Last summer I had the opportunity to attend a two-day, intensive, introductory training session on how to manage a clinical trial. The seminar was offered by the Institute of Translational Health Sciences (ITHS) in Seattle, WA, and was supported by grants from the National Institutes of Health (NIH) National Center for Advancing Translational Sciences. The ITHS at the University of Washington is one of 50 Clinical and Translational Science Award sites across the country aimed at transforming how biomedical research and training are conducted. It serves as the hub for the Pacific Northwest region (Washington, Wyoming, Alaska, Montana, and Idaho).

Participants—both staff and faculty—hailed from a range of professions and disciplines. Though the information was not presented from an RDN’s perspective, the following list of ten lessons learned is offered through the lens of a dietitian.

**Lesson 1: Research Differs from Clinical Care**

Research is diligent and systematic inquiry, designed to find and enhance understanding, test theories, and evaluate new interventions with the goal of improving health outcomes. Researchers follow a plan, gather reliable data to draw conclusions, and aggregate those conclusions. Their focus is on the application of study findings to populations.

Clinical dietitians employ practice guidelines, scientific literature findings, work experience, and patient beliefs and values when selecting appropriate nutrition interventions for patient and client...
Continued on page 3
Lesson 3: It’s All About Project Management

Throughout the seminar, almost every presenter emphasized the importance of good project management. They suggested viewing a clinical trial as a small business, creating a clearly written management plan, and assigning a skillful project manager to implement that plan.

The project manager must be able to continuously negotiate the triple constraints of project management: budget, scope, and timeline. The project management triangle (see above) is a schematic that depicts the challenges of finding that optimal balance. During the trial, project managers monitor the budget closely, identify root causes of variance, and address any precipitating concerns.

Low Cost
High Quality
SLOW

High Quality
Quick
COSTLY

COST
TIME

LOW QUALITY

Project Management Triangle

Lesson 4: Rally a Team with Diverse Skill Sets

Clinical research typically involves a multidisciplinary, multi-professional team working together to help find answers to a research hypothesis. A diverse skill set is advantageous. Team members must embrace the reality that the team leader may not be the most senior person on the clinical trial team. A few tips were gleaned on effective team management:

- Make sure everyone on the team reads the protocol and considers everyone’s insights and ideas.
- Respect each team member’s expertise.
- Create team agreements and make the time to review them with all of the team members. Ideally, everyone is aware of how the team works.
- Encourage clear communication and address issues as they arise.
- Don’t start meetings at the top of the hour. For example, schedule meetings at 9:05 am vs. 9:00 am so that everyone has time to get there.

Lesson 5: Make Sure Your Budget Aligns with Your Protocol

Clinical trial budgets are never perfect; however, if you take the time to “process map” the specifics of the protocol to labor and other costs, you’ll come pretty darn close. Process mapping involves breaking each task into a detailed list of associated costs. Mapping helps make sure that your grant application captures both adequate labor funds for additional costs. For example, if you are working with a diverse population, you may need to include funds for document translation. Or you may need to add both labor and software costs for statistical analysis tasks. If overhead is allowed, be sure to include those costs, too. It is also important to prepare for shortfalls.

8. Respect for participants and communities: Ethical requirements of research go beyond simply signing a consent form. The research protocol and research team must protect patient confidentiality, preserve participants’ right to withdraw, create a plan for monitoring with includes stopping and compensation for injury.

The bottom line: If you want to conduct a clinical trial and do not have any experience/training in project management:

- Find an experienced clinical trial project manager.
- Look for opportunities to develop project management skills before serving in that role.
- Take training courses in project management to prepare yourself to manage a clinical research project.
- Identify a mentor who can help guide you on the myriad of clinical trial management tasks.
Before you submit your budget, ask:

- Are the scientific value and ethical quality of the study acceptable?
- Would I enroll my family member?
- Is there access to an adequate participant pool?
- Will the budget support the work as described?

If any of the answers to these four questions are “no” then go back and rethink your protocol. After making adjustments to your protocol, ask yourself these questions again.

During the startup process of the clinical trial, there is a long and sometimes frustrating period of negotiations. This typically involves both the funder’s and your institution’s contracts, finance, clinical operations, and regulatory affairs. Stay engaged in these negotiations and ensure elements of the protocol designed to evaluate primary outcomes are not jeopardized during this negotiation process. Though at times trying, ultimately this is a positive process that helps to improve the rigor of the protocol (i.e., “waterproof” the trial).

Contract negotiations can delay the transfer of funds from the awarding organization to your institution. Be proactive and plan for a slow transfer of funds. With active project management, you can help to minimize variances in the budget. Management approaches vary but require continual monitoring of the budget to identify deviations, determine root cause, and determine possible responses.

Lesson 6: Never Sacrifice the Final Outcomes of the Study in Order to Meet the Budget

Sometimes funders only provide a portion of the monies requested which may require adaptations to the protocol to match a less than optimal budget. If this happens, never sacrifice the final outcomes of the study to meet the budget. In other words, do not forgo elements that yield primary outcome data and never reduce the trial’s enrollment target such that the trial is no longer adequately powered. Instead, identify secondary outcomes that can be eliminated from the research study.

Lesson 7: Patient Enrollment is More Challenging than Expected

One theme that strongly resonated during the seminar was that patient enrollment is often more challenging than expected. Furthermore, it was noted that about one-third of participants do not complete clinical trials. Thus, it is not uncommon for recruitment and enrollment goals to be higher than the number needed to adequately power the study.

The reality of clinical research is that failure to meet enrollment goals may force researchers to cut out parts of the protocol. After dedicating a considerable amount of time to develop the protocol, deciding what you cannot live with can be difficult. The premise in Lesson 6 (above) was emphasized again:

- Do not change the primary endpoint of the study or reduce the number of participants enrolled.
- Do consider cutting out secondary endpoints, which may fall more into the “nice to know” vs. the “need to know” category.

Lesson 8: Expect the Unexpected

Recruitment struggles, staffing changes, unintentional organizational barriers, ethical violations, and budgetary snafus were some of the experiences shared by the speakers. These real-life examples emphasized the need to expect the unexpected. A lot can, and does, go wrong especially when conducting a multi-year study. Flexibility and a strong team are paramount as all of you brainstorm about how to best adjust course as needed.

Lesson 9: Publish Even if Your Findings are Unfavorable

The results of clinical trials are not always published. This means that we are losing the findings and insights gleaned from a considerable body of research. The U.S. Food and Drug Modernization Act of 1997 aimed to increase public access to the findings of clinical trial efforts; the National Institutes of Health developed, a website, clinicaltrials.gov, to comply with this legislation. This free, online database tracks clinical trials done in both the private and public sector. A 2016 New England Journal of Medicine study (Zarin), however, found that only 23,000 of the 224,000 studies registered with a website, clinicaltrials.gov, shared their findings. To help mitigate this discrepancy, in 2017 the National Institutes of Health mandated that all grantees who received funds must report trial results.

Continued on page 5
While preparing the grant application, think about ways to share your findings. Some probing questions to help identify dissemination channels are:

- Who would be interested in the trial?
- Who might care about the outcomes?
- How do you take the findings to the next translational effort?

On a side note: The RDPG welcomes contributions to The Digest about member research efforts. In addition, we encourage you to consider sharing your outcomes with both your state affiliate and the Academy. Is it your first time publishing? Contact the RDPG mentorship chair about finding a mentor to help you navigate the publication process.

Lesson 10: Make Time to Conduct a Post Mortem

At the end of the trial, take time for team reflection. Get everyone together and facilitate a candid discussion about what went well and what went wrong. A few tips for these reflective exercises:

- Get prepped before the meeting: What do you hope to get out of the meeting? Were there certain issues that you know emerged during the trial? How might you best present those scenarios to the group? Are there individuals that might find this exercise difficult, e.g., someone who is very sensitive about perceived criticism?
- Budget enough time but not too much time: You want plenty of time to go over the full experience. However, for multi-year trials, you may need to focus on key areas of the process/experience in order to keep the meeting time productive.

- Start by reviewing the goals and laying ground rules: Provide everyone with the agenda for the meeting. Go over basic rules of etiquette, e.g., not interrupting, not dominating the discussion, letting everyone have a chance to share their perspectives, etc.
- Get everyone’s buy-in: If someone has an issue about the goals and/or rules, give them time to be heard and address concerns as best as possible.
- Don’t make it personal: You don’t want one person to feel like they are being publicly criticized in front of peers and colleagues. To help depersonalize issues, focus on job titles versus names of individual team members.
- Be cautious about the meeting becoming a gripe session: A little bit of complaining is natural and can be helpful for some people; but, if allowed to go on for too long this can inhibit you from collecting a full list of lessons learned.

The Boot Camp was a worthwhile experience. I left eager to put this new knowledge into practice and highly recommend the training.

References

Institute of Translational Health Sciences. Introduction to Clinical Research Boot Camp 2019; July 30-31, 2019; Seattle, WA.

Recently, I’ve been thinking a lot about predatory journals and how to help Research DPG members and other RDNs avoid this aggressive web of fake scientific publishers. I first learned about this phenomenon via John Bohannon’s (2013) article, “Who’s Afraid of Peer Review?” If you missed this article, it’s a must-read. Predatory journals, pay-for-play scammers that publish manuscripts with disregard for the quality of the science and/or writing, emerged about five years before Bohannon wrote about his sting operation aimed at exposing this rapidly expanding global network.

Bohannon submitted an intentionally flawed paper to 304 open-access journals. The science in the paper was poor, and the authors and their institutional affiliations were fictitious. More than half of them accepted his manuscript. Of the 255 versions of the paper that went under review, the vast majority (60%) appeared to be published without peer review. Perhaps that was the reason for their rapid acceptance time (40 days on average). About 12% of the papers received legitimate concerns from reviewers; nearly all of those (82%) were published without addressing these comments.

Six years later, Alan Chambers (2019) wrote that the pressure to publish led him to trust an unsolicited offer from a new journal. The journal was not on Beall’s List, of Predatory Journals and Publishers, and a colleague was on its editorial board. After submitting his manuscript, Chambers rechecked Beall’s list, and the publisher’s name was now included. He also soon learned that, though listed on the journal website, his colleague was not on the editorial board. Chambers tried to stop the publication process by not paying the fee. Despite this, his paper appeared on the journal’s site. The publisher agreed to remove the article for a fee. Chambers refused to pay but continued to negotiate with the publisher. Though the journal eventually agreed to remove Chamber’s article, it remains on the journal’s website.

Beall’s List was one of the first blacklists of predatory journals. Though it is no longer active, an archive of the list remains accessible online. Other lists are also now available. Cabells Scholarly Analytics, for example, includes a blacklist of deceptive, fraudulent, and predatory journals for subscribers. Grudniewicz, et al. (2019) explore the challenges of keeping both blacklists and whitelists up-to-date and accurate. These authors suggest that researchers approach publishing with caution. They offer the following predatory journal red flags:

- **False or misleading information offered by the publisher.** Researchers must now take time to review publisher websites and fact-check impact factors, addresses, editorial board members, indexing services, etc.
- **Poor quality websites.** To optimize ROI, predatory journals minimize how much is spent on their website and the online journal platform. Typos and odd phrasing are common.
- **Alternative editorial and publication practices.** Legitimate publishers abide by industry best practices. For example, this includes a copyright transfer policy. One way predatory journals lure in victims is by promising that the author(s) will retain copyright.
- **Lack of transparency.** Predatory journals may be vague about the editorial and peer review processes as well as the fee structure.
- **Aggressive, indiscriminate solicitations.** Sometimes these are poorly written. Other times, they are well-written and may even flatter you by commenting on a previous article you published.

**My question for all of you...is there something that the RDPG could do to help address this challenge? Would it be helpful to create a section of the RDPG website that discusses what predatory journals are and include links to blacklists? Perhaps, we might also include predatory conferences? Would you find a webinar on the topic helpful? I appreciate your insights. Please email me at chair@rdpg.org with your thoughts.**

Sincerely,

Barb

**References**


### RDPG Budget for 2019-2020

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**Reserve as of January 31, 2020**

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Valisa Hedrick, PhD, RDN
Assistant Professor, Department of Human Nutrition, Foods, and Exercise, Virginia Tech

Research DPG Member Spotlight Questions

1. Please provide your full name, job title, and a brief description of your current position.

Valisa Hedrick, PhD, RDN
Assistant Professor, Department of Human Nutrition, Foods, and Exercise, Virginia Tech

My research is centered around the development and translation of dietary assessment methodology for the prevention and treatment of obesity and related comorbidities. I also teach Medical Nutrition Therapy 1 and 2 to undergraduate and graduate dietetics students.

2. Please provide a description of your background (e.g., academic, research, and anything else you want to tell us). How did you get to where you are now?

I began my academic studies with a focus in nutrition and dietetics at Virginia Tech in 2002, completing my undergraduate degree in 2006. I then successfully completed my dietetic internship with the university, earning my certification as a Registered Dietitian in 2007. Next, I obtained my Ph.D. in 2011 with a focus in clinical nutrition. My postdoctoral scholar position from 2012 to 2014 enabled me to expand my research into the areas of behavioral and community nutrition as well as further develop other skills such as statistical analysis, graduate student mentoring, and research management. These pursuits helped me to develop a comprehensive range of expertise enhancing my ability to conduct high impact translational research. I joined the faculty in the Department of Human Nutrition, Foods, and Exercise (HNFE) at Virginia Tech in August of 2014 where I was tasked to develop an independent and collaborative program of research in human clinical nutrition and to instruct undergraduate and graduate courses in clinical nutrition.

3. Please summarize your current research.

My specific research areas are focused on the quantification and dietary analysis of sugar-sweetened beverage (SSB) intake as well as the effects of SSB and artificially-sweetened or non-nutritive sweetened beverages on cardiovascular-related outcomes using subjective and objective dietary assessment methods within clinical-community based settings.

4. How did you become involved/interested in your current line of research?

This line of research originated during my doctoral work with the development of the Beverage Intake Questionnaire (BEVQ-15), a habitual beverage intake questionnaire. Due to the demand for the BEVQ-15 over the last eight years (214 requests for scoring instructions from 28 countries and 38 US states), the use of the BEVQ-15 has been center stage of my research. Efforts surrounding the BEVQ-15 include the validation of an updated version to reflect changes in beverage patterns over the past decade, the development of a method to use the BEVQ-15 to rapidly measure Healthy Beverage Index scores (HBI) which provide a measure of overall beverage intake quality, and the development of an online BEVQ-15 platform that will be available to researchers and clinicians around the world. Furthermore, the BEVQ-15 is currently used by the Virginia Supplemental Nutrition Assistance Program Education (SNAP-Ed) to measure beverage consumption at a population level.

5. What advice would you give to a young researcher for developing a successful line of research?

Research what you are passionate about! I find artificial sweeteners fascinating, especially the way so many studies group them together as one variable. The different chemical compounds and metabolic pathways that they all undergo are so varied that they could not have identical impacts on the body. Working towards clarifying these factors has been very rewarding for me. Also, find collaborators who you enjoy working with; these relationships will help your career progress and provide you with opportunities you never would have dreamed of happening.

6. What are your career goals?

I enjoy developing novel dietary assessment methods. Through this, I can reach my goals of providing useful tools to clinicians and researchers to help improve, monitor, and evaluate changes in dietary intake. Furthermore, related to mentoring, I am committed to training graduate level registered dietitians. With less than 5% of RDNs having a PhD, I

Continued on page 9
am working towards increasing this number because evidence-based RDN researchers are needed.

7. How has your affiliation with the Academy impacted your career progression?

My affiliation with the Academy has impacted my career in several ways. First, being able to present my research (and having my students present their research) at FNCE has allowed my work to become more visible, and I have been able to make many professional contacts. Secondly, serving on the Executive Committee for the Research DGP has also provided me with multiple collaborators, and friends, as well as the knowledge and skills to help improve my research capabilities.

8. If someone were to ask you to explain why research is important to the field of dietetics, what would you say?

Evidence-based practice. Research findings provide RDNs with the evidence-based tools to assess and treat clinical subjects and/or assess and plan for population interventions. I see how important this is every single day, completely independently of my research but rather through teaching medical nutrition therapy. Everything I talk about in class is available because of previous and ongoing research. This is what sets us apart from other nutrition professionals. We do not base our advice or practice on what we think works - we implement our interventions by using what we KNOW works because of research.

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Research DPG Student Spotlight

Abby Gillman  
Drexel University

1. Please list your research interests.

My main research interests are childhood obesity, school-based interventions, and parental involvement.

2. Please describe your path (i.e., education, work experience, etc.) that led you to pursue a degree in nutrition and/or nutrition research.

I received my undergraduate degree in Health & Exercise Science from Syracuse University. Thereafter, I became certified to Teach English as a Foreign Language (TEFL) in Prague, Czech Republic and taught English for a year. While abroad, I identified that my interests revolved around food, cooking, and science. This led me to pursue a master’s degree in Human Nutrition at Drexel University in Philadelphia, PA. While studying at Drexel, I also worked as a graduate assistant in the Center for Nutrition & Performance where I was first introduced to the research and programmatic work of several of my mentors at Drexel. As a graduate assistant, I provided evidence-based sports nutrition information to university students and staff and helped develop a weekly weight-maintenance program for faculty and staff. I then completed my dietetic intern-

3. What is the focus of your graduate work? Please describe one or two highlights of your research career thus far.

This past September, I defended my dissertation titled, “The Effect of a Multicomponent, School-based Obesity Intervention on the Health Outcomes and Behaviors of Children.” My focus is decreasing obesity in childhood through school-based interventions. This carries into my current post-doctoral work by providing SNAP-Ed nutrition education programming to SNAP-eligible participants in schools and community centers. I am further interested in developing and evaluating effective school-based interventions for children and their parents. I am also very interested in the connection between school-based interventions and worked as an inpatient dietitian. I returned to Drexel University as a project manager to oversee a multisite, multi-component, school-based childhood obesity intervention. This sparked my interest in research and led to the development of my research questions and the path toward my PhD.

Continued on page 10
and the home environment. Specifically, I am interested in discovering how to bridge the gap from programming directed to children in school to programming that involves families in the home and larger community.

4. What are your plans for the future (e.g., academia, government, and/or industry)?

My plans are still very much a work-in-progress. I am very interested in continuing my work in research, specifically with translating evidence-based recommendations into practical applications and evaluating such programs and interventions. However, I have also always enjoyed teaching and hope that it is a part of my future career path.

5. Do you have any advice or words of wisdom to share with students interested in the nutrition field?

My first bit of advice for a student would be to never say “no” to an opportunity. Make yourself present and available for professors or professionals in the field to call upon you to volunteer your time. You learn a tremendous amount by simply being present while also creating and building your network of connections. Secondly, let the path take you where it wants to go. Being open to new opportunities and career directions may open new doors that you didn’t even know existed. I never expected to pursue a PhD, let alone a career in research, but I was open to the possibilities that have taken me in a wonderful and exciting direction!

6. List any published work, if applicable.

Below is a sampling of my publications. I have two original manuscripts in development for publication in the next few months.

Published Review Articles:

Published Abstracts:

Published Book Chapters:
Cancer as a Metabolic Disease: Implications in Prevention and Treatment Strategies
Sarah B. McSpadden, MS
University of Southern California
mcspadde@usc.edu

Abstract
According to the World Health Organization, cancer is the second leading cause of death worldwide, with the economic burden estimated at over one trillion dollars in 2010. Despite ongoing research and advances made in cancer prevention and treatment, such as those within organizations like the American Cancer Society, cures remain elusive.

It is estimated that 30-50% of cancers can be prevented through lifestyle changes such as following a healthy diet and increasing physical activity, which are standard recommendations for the reduction of cancer risk. One treatment option gaining momentum is metabolic manipulation through dietary intervention. This strategy is utilized as an adjunct to increase the efficacy of current cancer therapies. Researchers in this area categorize cancer as a metabolic disease and capitalize on the cancer cell’s preference for glucose to promote the effectiveness of chemotherapy and radiation.

This review will focus on the theory of cancer as a metabolic disease with a discussion of how current treatment options can be optimized through diet to achieve metabolic manipulation. The review will also explore the link between metabolic disease and cancer, focusing on the role RDNs can play in cancer prevention through diet and lifestyle interventions.

Introduction
Because cancer is a multifaceted disease, many treatment options exist and are tailored based on type, location, and cancer stage. Most cancers are usually treated with one or more of the following: chemotherapy, immunotherapy, surgical removal, radiation, and/or hormone therapy. Side effects from these treatments, such as nausea and vomiting, fatigue, constipation, and hair loss, can drastically diminish an individual’s quality of life. More severe side effects can result in damage to organ systems, e.g. cardiotoxicity, hepatotoxicity, nephrotoxicity, ototoxicity, and peripheral neuropathy. Consequently, it is imperative to discover new ways to decrease healthy cell toxicity while simultaneously increasing efficacy in the destruction of cancer cells. One approach to treatment is utilizing the Warburg Effect to weaken cancer cells, allowing current treatments to be more effective at the same or lower doses.

The Warburg Effect: What is it, and why does it matter?
In 1924, German scientist Otto Warburg applied Louis Pasteur’s discoveries of microbial fermentation to his observations of cancer cells. Warburg noted that after cancer cells undergo aerobic glycolysis to create pyruvate, the cells will then ferment pyruvate into lactic acid (an anaerobic process) for energy, even in the presence of oxygen. Normal cells typically shunt pyruvate to the mitochondria for oxidative phosphorylation (see Figure 1). When comparing glycolysis (favored by cancer cells) to oxidative phosphorylation (favored by healthy cells), glycolysis is ten times faster at producing cellular energy in the form of adenosine triphosphate (ATP) but is much less efficient in overall ATP production (approximately 2 ATP versus 36 ATP produced, respectively, and a total of 38 ATP per molecule of glucose). Both Vander Heiden et al. and Lu et al. proposed that this metabolic ‘choice’ is not focused on cellular energy (ATP) production but rather the metabolites of glycolysis that the cell needs for proliferation. In most tumors, glucose is abundant, and ATP generation is rarely a limiting step in cellular proliferation. The availability of other glycolytic intermediates providing carbon, such as nicotinamide adenine dinucleotide (NADH) and acetyl-CoA, can halt proliferation. By using pyruvate for lactic acid fermentation rather than oxidative phosphorylation, the cell creates a mechanism for the regeneration of...
Chronic inflammation has gained traction as a risk factor for cancer and a by-product of nutrient-poor diets. Shen et al. identified several upregulated inflammation-related pathways within both genetic and dietary models of non-alcoholic fatty liver disease progressing to hepatocellular carcinoma. This study highlighted the role obesity can play in cancer development and genetic repercussions observed from obesity. Lifestyle interventions, including a balanced nutrient-rich diet and exercise, decrease oxidative stress and consequently decrease cancer risk. Epidemiological studies indicate that a whole-foods dietary pattern, such as the Mediterranean Diet, is possibly protective in the initiation and progression of cancers (see Table 1 for more specific recommendations). Thus, diet therapy should be the first line of defense against cancer.

Using metabolic pathways to treat cancer

Though the principles set out by Warburg were published nearly a century ago, it is only in the last decade that we have seen them utilized as cancer treatments. Perhaps the most well-known pioneer in this field is Dr. Thomas Seyfried, who has outlined the Press-Pulse theory for using the ketogenic diet in combination with current treatment options to optimize efficacy. The ketogenic diet is high in fat, adequate in protein, and low in carbohydrate which leads to the production of ketone bodies from fats for energy metabolism and by definition provides very little glucose to all cells. Fasting and fast-mimicking diets (outlined in Table 1) produce similar changes in metabolism; however, they are also accompanied by a noticeable decrease in calories. The authors of the Press-Pulse theory describe the ketogenic diet as a ‘press’ on cancer cells, a stressor which weakens the cells due to their decreased metabolic flexibility and reliance on glucose. Current treatment options, such as chemotherapy or radiation, can then be applied as the ‘pulse’ and will theoretically be more effective in killing the weakened cancer cells. Klement discusses the use of ketogenic diets as well as short-term fasting in conjunction with radiation and chemotherapy treatments, citing several ‘integrated treatment’ approaches under current investigation.

In vitro studies have investigated the use of medium- and long-chain triglyceride application on benign and cancerous cell lines with and without the presence of glucose. In mouse prostate cell lines, cancer cells had a decreased capacity to oxidize fatty acids as compared to a benign line, especially under low glucose availabil-

Continued on page 13
Cancer as a Metabolic Disease: Implications in Prevention and Treatment Strategies

...ity, highlighting their need for glucose for survival and proliferation.20 Kadochi et al. observed a murine colon cancer line under glucose starvation with the addition of beta-hydroxybutyrate (a ketone) and lauric acid and noted decreased lactate fermentation with increased oxidative stress and energy production in the mitochondria. Data also indicated increased mitochondrial dysfunction, possibly due to the accumulation of reactive oxygen species (ROS).16 In human cell lines, Mungo et al. demonstrated a metabolic switch through the incubation of chemotherapeutic agents, and decreased chemotherapy resistance.21 Importantly, this research highlights the protective effects of glycolysis towards chemotherapeutic agents in tumor cells. Furthermore, a metabolic switch in these cells towards oxidative phosphorylation, as is seen in short-term fasting and ketogenic diets, can prime these cells to be more susceptible to current treatment options.

In a mouse model of glioma, Woolf et al. showed that the ketogenic diet has profound effects on tumor angiogenesis.22 Impressively, previous research by this same group demonstrated that radiation therapy combined with the ketogenic diet eradicated the gliomas in nine of 11 mice with no recurrence, even after switching the mice back to normal chow.23 Mouse models employing chemotherapy in combination with either ketogenic or short-term fasting diets demonstrate similar findings in pancreatic cancer cells24 and a model of neuroblastoma.25 Interestingly, in one study, mice on a short-term starvation protocol not only had better survival but also regained any weight lost during fasting within four days after chemotherapy.26 This could translate to important implications with regards to weight loss and cachexia during cancer treatments; however, much more research in this area is needed.

In humans, short-term fasting protocols render healthy cells more immune to oxidative stress, unlike cancer cells. Dorff et al. explored this property in their study of 24 to 72-hour fasting protocols in human subjects.17 They found that the 48- and 72-hour fasting groups did in fact have less damage to cells after chemotherapy as compared to the 24-hour group. Fasting not only reduced Insulin-like Growth Factor (IGF)-1 levels (higher levels support cell proliferation), but also the side effects were fewer, and diet compliance was over 50% in all groups. One of the known side effects of cancer is cachexia with anorexia;27 and thus, fasting protocols during which patients lose weight (even if it is regained) may have other associated risk factors.17 Clinical trials focused on cachexia reduction using fast-mimicking and ketogenic diets are underway. Interim data suggests a six-week regimen in conjunction with cancer therapy and an interdisciplinary team, including registered dietitians, is feasible and improves quality of life.28 The available data in human trials suggest that short-term fasting and ketogenic diet regimens are safe and require further study (researched diets are summarized in Table 1).

Discussion

Dietitians play a pivotal role in promoting disease prevention through diet and lifestyle education and counseling (see Table 1). Though prevention is the first line of defense, dietary interventions after diagnosis can still be powerful in their ability to enhance current treatment options. Several mouse studies demonstrated the power of a ketogenic diet in conjunction with radiation and chemotherapy,23-26 theoretically working through the metabolic preference of cancer cells for glycolysis and creating a stressful environment to which the cells cannot adapt. There is evidence that glycolysis provides cancer cells protection against chemotherapeutic agents.33 Preliminary clinical trials have shown that the ketogenic diet is tolerable for up to six weeks; however, compliance may be dependent on the motivational level of the patient as well as their support system and care from their interdisciplinary team.28 Overall, there is evidence to support the hypothesis that metabolism, specifically the glycolysis/oxidative phosphorylation axis, plays a large role in cancer initiation, progression, and even drug resistance. Some studies demonstrated that the reduction of metabolic substrates, either through fasting or ketogenic diets, causes tumors to be more susceptible to treatment therapies. In humans, further research is needed to determine if dietary interventions enhance cancer treatments, and if so, to identify the best regimen(s). However it must be emphasized that fasting, ketogenic diets, and fast-mimicking diets are being explored as adjuvant therapies for cancer treatment and are not recommended for cancer prevention and general health and well-being. Considering cancer as a multifaceted disease in which metabolism plays a large role may encourage more effective treatments and allow both client and dietitian a more active role in cancer prevention through diet and lifestyle interventions.

Continued on page 14
Table 1. Summary of Diets
A summary of dietary recommendations for cancer prevention with information provided by the literature, the American Cancer Society, and the Academy of Nutrition and Dietetics. A summary of the diets researched for adjuvant therapy in cancer treatment is also summarized below.

<table>
<thead>
<tr>
<th>Dietary Recommendations for Cancer Prevention</th>
<th>Diets Researched as Adjuvant Therapies with Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diet</strong></td>
<td><strong>Definition and Recommendations</strong></td>
</tr>
<tr>
<td>Mediterranean Diet(^{15,17,29})</td>
<td>Majority of intake from vegetables, legumes, fruits and nuts, and cereals.</td>
</tr>
<tr>
<td></td>
<td>For fats, a high intake of olive oil but a low intake of saturated lipids.</td>
</tr>
<tr>
<td></td>
<td>A moderately-high intake of fish.</td>
</tr>
<tr>
<td></td>
<td>A low-to-moderate intake of dairy products.</td>
</tr>
<tr>
<td></td>
<td>A low intake of meat and poultry.</td>
</tr>
<tr>
<td></td>
<td>A regular but moderate intake of ethanol, primarily in the form of wine.</td>
</tr>
<tr>
<td></td>
<td>Observational studies suggest that high adherence to the Mediterranean Diet is associated with significant decrease in overall cancer risk/mortality.</td>
</tr>
<tr>
<td>American Cancer Society(^{30})</td>
<td>“Maintain a healthy weight throughout life.”</td>
</tr>
<tr>
<td></td>
<td>Adopt a physically active lifestyle.</td>
</tr>
<tr>
<td></td>
<td>Eat five or more servings of a variety of vegetables and fruits each day.</td>
</tr>
<tr>
<td></td>
<td>Choose whole grains instead of refined grains.</td>
</tr>
<tr>
<td></td>
<td>Limit consumption of processed and red meats.</td>
</tr>
<tr>
<td></td>
<td>If you drink, limit consumption to one drink/day for women or two drinks/day for men.”</td>
</tr>
<tr>
<td>Academy of Nutrition and Dietetic(^{31})</td>
<td>Maintain a healthy weight.</td>
</tr>
<tr>
<td></td>
<td>Limit calorie-dense, nutrient-deficient foods.</td>
</tr>
<tr>
<td></td>
<td>Eat vegetables, fruits, whole grains, and legumes.</td>
</tr>
<tr>
<td></td>
<td>Moderate your meat portions.</td>
</tr>
<tr>
<td></td>
<td>Focus on plant proteins.</td>
</tr>
<tr>
<td></td>
<td>Limit alcohol.</td>
</tr>
<tr>
<td></td>
<td>Eat whole foods.</td>
</tr>
<tr>
<td>Fasting Regimen(^{17})</td>
<td>24, 48, or 72 hours prior to chemo- or radiation therapy.</td>
</tr>
<tr>
<td></td>
<td>Caloric intake is &lt;200 kcal/24-hour period.</td>
</tr>
<tr>
<td>Ketogenic Diet(^{17})</td>
<td>A diet generally very low in carbohydrate, adequate in protein, and high in fat.</td>
</tr>
<tr>
<td></td>
<td>Causes serum levels of the ketone bodies -hydroxybutyrate (BHB), acetoacetate (AcAc) and acetone to increase (~0.3 mmol/l or more for BHB).</td>
</tr>
<tr>
<td></td>
<td>Occurs naturally in neonates, and in adults during intermittent and longer-term fasting.</td>
</tr>
<tr>
<td></td>
<td>May also be combined with caloric restriction.</td>
</tr>
<tr>
<td>Fast-Mimicking Diet(^{32})</td>
<td>Provides between 34% and 54% of typical caloric intake.</td>
</tr>
<tr>
<td></td>
<td>At least 9%–10% protein, 34%–47% carbohydrate, and 44%–56% fat.</td>
</tr>
<tr>
<td></td>
<td>Typically consumed for five days every month for three months (or three cycles).</td>
</tr>
<tr>
<td></td>
<td>Other days, typical caloric intake is consumed.</td>
</tr>
</tbody>
</table>
Cancer as a Metabolic Disease: Implications in Prevention and Treatment Strategies

References

Volumes have been written about Clara Harlowe Barton (1821-1912) whose work experience ranged from teacher patent office clerk, battlefield supplier, and nurse to finding missing persons after the Civil War, and later in life becoming the president of American Red Cross (1, p 173). This article focuses on her role as expert procurer of food and supplies under extremely dangerous conditions of an army on the move between battles with selected examples of relevance to dietitians who have an interest in health care and feeding in disaster conditions.

Her activities, particularly fierce battles with staggering casualties (notably Antietam and Fredericksburg in 1862), demonstrate how her experience and independent spirit combined prove her to be “a one-woman relief agency…” (2, p 70) from Maryland to South Carolina during the Civil War years (3, pp 115-127).

What prepared Barton for this unique role during this dramatic chapter of her life? Born in North Oxford, Massachusetts (3, p 112) on Christmas in 1821, she was 40 at the start of the Civil War (4, p 42). Leading up to this was an impressive resume of experience and qualities:

- Educator at the early age of 17; she taught school in Massachusetts (5); several of her students later enlisted in the 21st Massachusetts Regiment.
- Organization, record-keeping, and business experience working in the US Patent Office from 1854-1857 (3, p 113). Brockett and Vaughan wrote their 1867 report while Barton was still operating the “Bureau of Missing Men” she created after the war; they described her as “remarkably devoted to her work, and her organizing abilities are unsurpassed…” (3, p 132).
- Caregiving experience for her brother and father who even on his deathbed supported his daughter’s call to duty in 1861 (3, pp 117-118; 4, pp 41-42). He was a war veteran and Mason; he appeared to have instilled a sense of patriotism and desire to serve their country (3, p 112).
- Spirit of independence and determination necessary to forge ahead despite forces against women in the workforce and government (1, p 174). Despite pressures against women serving in the war at the time, “...at 40, Clara Barton had long ceased to take orders from anyone…” (6, p 46).
- Nutrition note – Barton notably followed a restricted vegetarian diet “eating meat only when necessity or circumstances required it” and was in the habit of light meals and “protracted fasts” for weight control. Despite digestive issues, she managed to stay healthy and fit (4, p 32).

Supply wagons were moving targets for the opposing forces; Barton knew this. In fact, if she anticipated a battle was imminent, she followed with supplies that she had purchased or collected from donors. In this way, she had provisions in place before, during, and in the aftermath of fighting for thousands of wounded. Barton won an ally in the US Army, Quartermaster Major (later General) Daniel Rucker. Aware of the tragic delay in aid after the first battle of Bull Run (Manassas, VA) in July 1861, she brought much-needed supplies to Washington, DC. With his help, she was soon afforded additional storage space and given passage to drive wagons or take railcars to the frontlines of battle to issue supplies directly (1 pp 169-170; 3, p 116-117; 5). She delivered supplies which served the wounded from Cedar Mountain, Chantilly, Second Bull Run, Fredericksburg (VA), Antietam (Sharpsburg, MD), and later, many locations in the South Carolina Sea Islands.

Behind the lines in a cornfield at Antietam in September of 1862, she combined her own supplies with those she foraged in a farm nearby and directed emergency feeding and nursing care, setting up a makeshift hospital kitchen and providing surgeons with lanterns and candles needed for surgery throughout the night (3 pp 119-120). She was given credit for her service to the 21st Massachusetts Regiment at Antietam: “Our true friend, Miss Clara Barton... was now permanently associated with the regiment, and, with two, four-mule covered wagons, which by her untiring efforts she kept well-supplied with delicacies in the...
way of food and articles of clothing, was a ministering angel to our sick...never sparing herself or failing in her devotion to our suffering men...won the lasting respect and love of our officers and men” (7, pp 213-214).

In the cold winter of December 1862, the Union Army temporarily occupied the city of Fredericksburg, VA. Barton was there “organizing the hospital kitchens; and after the withdrawal of the troops, she established a private kitchen for supplying delicacies to the wounded...cooking was performed in the open air.” She directed that “large fires [be] built and the men wrapped in blankets. An old chimney was torn down, the bricks heated in the fire, and placed around them” to keep them as warm as possible (3, p 123). This was no small feat in the aftermath at Fredericksburg, where thousands of wounded soldiers lay freezing to death on the battlefield (8, pp 148-149).

In July of 1863, Barton was at Morris Island, SC during the siege at Fort Wagner. “Her employment was, with three or four men detailed to assist her, to boil water in the lee of a sand-hill, to wash the wounds of the men...to prepare tea and coffee, and various dishes made from dried fruits, farina, and desiccated milk and eggs...she alone...kept up her fires and preparations...[and]...had anything suitable to offer the wounded and exhausted men” (3, p 126). Earlier that summer, she had an opportunity to visit a hospital at Beaufort where she was introduced to Susie King Taylor and visited African American troops of the 1st Carolina USCT (4, p 155). Taylor was impressed by Barton’s attention to the soldiers and wrote, “…I honored her for her devotion and care for those men” (9, p 67).

While Barton operated independently from established organizations, such as the United States Sanitary Commission, in 1892 she delivered a moving address in the form of a poem she had written, “Women of the Field,” (10, pp 83-86) to recognize unconventional women who gave service to soldiers during the war, risking physical danger and social disapproval. Her poem included over a dozen names of Sanitary Commission women. Several of these have been featured in this Pioneers series, such as Annie Wittenmyer and Mary Livermore.

Further research tips to learn more about Clara Barton: The works cited here by Oates and Massey are worth reading for their extensive and thorough endnotes. These will guide those who wish to research further to primary sources and documents. Another excellent resource is the extensive collection of Clara Barton papers at the Library of Congress in Washington, DC and online (11). Additionally, readers are encouraged to visit the Clara Barton Missing Soldiers Office Museum (12) – or utilize their online resources in the references below.


Photo Source: catalog.archives.gov/id/526057.
As always, FNCE® did not disappoint! We spent time hearing the latest research, catching up with colleagues and friends, and learning about countless food and nutrition products at the Expo. The Research DPG events included a pre-conference symposium, *The Gut Microbiome and Prebiotics: a powerful synergy for health and prevention*, sponsored by the Beneo Institute and a member reception.

During the symposium, the science behind the role of prebiotics in supporting health and in managing metabolic disease was presented, along with a technical demonstration of fiber properties and how they impact a food matrix to improve gut dysbiosis. The member reception included networking, member awards and honors, and Q&A with Milton Stokes from the Academy’s Board of Directors. The very deserving award recipients recognized included:

- **Pradtana Tapanee** from Mississippi State University who received the Sugar Association/Research DPG Laboratory-based Grant Award, a $10,000 pilot grant, for her project titled, *Exploring the relationship between genetic variation in taste receptor genes and salt taste perception among people with hypertension*.

- **LesLee Karen Funderburk** of Baylor University, recipient of the Sugar Association/Research DPG Non-laboratory Grant Award, a $8,000 pilot grant, for her project titled, *Omega-3 fatty acid supplementation to enhance performance in collegiate athletes*.

- **Katelyn E. Senkus** from the University of Alabama received the Mead Johnson Nutrition/Research DPG Student Pilot Grant Award, a $1,750 student pilot grant, for her project titled, *Characterization of the oral microbiome for optimal blood pressure*.

Three awardees of the Mead Johnson Nutrition/RDPG Student Research Award, a $250 award

**Emily Hill** from The Ohio State University for her abstract titled, *Diet quality, body composition, and carotenoid status in NCAA Division 1 Athletes*.

**Matthew Landry** from the University of Texas at Austin for his abstract titled, *Association between cooking attitudes and self-efficacy and food insecurity*.

**Ashlea Braun** from The Ohio State University College of Medicine for her abstract titled, *Impact of participant engagement in a RDN-delivered remote motivational interviewing base intervention for survivors of cancer with overweight and obesity*.

Continued on page 19
FNCE® 2019 Recap

- Maya Vadiveloo from the University of Rhode Island received the Research DPG First Author Award for the paper, **Associations between timing and quality of solid food introduction with infant weight-for-length z-scores at 12-months: Findings from the Nurture cohort**, which was published in *Appetite* in 2019 with co-authors Alison Tovar, Truls Ostbye, and Sara E. Benjamin-Neelon.

- Tanya M. Halliday of the University of Colorado School of Medicine and the University of Utah was the recipient of the Research DPG Emerging Researcher Author Award for her article titled, **Comparison of surgical versus diet-induced weight loss on appetite regulation and metabolic health outcomes**, which was published in *Physiological Reports* in 2019 with co-authors Sarit Polsky, Jonathan A. Schoen, Kristina T. Legget, Jason R. Tregellas, Kayla M. Williamson, and Marc-Andre Cornier.

These awards would not be possible without the dedicated awards committee co-chairs, Joann McDermid and Tracey Ledoux, the applicant reviewers who volunteer their time and expertise, and the generous sponsorship of The Sugar Association and Mead Johnson Nutrition.

Prior to FNCE®, the fall House of Delegates, meeting was held and our delegate, David H. Holben, PhD, RDN, LD, FAND, represented the Research DPG. The topics of Technology/Big Data and the Total Diet Approach were discussed. A recap of this meeting and links to supporting materials can be found on pages 20 and 21.

I hope you enjoy these photos highlighting some of the Research DPG activities at FNCE® 2019 and look forward to seeing many of you again at FNCE®2020!

Meet the 2020-2021 Research DPG Executive Committee Members
Taking office June 1, 2020

- **Chair-elect:** Maria Morgan-Bathke, PhD, RD, CD, Assistant Professor and Dietetic Internship Director in the Nutrition and Dietetics Department at Viterbo University and Research Collaborator at the Mayo Clinic

- **Treasurer:** Pao Ying Hsiao, PhD, MS, RD, LDN, Associate Professor in the Department of Food and Nutrition at Indiana University of Pennsylvania

- **Nominating Committee:** Kellie E. Mayfield, PhD, Assistant Professor in the Department of Nutrition at Georgia State University and Affiliate Faculty Member for the Partnership for Urban Health Research and Gerontology Institute

- **HOD Delegate:** Kim Beals, PhD, RD, CSSD, LDN, Associate Professor in the Department of Sports Medicine and Nutrition at the University of Pittsburgh and Director of the Neuromuscular Research Laboratory at the Warrior Human Performance Research Center

Congratulations to our new Executive Committee members and to the RDPG members who were on the national ballot that were elected - Kevin Sauer, PhD, RDN, LD, FAND as President-Elect and Susan Roberts, DCN, RDN, LD, FAND as Director-at-Large.
The Academy of Nutrition and Dietetics’ House of Delegates (HOD) held its Fall 2019 meeting on Friday, October 24 and Saturday, October 25, 2019, where delegates discussed the topics of Technology/Big Data and the Total Diet Approach through the lens of thriving in a VUCA (Volatile, Uncertain, Complex, and Ambiguous) World. The profession must adapt and be responsive, agile, and systems-oriented in its solutions for these issues and others to remain relevant in a VUCA environment.

**Technology/Big Data Strategic Issue Question:**

How does the Academy and its members leverage Big Data and Artificial Intelligence technology to improve outcomes in all areas of practice and elevate the roles of credentialed nutrition and dietetics practitioners?

- VUCA and Technology presentations set the stage for the dialogue, and subject matter experts served as resources for delegates.
- Delegates explored the areas of data sets, improved outcomes, and elevated roles for RDNs/NDTRs.
- Additionally, gaps and opportunities were reviewed in these areas:
  - Knowledge expansion
  - Career growth
  - Collaboration and cross-pollination.

**Next Steps:**

A HOD Technology/Big Data Task Force, with delegates and other subject matter experts, will be appointed to prioritize and develop action plans for gaps identified during the dialogue. Action plans will be presented to the HOD in the spring to determine final recommendations to forward to the Board of Directors.
Fall 2019 House of Delegates Meeting Recap: Technology/Big Data and the Total Diet Approach

Total Diet Approach for Healthy Eating Professional Issue Question:
Is the “Total Diet Approach” still relevant for a healthy population?
- Presentations on the history of and updates to the Total Diet Approach were provided, along with feedback from member surveys. Delegates also heard from a panel of nutrition communicators on how they discuss healthy eating with consumers.
- Delegates discussed the relevance of total diet approach terminology as well as the proposed stance.

Proposed Stance: The Academy of Nutrition and Dietetics supports the Total Diet Approach as the foundation for healthful eating. This approach focuses on the overall pattern of foods a person consumes over time, in moderation, combined with appropriate portion sizes and physical activity. A registered dietitian nutritionist is the best source of science-based advice for choosing an eating plan that is personalized for each individual.

Next Steps:
A qualitative analysis of the delegate discussion is underway to identify the common themes from the dialogue. Delegates and Academy Committees will be engaged in activities to determine recommendations for the stance to share with the Academy’s Board of Directors in February.

Additional Information
- Meeting materials, including background and follow-up information, will continue to be posted on the Fall 2019 Meeting Materials page.
- Review the Academy Committees and Taskforce Reports.
- The Council on Future Practice (CFP) will be releasing a change driver on VUCA in 2020, so stay tuned for implications for the profession in a VUCA World.

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