

Warren J. Baker Endowment
for Excellence in Project-Based Learning
Robert D. Koob Endowment for Student Success
PROPOSAL NARRATIVE

I. Abstract

Bisphenol A (BPA) exposure is recognized as having negative health effects and is related to weight gain, obesity, and some cancers³. More troubling is that BPA is present in all aspects of life, including most plastic containers, make-up and shave creams, non-organic foods, etc. The aim of this project is to determine the effectiveness of a lifestyle intervention program designed to limit exposure to BPA. Twenty, healthy women with high baseline BPA exposure will be randomized (N=10) to reduce BPA exposure or control (N=10). The control group (n=10) will receive basic health care information about BPA exposure, and the intervention group will receive the same health care information PLUS a weekly intervention to reduce BPA exposure including: replacing plastic containers with glass containers, provided BPA make-up and beauty supplies, and behavior techniques (e.g. problem-solving, etc.) to reduce BPA exposure. Main outcome will be urine BPA concentrations assessed at baseline and after 4-weeks. The results of the current study, if shown to reduce BPA exposure, will have a profound effect and inform future large scale clinical research lifestyle interventions designed to reduce weight, obesity, and risk for chronic disease.

II. Introduction

In the United States, obesity has reached epidemic proportion as approximately 69% of adults are overweight or obese⁶. This greatly increases the risk for chronic diseases, such as diabetes, cancer, and cardiovascular disease⁶. Emerging research has shown that obesogens, which are chemical compounds that disrupts metabolism and weight control, are related to obesity. Bisphenol A (BPA), the most established obesogen, has been shown to mimic hormones/enzymes to alter homeostasis negatively². In humans, epidemiological data has shown a strong relationship between

high BPA exposure and obesity^{4,5}. More troubling is that BPA is abundant in our environment, from what we put on our face/body (e.g. make-up, lotion, shave cream, etc.) to what we eat.

Surprisingly, there have been no published randomized trials testing the effects of a lifestyle intervention to reduce human BPA concentrations. Thus, 20 healthy women, with high BPA exposure, will be randomly assigned to a 4-week lifestyle intervention to reduce BPA or control and their Urine BPA concentrations assessed at baseline and 4 weeks.

III. Objective(s)

(1) To determine whether a lifestyle intervention targeting BPA exposure will alter urine concentrations of BPA. We hypothesize that women randomized to the lifestyle intervention, relative to control, will have lower urine BPA after 4-weeks; Intervention women will have greater change from baseline in BPA.

(2) To determine whether BPA exposure alters perceived health. We hypothesize that women randomized to the lifestyle intervention, will have improved quality of health.

IV. Methodology

Subjects: Twenty, healthy women will be recruited to participate in this study from Cal Poly and the surrounding areas. Inclusion criteria includes, 1) high exposure to BPA as previously described⁸, 2) BMI between 18.5-40 kg/m², 3) 18-40 years old, and 4) wear make-up or use lotion/sunscreen daily. Exclusion criteria include any metabolic or chronic disease, or any extreme diet (e.g. Atkins, Paleo) that may impact BPA concentrations. For this study, only women were chosen because they are at increased risk for high BPA exposure given the high levels in make-up, lotion, sunscreen, etc. This study will be approved by the Human Subjects Committee at Cal Poly San Luis Obispo.

Screening and Informed Consent: Women who express interest in the study will be provided a general overview of the study and, if interested, will meet researchers in the Human Performance laboratory in the 2nd floor of the Kinesiology tower. The study will be explained in detail, and women will then read the informed consent and be given the opportunity to ask questions. Once given verbal and written consented, women will complete a general BPA exposure questionnaire⁸,

health history questionnaire, and height and weight will be measured.

Assessment visits: Urine BPA, weight, height, and perceived health will be assessed at baseline prior

to randomization and after 4-weeks of intervention or control.⁷ After baseline assessments are completed, women will be randomized by body mass index to a lifestyle intervention to reduce BPA exposure or control (see below for details).

Group 1: Control: Women randomized to control will receive a general health newsletter to reduce BPA exposure. In other lifestyle intervention studies, subjects given “general education” does not alter behavior¹

Group 2: Intervention Women randomized to the intervention designed to reduce BPA exposure will receive all aspects of the control group PLUS a lifestyle intervention designed to reduce BPA exposure. These women will attend an intervention meeting once a week for three weeks.

Week 1: Women trade in all their daily makeup and beauty products for BPA-free products and will be provided will glass food storage containers. Week 2: Women will be given additional information on how to reduce BPA exposure (Eating Organic, Avoiding packaged foods, etc.).

Week 3: Address problem-solving and stimulus control techniques.

<u>Group 1: Control:</u> <ul style="list-style-type: none">• Receive brochures on how to avoid exposure.	<u>Group 2: Intervention</u> <ul style="list-style-type: none">• Receive control information PLUS:• Change out all makeup, hair products, skin products for BPA free products from Beautycounter©• Receive glass containers for all food storage.• Participate in individual weekly intervention meetings designated to reduce BPA exposure.
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Outcome measures: The main outcome is urine BPA concentrations. After an overnight fast, women will come to the Human Performance laboratory and provide 5 ml of mid-stream urine in a polystyrene tube and stored at -80°C. Once the study has been completed urine BPA and creatinine concentrations will be assessed by HPLC (Quest Diagnostic Laboratory).

Statistics This study uses a randomized repeated measures design. The ultimate goal in our analyses will be to compare Lifestyle Intervention vs. Control. We expect <5% of participants will be lost to follow up due to the longitudinal study design. All analyses will be structured such that

comparisons are made using the principle of intention to treat (baseline data carried forward). A repeated measures analysis of variance (RMANOVA) will be used to examine differences in urine BPA concentrations and perceived health adjusting for BMI, baseline BPA exposure, age, education, income, and ethnicity/race. By convention, $P < 0.05$ will be considered significant, and a Tukey's post-hoc will be used in a significant interaction occurs.

V. Timeline

The earliest start date for this study will be week one of Winter Quarter 2014 starting with recruitment. Data collection will continue through the end of finals week of winter quarter. Each participant is enrolled in the study for 30 consecutive days. All data collection will be complete by the last week of Winter Quarter. Data analysis and presentation writing will occur during the Spring Quarter.

Table 1- Timeline, 2014-2015 Academic Year	Fall Quarter Week 6-10	Winter Quarter Week 1-5	Winter Quarter Week 5-10	Spring Quarter Week 1-2	Spring Quarter Week 3-4	Spring Quarter Week 5-7
Submit Project Proposal for IRB approval						
Study Recruitment						
Baseline assessments/ randomization						
All other assessments and interventions						
Data Analysis- Sent to Quest Laboratory						
Data Cleaning						
Presentation and Manuscript Writing						

VI. Final Products and Dissemination

This project will serve as an Honors Senior Project for Allison Smouse and Mikaela Streeter. The project will also be written as a scientific research paper and uploaded to Cal Poly Digital Commons. Furthermore it will be presented at the CSM Research Fair in the Spring of 2015. Moreover, the results of this study will be submitted to a peer-reviewed journal in 2015.

VII. Budget Justification

Non-Computer Supplies and Materials- BPA free glassware, utensils, and beauty supplies will be purchased for all intervention women. The beauty supplies will be purchased from

BeautyCounter©. Each intervention participant will receive a 30 day supply of all basic beauty supplies including soap, shampoo, conditioner, face wash, and makeup. Due to the price of glassware and beauty supplies, we are budgeting \$900 for supplies.

Contracted Services- The Bisphenol A and Creatinine random urine test was quoted by Quest Diagnostic at \$100 per sample for 40 samples (2 samples per participant, 1 pre, 1 post), for a total cost of \$4,000.

Postage/Shipping- Biological samples will be shipped to and assessed by Quest Diagnostic Laboratory. Thus, \$100 for shipping of samples on dry ice.

References:

1. Looney, Shannon M., and Hollie Raynor. "Behavioral Lifestyle Intervention in the Treatment of Obesity." *Health Service Insights* 6 (2013): 15-31. PubMed. Web.
2. Janesick A, Blumberg B. Obesogens, stem cells and the developmental programming of obesity. *Int J Androl.* 2012;35(3):437–448.
3. Kun-Shui Zhang, Hui-Qing Chen, Bisphenol A stimulates human lung cancer cell migration, *Biomedicine & Pharmacotherapy*, Available online 18 September 2014, ISSN 0753-3322
4. Lang IA, Galloway TS, Scarlett A, et al. Association of Urinary Bisphenol A Concentration With Medical Disorders and Laboratory Abnormalities in Adults. *JAMA.* 2008;300(11):1303-1310.
5. Uzumcu M. Developmental exposure to environmental endocrine disruptors: consequences within the ovary and on female reproductive function. *Reproductive Toxicology.* 2007;23(3):337–352.
6. Ogden CL, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA.* 2014;311(8):806-814.
7. Princeton Survey Research Associates for the Commonwealth Fund. Survey on Disparities in Quality of Health Care, 2001
8. LaKind, Judy. Daily Intake of Bisphenol A and Potential Sources of Exposure: 2005–2006 National Health and Nutrition Examination Survey. *Journal of Exposure Science*, 17 Mar. 2010.

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PROPOSAL BUDGET

Student Applicant(s):	
Faculty Advisor:	Todd Hagobian
Project Title:	Requested Baker Endowment Funding
Travel <i>subtotal</i>	\$0
Travel: In-state	\$0
Travel: Out-of-state	\$0
Travel: International	\$0
Operating Expenses <i>subtotal</i>	\$ 1000
Non-computer Supplies & Materials	\$900
Computer Supplies & Materials	\$0
Software/Software Licenses	\$0
Printing/Duplication	\$0
Postage/Shipping	\$100
Registration	\$0
Membership Dues & Subscriptions	\$0
Multimedia Services	\$0
Advertising	\$0
Journal Publication Costs	\$0
Contractual Services <i>subtotal</i>	\$4000
Contracted Services	\$4000
Equipment Rental/Lease Agreements	\$0
Service/Maintenance Agreements	\$0
TOTAL	\$5000



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October 23, 2014

To Warren J. Baker Endowment Committee,

This letter is in strong support of Allison Smouse's and Mikaela Streeter's pursuit of the Warren J. Baker Endowment award. I have known Allison and Mikaela for more than 2 years in an academic, research, and mentorship setting at California Polytechnic State University, and overall, both students are in the top 10 of all students I have been associated with. Both Allison and Mikaela are entering their final year at Cal Poly, and are exceptional academic students, and have received excellent research training. For the past year, Allison and Mikaela have been working on my National Institutes of Health funded study, and gained a solid foundation in clinical human research. The proposed project is an extension of their hard work in my laboratory. Moreover, developing an intervention to reduce BPA levels is highly novel and innovative, and, if shown to be efficacious, will inform and may move lifestyle intervention clinical research substantially forward. In regards to the current application by Alison and Mikaela, they both were involved with conception of the idea and wrote the application. The proposed project will expand their research skills and knowledge, and I have no doubt that they will meet both objectives of the study.

I will have formal, weekly meetings with both Allison and Mikaela, and more frequently as needed, especially during recruitment and data collection periods. They will have access to equipment and supplies in the Human Performance Laboratory on the 2nd floor of the Kinesiology tower and to the STRIDE research center. This includes, but not limited to, using the clinical exam rooms for assessment and intervention visits, urine collection supplies, -80 C freezer, stadiometer, Tanita body weight scale, and copier supplies. In addition, Allison and Mikaela will attend our weekly laboratory meeting, where they will update me and research staff on recruitment and data collection of their study. This is a standard procedure for all of our research studies. Additionally, attending this meeting will allow them to learn from our experienced clinical research staff and aid in problem solving of their study. As part of their Senior Project, I am requiring (and will oversee) that they submit a scientifically written research paper based on their results to Digital Commons in spring 2015, and they must present at the College of Science and Math Student Research conference. Finally, this study will be submitted to a refereed journal for publication, and both students will be heavily involved in that process.

In summary, the proposed research project by Allison and Mikaela is highly novel, and will inform and may move clinical research substantially forward. They will have all the necessary equipment and supplies of the Kinesiology Department, STRIDE research center, and my funded laboratory. Most importantly, this project will enhance their skills and knowledge, and is consistent with Cal Poly's "Learn by Doing" approach. It is without hesitation that I highly recommend Allison Smouse and Mikaela for the Warren J. Baker Endowment award.

Sincerely,

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