.

Adopted by the Sustain Executive Council Chairperson, November 2012

SUSTAIN QUESTIONS AND ANSWERS

Is there a fee to participate in Sustain? No. Unlike most studies and registries who charge organizations to participate, Sustain does not charge organizations to participate or to receive their quarterly data.

Do we have to obtain IRB approval, or is this optional/only need it if our organization requires it? If there is an Institutional Review Board (IRB) at your organization, you must get approval from them to participate. However, if you do not have an IRB, your organization would be covered by our independent IRB.

Our organization does not have an IRB. Can we still participate in Sustain? Yes. For those organizations that do not have an IRB, Sustain has been approved by an Independent Review Board and your organization can use this IRB approval.

Who will have access to the data? Site participants will have access to the data through system generated reports. The site and all data will be protected through a secure, password protected system. Site participants will receive benchmarking reports to compare their own results against aggregate results of all sites participating in the program.

How is confidentiality maintained? Patient information is deidentified. The site will keep a log of patient name, date of birth and Sustain patient number assigned by Sustain database either locked in an office or password protected. Sustain only tracks patients by their Sustain patient number.

What are the registry requirements? Do we need to purchase any special software? Sustain is web-based. Users only need to have access to an Internet connection and a current browser (Internet Explorer 7, Firefox, or Safari). No additional software is necessary. A password protected system will be accessed via the web and data stored by Sustain will be on a secure web server with access limited to those with a user ID and password.

How many people from one site can enter patient data into Sustain's on-line database?

Sustain allows 10 users from each site to enter patient data.

How much time is involved in enrolling a patient and then subsequently adding data? It takes approximately 15 minutes per patient to enter baseline info, possibly less. Follow-up visits should take less time since you are basically updating information and some information is auto-populated. We have

identified critical elements to cut down on data entry time. View Blank Data collection forms.

What kind of patients can be entered into Sustain?

Patients on Home Parenteral Nutrition, either newly discharged or existing on HPN can be entered into Sustain. We will include adult and pediatric patients. We will not include HPN patients in long-term care or rehabilitation facilities, nor will we accept patients on IDPN. Patients in the U.S. are now eligible and international sites will be accepted on a case by case basis.

With regard to the collection of follow-up information on the patients, for how long, and over what time intervals, will this be done?

We suggest that for new patients, follow-up visits should be entered monthly, or at a minimum, quarterly. Existing patients' follow up visits should be entered quarterly, or at a minimum, semi-annually, or when there is a significant clinician encounter or event.

How long the data will be kept by the registry? Indefinitely

Any data collected on co-morbidities/other diagnoses?

There is a lot of data collected on multiple diagnostic categories and co-morbidities – again please feel free to review the data collection sheets which have all of the diagnoses listed.

Complete List of Frequently Asked Questions

Feedback and Suggestions



Have any suggestions or comments? Send it our way; we value your feedback and insight to help improve Sustain.

Have a story to tell about your experiences with Sustain? You could be featured in the next issue of Sustain Newsline.

Send your suggestions, comments and feedback to sustain@aspen.nutr.org.