ILSI North America Low-Calorie Sweeteners Committee
Request for Proposals

Assessing the Effect of Medical Nutrition Therapy (MNT) that Includes Low-Calorie Sweeteners on Quality of Life Measures Using Family Patient Surveys
June 2020

The International Life Sciences Institute (ILSI) North America is a public, non-profit scientific foundation that advances the understanding and application of science related to the nutritional quality and safety of the food supply. The organization carries out its mission by catalyzing relevant research projects, professional education programs and workshops, seminars, and publications, as well as providing a neutral forum for government, academic, and industry scientists to address scientific issues of common concern for the well-being of the public. ILSI North America’s programs are supported primarily by its industry membership.

The ILSI North America Low-Calorie Sweeteners Committee seeks to improve and communicate the physiological, metabolic and cognitive/behavioral science of low-calorie sweeteners and the general understanding of their role in dietary management, as well as evaluate how the consumption of LCS can contribute to overall health and wellness.

ILSI North America adheres to strict procedures to maintain scientific integrity in all work we support. These requirements are described further in the attached TOP Guidelines and 8 Guiding Principles for Scientific Integrity addendums.

Background: Low calorie sweeteners (LCSs) have been acknowledged as a tool for lowering sugar intake in meal planning for diabetes management (ADA 2019). They may also help to improve Quality of Life (QoL), by enabling more satisfactory meals. Using LCSs in place of sugar allows more room in the diet for other sources of carbohydrate, such as whole grains, fruit, and vegetables, while satisfying desire for sweet taste. LCS in place of sugars also helps reduce total carbohydrate in the diet, helping to manage post-absorptive blood sugar levels. QoL is an important aspect in Medical Nutrition Therapy (MNT) for diabetes (Wit et al. 2020) as reduced QoL can negatively affect diabetes management (ADA 2009). Effective blood glucose control is also associated with better QoL in children with diabetes (Hoey et al. 2001), suggesting that decreased QoL may negatively impact successful diabetes management in children. As such, understanding the potential effect of MNT that includes use of a/any LCS on QoL in families that include a child with diabetes is important. This knowledge may also be useful to clinicians who generally field parents’ questions about the utility of LCSs, particularly when there has been increasing public misunderstanding of both their safety and utility.
A recent systematic review sponsored by the World Health Organization and designed to investigate the effects of LCS use for people with types I and II diabetes included health related QoL as an outcome measure. However, no data were identified in the peer-reviewed literature that met the inclusion-exclusion criteria specified. Authors concluded that data on this patient-important outcome were “scarce or lacking” (Lohner et al. 2020).

Links between diet and QoL have been studied previously, but links between use of LCSs and QoL have not been studied. A Food-Related Quality of Life validated survey has been created (Hughes et al. 2015). Although specific to IBD and IBS, this tool has been used to demonstrate that when food is a component of disease management, quality of life can be linked to food (Guadgnoli et al. 2019). Other QoL measures may be useful to employ as well, for example, the Pediatric Quality of Life Inventory that has been validated for use in children ages 2-18 years of age with either Type 1 or Type 2 diabetes (PedsQLTM) (Varni et al. 2003). Lohner et al. (2020) mentions the Audit of Diabetes-Dependent Quality of Life (ADDQoL) or 36-Item Short Form Health Survey (SF-36).

**Objective:** Assess the effect of Medical Nutrition Therapy (MNT) that includes the use of LCSs on Quality of Life (QoL) measures in families with children with newly diagnosed diabetes. The committee is open to a pilot study if a better fit for the funding parameters.

**Proposal Content:**
The Committee requests that applicants address each of the following components below. Note that any details outlined are suggestions only, and the committee is open to applicant recommendations.

1. **Background:** Please provide a short description of the project (you may use excerpts from the background provided above as appropriate).

2. **Research Approach:** Please provide your approach to the critical elements of the project as referenced above. This could include your recommendation for the survey instrument and justification, recommended study population size, other study design elements, etc.

To provide clarity on the committee’s thinking, the following parameters are proposed. However, the committee is open to the applicant’s suggestions.

A. **Participants:** Families with a child with newly diagnosed diabetes who is otherwise healthy
   I. Inclusion criteria:
      a. Children: propose ages 4-12 with a diagnosis of diabetes within the last 3 months
b. Not more than one previous session with a dietitian for Medical MNT advice

c. Families willing to include use of a LCS in family’s/child’s meal planning

II. Exclusion criteria:

Children: propose ages < 4 and > 12 (upper age limit to increase likelihood of a more homogeneous population with respect to lower potential for engrained dietary habits; lower age limit because of greater likelihood of increased difficulty in diabetes management with very young children, which could affect study participation)

B. Intervention:

I. Validated family patient survey conducted after 1, 3, and 6 months’ provision of MNT that allows use of a/any LCS. Lohner et al. (2020) mentions the Audit of Diabetes-Dependent Quality of Life (ADDQoL) or 36-Item Short Form Health Survey (SF-36).

II. For interested researchers, it may be beneficial to note information sources in the RFP that could be used to help families understand how LCSs can be successfully incorporated into recipes. The study could be done, however, with or without such aids. If utilized, it would be best to have such tools utilized by all participating dietitians.

C. Setting:

I. Study could be within a single center with a reasonably large juvenile diabetes patient base, or a multi-center study.

II. Dietitians/other involved HCPs must be willing to include the potential for use of a LCS in administering advice on diabetes meal-planning without negative bias.

III. Alternative approaches (e.g., online survey) could be an option given the ongoing COVID-19 epidemic.

3. Research Team: Please provide information on the team members that would be involved in the project as well as their specific roles and rationale for inclusion.

4. Anticipated Challenges: Describe likely challenges and means to address or mitigate.

5. Publication Plan: The Committee wishes the researchers to publish this work in a peer-reviewed journal. Please provide your suggested publication plan.

6. Investigator Credentials: Please describe the experiences that make you and your team a candidate for carrying out this project. Please attach one or two published papers in this area. In addition, the CV of the principal investigator(s) is required.

7. Resources: Please describe the resources available to you to allow completion of the project.
8. **Budget:** Please provide a budget summary indicating the allocation of the requested funds (including time and staffing per phase), as well as a corresponding timeline to project completion [milestones, paper(s) submitted for publication]. Please indicate which, if any, additional funding sources will be used for this project. Budgets within the range of $40K-$50K will be considered.
   a. Please note that ILSI North America limits overhead to 10% of project costs.
   b. ILSI North America will pay publication fees for open access directly.

9. **Timeline and Key Deliverables:** Minimally, deliverables should include:
   a. Presentation of results to committee in-person or by webinar
   b. Final manuscript submitted to peer-reviewed journal for publication

10. **Potential Conflicts of Interest:** List any potential conflicts of interests for all investigators, co-investigators, collaborators. We suggest using the Conflict of Interest Guidelines as set forth by the American Society for Nutrition: [https://nutrition.org/publications/guidelines-and-policies/conflict-of-interest/](https://nutrition.org/publications/guidelines-and-policies/conflict-of-interest/)

**Page Limit**
The committee is requesting a proposal of no more than *five pages* in response to the above outlined questions.

**Deadline**
Proposal must be received by 12:00 am ET on Friday, August 14, 2020.

**Submission Instructions**
Submit by email to Marie Latulippe at mlatulippe@ilsi.org and cc Char Myers at cmyers@ilsi.org. Questions may also be directed to Marie Latulippe at 202-659-0074 ext. 151.

**Proposal Review Process**
The Committee, which is composed of industry, government, and academic scientists, will review proposals and select the grantee. It is possible that the committee will require responses to supplemental questions before a final decision is made. Only projects meeting minimum requested criteria are considered. Proposals are evaluated based on:

- Demonstrated expertise of the research team
- Understanding of the research question and relevant nuances
- Clarity of proposed approach
- Demonstrated validity of the proposed approach (e.g., application of a previously validated/published method or references that have used this method)
- Timeline and budget aligned with committee resources
References


Addendum
Adoption of the Center of Open Science’s Transparency and Openness Promotion Guidelines
by ILSI North America

Background:
The Center for Open Science's Transparency and Openness Promotion (TOP) Guidelines provide actionable steps for institutions to practice and promote transparent, reproducible, and rigorous research. ILSI North America is a TOP Guidelines signatory. By becoming a signatory, ILSI North America is supporting the principles expressed in the guidelines through their implementation by its funded researchers. The TOP Guidelines include eight modular standards for promoting transparent, reproducible, and rigorous research, each with three levels of increasing stringency. Beginning July 1, 2018, all new research studies moving forward will strive to adhere to the levels of the TOP Guidelines specified below, recognizing that this process will take time and effort to achieve.

TOP Guidelines:
1. **Data Citation Standards (Level 3):** Cite shared data. Don’t publish until it is appropriately cited.
2. **Data Transparency (Level 2):** Data must be shared to the maximal extent allowed by ethical and legal constraints.
3. **Analytic Methods (Code) Transparency (Level 2):** Analytic methods (code) must be shared to the maximal extent allowed by ethical and legal constraints.
4. **Research Materials Transparency Level 2):** Materials must be shared to the maximal extent allowed by ethical and legal constraints.
5. **Design and Analysis Transparency (Level 2):** The researcher must use reporting guidelines when writing up publications. Equator-network website provides a huge choice of standards for research designs. [http://www.equator-network.org/](http://www.equator-network.org/) The researcher is asked to select one and register the standard you have selected.
6. **Study Preregistration (Level 2):** When the researcher preregisters his/her study in an independent, institutional registry (e.g., [http://osf.io/](http://osf.io/), [https://www.crd.york.ac.uk/prospero/](https://www.crd.york.ac.uk/prospero/), [http://clinicaltrials.gov/](http://clinicaltrials.gov/)), which is encouraged but not required, ILSI North America will request a third party (e.g., Center for Open Science) verify that preregistration adheres to the specifications for preregistration before data collection.
7. **Analysis Plan Preregistration (Level 2):** When the researcher preregisters his/her study analysis plan in an independent, institutional registry (e.g., [http://osf.io/](http://osf.io/), [https://www.crd.york.ac.uk/prospero/](https://www.crd.york.ac.uk/prospero/), [http://clinicaltrials.gov/](http://clinicaltrials.gov/)), which is encouraged but not required, ILSI North America will request a third party (e.g., Center for Open Science) verify for adherence to preregistered plan (deviations must be transparently reported) before data collection.
8. **Replication (Level 1):** ILSI North America will occasionally put out a call for replication studies as part of our RFP process.

Learn more about ILSI North America's implementation of the TOP Guidelines [here](#).
Background:
The scientific process requires open, transparent examination and honest interpretation of
data, regardless of a researcher’s affiliation or source of funding. To address the potential
influence of funding source on scientific research, ILSI North America developed 8 Guiding
Principles for Funding of Food Science and Nutrition Research.1 These guidelines were
specifically designed to protect the integrity and credibility of the scientific record. All projects
supported by ILSI North America must adhere to these principles.

Guiding Principles for Funding Food Science and Nutrition Research:
In the conduct of public/private research relations, all relevant parties shall:
1. Conduct or sponsor research that is factual, transparent, and designed objectively, and,
   according to accepted principles of scientific inquiry, the research design will generate
   an appropriately phrased hypothesis and the research will answer the appropriate
   questions, rather than favor a particular outcome;
2. Require control of both study design and research itself to remain with scientific
   investigators;
3. Not offer or accept remuneration geared to the outcome of a research project;
4. Ensure, before the commencement of studies, that there is a written agreement that
   the investigative team has the freedom and obligation to attempt to publish the findings
   within some specified time frame;
5. Require, in publications and conference presentations, full signed disclosure of all
   financial interests;
6. Not participate in undisclosed paid authorship arrangements in industry-sponsored
   publications or presentations;
7. Guarantee accessibility to all data and control of statistical analysis by investigators and
   appropriate auditors/reviewers;
8. Require that academic researchers, when they work in contract research organizations
   (CRO) or act as contract researchers, make clear statements of their affiliation; and
   require that such researchers publish only under the auspices of the CRO.

Learn more about ILSI North America’s 8 Guiding Principles for Funding Food Science and
Nutrition Research here.

Reference
1. Rowe S, et al., Funding food science and nutrition research: financial conflicts and