Healthy weight management and successful diabetes care require a person to make the “right” choices many times a day. In many cases, these choices not only affect that person, but also their close family members, sometimes even those not yet born! This is most apparent for the women that my research team works with in my exercise psychology laboratory. That is, the health and behavior decisions made by pregnant women with gestational diabetes not only affect them but also their baby, both in the short and long term. Children of mothers with uncontrolled diabetes during pregnancy have a significantly increased chance of developing weight problems and type 2 diabetes later in life.

In our Active MOMS intervention (see “Ongoing Research,” page 2), we are teaching pregnant women about the benefits of regular exercise and how to make the “right” choices for an active lifestyle to manage their diabetes.

In this newsletter you will find a host of announcements and updates on projects that other Penn State Institute for Diabetes and Obesity researchers and clinicians are conducting to investigate new ways of helping people make the “right” choices for better health in the short and long term. I especially encourage you to review the list of studies at the end of the newsletter to see how you might become more directly involved in research, by volunteering for a study seeking to reinvent diabetes and obesity care. Making progress in health care through research is not somebody else’s responsibility—it is our own.
Ongoing PSIDO Research Studies

Volunteers are needed for the following research studies. All studies listed have been approved by either the Penn State, University Park, or Penn State Milton S. Hershey Medical Center Institutional Review Boards. More information about these and additional studies may be found at www.pennstatehershey.org/web/diabetesandobesity/patientcare/clinicaltrials.

Interactive Web-Based Diabetes Self-Management Tool
We are inviting you to help us in a Web-based research study. The program is designed to involve you by asking interactive questions and providing answers about your diabetes. It also has a place to encourage you to share your own success stories and read others’ helpful hints about how to better manage diabetes. To be included in the study, you must be diagnosed with type 2 diabetes, be English speaking, have internet access, and be between the ages of 18 and 75. Compensation is provided. You can read more about the study and enroll online at http://playbook.ist.psu.edu/registration. IRB# 28725; PI: R. Gabbay.

Diabetic Retinopathy (Eye) Studies
This research study is seeking adults with diabetic retinopathy to participate in two different twenty-four month studies evaluating the effects of doxycycline on slowing the progression of diabetic retinopathy and improving eye function. Participants must be willing to come for study visits once every three months for twenty-four months. Compensation is available. For more information, contact Mary Hershey, COMT, at 717-531-6779 or mhershey@hmc.psu.edu. IRB# 25234; PI: I.U. Scott.

Body Measurement Study for Children
Children aged 6 months to 3 years old are needed for a child growth study. The purpose of the research is to test new equipment for measuring body fatness in children. The study involves one visit to the Human Body Composition Lab in Noll Laboratory, University Park (State College). Compensation is provided for participation. For additional information or to enroll in this study, contact Ryan Rosendale at rpr135@psu.edu or call 814-867-0776. IRB# 30418; PI: C. Bartok.

Polycystic Ovary Syndrome and Vitamin D Study
Penn State Milton S. Hershey Medical Center researchers are trying to determine the effects of vitamin D on insulin sensitivity and psychological health in women with PCOS. Participants will be asked to have a blood draw, take a study medication, be screened for diabetes, and complete questionnaires and a menstrual diary. Compensation is provided. You may be eligible to participate if you are a woman between 18 and 45 years of age and have eight or fewer periods each year (or have been diagnosed with PCOS). For more information, contact Barbara Scheetz at 717-531-4483. IRB#29714 PI: N. Raja-Khan.

Blood Vessel Changes and Diabetes Study
Healthy volunteers and diabetes patients are needed for a Penn State Milton S. Hershey Medical Center research study. Researchers are trying to determine the relationship between blood vessels in the heart, brain, and eyes in healthy volunteers, volunteers with impaired fasting glucose (pre-diabetic), and volunteers with type 2 diabetes with or without vascular complications. Participants will be asked to breathe a high concentration of oxygen and then a low concentration of carbon dioxide, while researchers measure the blood flowing through the arteries using Doppler ultrasound, a painless technique that measures blood flow speed. Participants will then be asked to breathe the same gas mixtures while staring with one eye at a bright light, while researchers measure the blow flowing through the blood vessels in the eye, which is also painless. Compensation is provided. To be eligible, participants should be between the ages of 21 and 75; healthy, have type 2 diabetes, or have impaired fasting glucose (pre-diabetic). For more information, call Cheryl Blaha, R.N., at 717-531-1605. IRB#29480; PI: K. Betterman.

PSIDO Diabetes Playbook
PSIDO is focused on reinventing diabetes and obesity care. One of the ways we are reaching this goal is by listening to our patients. When patients asked for an easy way to keep track of their diabetes care, we created the Diabetes Playbook.
Not only does the book offer tips on how to manage diabetes from people who treat diabetes, but it also offers tips from people who live with diabetes every day. To order a copy, go to www.hmc.psu.edu/diabetes.
Exercise Blood Flow Study
Healthy men and women age 21-30 or 60-75 are needed for a study in Noll Laboratory (University Park/State College) examining the effects of age on blood flow to exercising muscles. Eligible subjects will perform single leg exercise at light and moderate workloads on two study visits while blood flow to their contracting limb is measured (Doppler ultrasound); all tests and interventions use noninvasive techniques. Three hours prior to each of these two visits, subjects will consume a dietary supplement or placebo (non-active ingredient), in random order, and have a blood draw upon arrival to Noll Laboratory to confirm the effectiveness of the dietary supplement. Subjects will receive compensation for their participation and information obtained during two preliminary screening visits about their cardiovascular fitness, vascular health, and body composition. Interested men and women should contact the study coordinator, Sandy Smithmyer (sls35@psu.edu), or Matthew Barlow (mab76@psu.edu or 814-863-3182). IRB# 29152; PI: M. Barlow.

Effects of Pistachios on Cardiovascular Responses to Stress in Type 2 Diabetes
We are looking for men and postmenopausal women between the ages of 30 and 70 who have been diagnosed with type 2 diabetes for more than six months. Other exclusion criteria include taking insulin or blood-pressure-lowering medications. The study is approximately twelve to fourteen weeks long and consists of a two-week regular diet followed by two separate four-week test diet periods. Compensation is provided. For more information, contact kaf22@psu.edu or 814-863-0926. IRB#29970; PI: S. West.

Weight Loss and Walking Study
Healthy, premenopausal women aged 20 to 45 years with a body mass index between 25 and 35 (mild to moderate overweight) are needed to evaluate two dietary interventions on various markers of health. The purpose of the study is to evaluate the differences in two weight loss diets on inflammation, bone density, cholesterol levels, and blood pressure. This study will be conducted by a registered dietitian in the Department of Nutritional Sciences on the University Park campus. Participants must want to lose weight and be willing to follow a reduced calorie diet and participate in a supervised walking program for six months. Compensation will be provided. If interested, contact the Bone Lab at 814-863-7269 or YogurtStudy@gmail.com.

BEAP (Beliefs about Exercise after Pregnancy)
BEAP is a PSIDO-funded research study targeting postpartum women who had gestational diabetes in their most recent pregnancy. The study’s objective is to better understand a woman’s thoughts about exercise and other healthy behaviors in order to develop an intervention program. Compensation is provided. For more information, contact dsd11@psu.edu or 814-863-0456. IRB# 23986; PI: D. Downs.

Active MOMS
Active MOMS is an NIH-funded research study targeting pregnant women diagnosed with gestational diabetes. The purpose of the study is to examine physical activity, health beliefs, and behaviors during pregnancy in an effort to understand their impact on gestational diabetes for women and their babies. Women may be given simple advice about exercise, or may be give assistance to increase physical activity on their own time, or may be invited to participate in structured exercise. Compensation is provided. For more information, contact dsd11@psu.edu or 814-863-0456. IRB# 24174; PI: D. Downs.

The Footprints Study
The Footprints Study is looking for moms and infants to participate in a Penn State research study of infant growth and behavior patterns. Moms and babies must be healthy and enroll before the baby is 1 month old (moms can enroll when preg-nant). Babies should be in one of the following groups: formula fed, mostly/exclusively breastfed (nursed), or mostly/exclusively bottle fed with pumped breast milk for the first six months of life. The study involves six monthly visits to the laboratory and occasional record keeping of infant food intake and behavior. Compensation of up to $145 is provided. For more information, call Cynthia at 814-865-0311. IRB# 24790; PI: C. Bartok.
Study of the Health Benefits of Peanuts
We are conducting a study that examines the effects of peanuts on post-meal blood sugar, triglycerides, and inflammation. We are looking for overweight (BMI 28-39), nonsmoking men aged 30-50 years. Subjects must be healthy and able to visit our on-campus research center for three visits lasting five to six hours each. At the completion of the study you will receive lab results and compensation of $200. If you are interested in learning more about the study, please call toll free 1-866-PSU-DIET (1-866-778-3438) or e-mail Alison Hill (amh41@psu.edu). Mention the Peanut Study and leave your name and a contact number. Penn State IRB #30696; PI: Kris-Etherton.

Polycystic Ovary Syndrome and Pregnancy
Penn State Hershey Medical Center researchers need volunteers who want to become pregnant, are 18-40 years old, and who have been diagnosed with polycystic ovary syndrome (PCOS), for a research study comparing three treatment options. Participation includes physical exams, pelvic ultrasounds, DXA scans, exercise treadmill tests, hormonal blood work, oral glucose tolerance tests, and recording of daily exercise and dietary information. Study-related medications and a lifestyle intervention are included in the study. For more information contact Patsy at prawa@hmc.psu.edu or 717-531-3692 or 800-585-9585. IRB#27184; PI: R. Legro.

Endometrial Hyperplasia Study
Postmenopausal women, 45 to 75 years old, who are overweight and have diabetes and/or high blood pressure may qualify for this research study. The purpose of this study is to determine the effectiveness of endometrial cancer screening tests in women with certain risk factors. This research involves one study visit and compensation is provided. For more information, contact 717-531-1540 or seyer@psu.edu. IRB# 20175; PI: R.S. Legro.

Weight-Loss Study
Nonsmoking, premenopausal women, between the ages of 25 and 45 who want to lose weight and are willing to follow a reduced-calorie diet for eighteen weeks can get involved in a new study on the University Park campus. The purpose of the study is to evaluate the differences in how two diets affect inflammation, bone density, cholesterol levels, and blood pressure in premenopausal women. Nutrition education and snacks will be provided during the entirety of the study. All test sessions will take place in Chandlee Lab, under the supervision of Dr. Sharon Nichols-Richardson, RD. To qualify, women must be 25-45 years old; in good health; have a body mass index (BMI) of 25-43 (for help calculating your BMI please visit www.bmicalculator.net); be available to attend an orientation session, four blood draw sessions, and weekly diet sessions; be willing to discontinue all current supplement regimens during the study and follow a reduced calorie diet; and must not be pregnant or plan to become pregnant during the study. For more information, please call the Bone Laboratory at 814-865-5926 or e-mail Kathryn Piekowski, RD, at kep158@psu.edu.

TrialNet
TrialNet is an international research study that screens relatives of people with type 1 diabetes to assess their risk for developing diabetes. Relatives (ages 1-45) may be eligible to be screened with one blood test at no cost. This study is aimed at tracking the development of diabetes and includes experimental diabetes prevention treatments. For more information, contact Kathy Peters at 800-393-0782 or kfp1@psu.edu. IRB# 18620; PI: J.S. Ulbrecht.

PSIDO Research Volunteer Database
If the studies listed in this newsletter do not interest you, consider enrolling in the PSIDO Research Volunteer Database. This database is used to provide Penn State investigators with contact information for persons interested in participating in studies on diabetes and obesity. Signing up for the database will allow investigators to contact you directly with information about studies such as the ones described above, but it does not obligate you to participate.

For more information, contact us at 1-800-393-0782 or reinventcare@hhdev.psu.edu. You can sign up for the database online by going to www.pennstatehershey.org/web/diabetesandobesity/patientcare/clinicaltrials.
Clinical Questions and Answers:

Q. Since I have diabetes, will I develop foot problems?
A. Many people know someone who lost part of a leg to diabetes, but such amputations can almost always be prevented. The problems that can lead to an amputation usually start with nerve damage in the feet (neuropathy), which can come from diabetes. However, this is much less likely to develop if a person controls their blood sugar, blood pressure, and blood fats (cholesterol). But even if a person does develop neuropathy, amputations can be prevented.

Q. My feet feel cold all the time and sometimes they sting and burn, but my doctor keeps telling me my circulation is good; what’s the problem?
A. The feelings you have in your feet are from nerve damage also known by the medical term neuropathy. Neuropathy always starts in the longest nerves in the body—those to the big toes—and if it gets worse, it “moves” into the rest of the feet and up the legs. As nerves are damaged, they can send off false feelings—pins and needles; electric shock or “shooting” pains; feeling like feet are cold, hot, or burning; and so on. Normal feelings can also feel abnormal, so contact with shoes or bed sheets can be painful, and some people feel like they are walking on rolled up socks or pebbles. Another problem with neuropathy is that the nerves can stop sending information from the feet to the brain, and feet can be injured without the person knowing it—we call that loss of protective sensation (LOPS). And to make matters worse, some people can experience false feelings and LOPS at the same time. But neuropathy is not caused by poor circulation, which is why your doctor keeps telling you that your circulation is good.

Q. I was just diagnosed with diabetes and have read I should not walk barefoot; is that true?
A. People with diabetes can develop nerve damage in the feet. If that includes LOPS, it is possible that, without knowing it, those people can damage their feet when they step on something sharp. And that’s the important part, because, without knowing it, you may not take care of that cut or bruise. So people with LOPS should do everything they can to avoid getting their feet injured—and therefore should not walk barefoot. But if you have good feeling in the feet, which is usually the case when you are first diagnosed, walking barefoot is not a problem, even on the beach. How will you know if you have LOPS? There is a simple test your doctor will do once a year, and that’s all that’s needed.

Q. I have been told that I have neuropathy and that I should examine my feet every day, but what am I looking for?
A. When you have LOPS, you might not feel when you get a cut, a bruise, or a blister, and you might not feel if the bath water is too hot. You might also not feel if your shoes are too tight. If you have LOPS, you should try hard to avoid situations that might cause injury—your doctor or diabetes nurse can teach you how—and you need to look at your feet at least once a day to make sure there are no cuts, bruises, or blisters. If you find something, call your doctor that day for help getting it healed.

Do you have questions for our experts about diabetes or about how to keep or achieve a healthy weight? E-mail us at reinventcare@hhdev.psu.edu.

Ask the Expert: Foot Problems and Foot Care for Diabetes

Judy Pfleegor, PT, C.Ped., Director, Mount Nittany Medical Center Diabetes Foot Clinic, State College, PA
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Diabetes is a difficult and expensive condition to manage. When diagnosed, individuals must take new medications, make better food choices, and regularly monitor their health status at home (for example, by checking their blood sugar). Perhaps more importantly, individuals with diabetes must stick with these behaviors day in and day out to manage their condition and improve or at least maintain their health.

Doctors and nurses are used to telling patients what to do, but how can the doctor or nurse really know what will work best for each patient when it comes to making changes in their lives? And how often does telling somebody to do something really work?

DYNAMIC (Diabetes Nurse Case Management and Motivational Interviewing for Change) is a Penn State research study sponsored by the National Institutes of Health. The purpose of the study is to investigate if motivational interviewing can improve adherence to treatment recommendations for health for people with type 2 diabetes. Motivational interviewing is a patient-centered counseling style for helping patients change behavior by helping them define their own goals, their own reasons for changing, and their way toward making changes. It is a process that encourages patients to decide why and how to change for better health. This approach to dealing with patients is relatively new for doctors and nurses.

DYNAMIC is also seeking to help doctors change in other ways—by working as a team not just with each patient, but also with nurses, dietitians, social workers, and other professionals. Doctors and our health care system are good at dealing with what is called acute care—problems that can be cured like an injury or infection—but we are not very good at supporting people who have to live with chronic, incurable problems like diabetes. DYNAMIC is testing other ways of changing care toward better long-term outcomes. This type of study is an example of how researchers at Penn State are working to reinvent diabetes and obesity care.

Over the past three years, 549 adults have enrolled in the DYNAMIC study. An analysis of the information collected about these individuals at their first study visit showed that 40 percent were Hispanic and the average age was 52 years old. On average, participants had elevated HbA1c (average: 8.4), high blood pressure (average: 137/77), and high LDL cholesterol (average: 114). Importantly, many reported feeling significantly depressed and having a low quality of life. It is readily apparent that the individuals in the study are in need of an intervention to help improve their health and lives.

In this study, participants have responded favorably when they were involved in motivational interviewing. They report feeling that they are listened to and that the nurse truly understands the barriers they face in making behavior changes. Additionally, they report that they appreciate being able to choose the specific self-management goals they would like to work on.

Individuals in the study will come for study visits and have study related tests for two years. Half of the participants will meet with nurses who will use motivational interviewing techniques. The other half of the participants will have standard appointments. The final results will be available in 2010. The study participant characteristics were recently published in the journal Contemporary Clinical Trials.
Polycystic ovary syndrome (PCOS) is a condition that affects 5-10 percent of women. The name comes from the fact that women with the condition often have many small cysts in the ovaries, which are caused by poorly developed follicles in the ovaries. Ovarian follicles are “balloons” of cells in the ovary, each of which contains an egg cell. In PCOS, the follicles do not mature normally, and they fail to move to the edge of the ovary (where they normally release their eggs). Instead, the follicles remain in the ovary and become cysts. These cysts are readily seen by an ultrasound examination of the ovaries.

PCOS is one of the most common causes of fertility problems in the United States. Other features of PCOS include irregular periods, depression, excessive weight gain (despite diet and exercise efforts), acne, and excess facial and body hair. All of these problems are related to irregular hormone levels. Not all women are affected by PCOS to the same degree—some may have problems primarily with the menstrual cycle, while others more of the skin problems, etc.

Many women with PCOS also have insulin resistance, a condition that is a precursor to type 2 diabetes and leads to abnormal blood fat levels that can in turn cause heart attacks and strokes. Insulin resistance means that insulin has trouble doing its job, and like the other symptoms of PCOS, insulin resistance is thought to be related to the hormone imbalance that is part of PCOS.

Treatment of PCOS must deal with both the obvious problems (infertility, acne, excess body hair, etc.) and also with the problems not readily apparent—with helping women reduce their risk of developing type 2 diabetes vascular disease.

Most women with PCOS are diagnosed and treated by their primary care doctor and/or an endocrinologist. Medications are available to treat many of the symptoms of the condition. However, treatment is not perfect, and so a number of researchers at Penn State are conducting studies to help better the lives of women with PCOS. In fact Penn State researchers are recognized internationally as leaders in PCOS research and treatment.

One such study is being conducted by Dr. Richard Legro, of the Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology, at the Penn State Hershey Medical Center, in conjunction with researchers at the University of Pennsylvania headed by Dr. Christos Coutifaris. The study is looking at the effects of pre-pregnancy weight loss, oral contraceptive use (which can improve other symptoms of PCOS), and the combination of both interventions on pregnancy outcomes. Women with PCOS and those who are significantly overweight without PCOS are eligible for this study. Researchers hope to determine which pre-pregnancy strategy leads to the best chance for pregnancy and a healthy baby. For more information about this study and other studies for women with PCOS or who are overweight, refer to “Ongoing Research” on page 2.
Research News

Cholesterol and PCOS

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Adequate levels of sex hormones such as estrogen and testosterone are important for proper health. Women with polycystic ovary syndrome (PCOS) have an imbalance in their hormones, including elevated levels of testosterone. Since testosterone is made from cholesterol, elevated levels of cholesterol may contribute to elevated levels of testosterone in women with PCOS. Dr. Richard Legro and I recruited women with PCOS for a study to learn whether these women had elevated levels of LDL cholesterol. If so, the results would suggest that treating women with PCOS with cholesterol-lowering medications may alleviate some of the symptoms of PCOS (see Keynote Topic, page 7).

The results of the study showed that, at baseline, 71 percent of the women (twenty of twenty-eight) had elevated LDL cholesterol levels. We presented these results at the 2008 National Institutes of Health’s Office of Research on Women’s Health symposium.

These results served as the basis for a subsequent project of ours, which studies the effects of atorvastatin (a cholesterol lowering medication) on cholesterol levels, hormone levels, and other problems associated with PCOS. We have been enrolling and following women with PCOS who have agreed to take the study medication. The results of this study are currently under review and will be published shortly.

Upcoming Events

Information Session on Surgical Weight Loss

Are you more than 100 pounds overweight? Do you have medical problems that are getting worse as your weight goes up? Have you tried multiple ways to lose weight without any success? If you answered yes to any of these questions, you may be a candidate for surgical weight loss. To register for a free information session to learn if surgical weight loss is right for you, call Penn State Hershey Surgical Weight Loss at 1-877-609-6848 and press option 1 to start.

Other Events

The Penn State Institute for Diabetes and Obesity periodically sponsors or participates in community events to raise awareness about diabetes and healthy weight management. For more information about these events, visit www.pennstatehershey.org/web/diabetesandobesity/community/awarenessevents.

Connect with PSIDO

If you have any friends or family with whom you wish to share this newsletter, please feel free to forward it to them. They can also e-mail us at reinventcare@hhdev.psu.edu to be added to our distribution list. If you wish to be taken off of the electronic mailing list, please reply to reinventcare@hhdev.psu.edu and we will remove your name from the list.

If you have any topics that you would like to see covered in an upcoming newsletter, please send your suggestions to reinventcare@hhdev.psu.edu.