The first article in this issue, which I authored, is entitled, “The Four-Year Results of the Look AHEAD Trial: Implications for Evidence-based Practice in Type 2 Diabetes.” The Look AHEAD study is an excellent example of how a large long-term, randomized, controlled clinical trial can contribute powerful evidence about the impact of a lifestyle intervention on weight loss, glycemic control, other cardiovascular risk factors; and the ability to reduce the use of medications for these conditions. It is important to remember that the Look AHEAD Study is an efficacy trial. Efficacy trials (explanatory trials) determine whether an intervention produces the expected result under ideal circumstances, i.e., they are proof of concept trials. Therefore, it is critical that the intervention dose and frequency are intensive enough to produce changes in weight and physical activity significant enough to answer the study question, “Will a lifestyle intervention aimed at 7% weight loss and at least 175 minutes of physical activity reduce cardiovascular morbidity and mortality in people with type 2 diabetes (T2DM)?” Evidence from efficacy trials is often applied to MNT practice guidelines and thus it is important to examine their results carefully for clinical practice implications.

Efficacy and effectiveness exist on a continuum. Effectiveness trials (pragmatic trials) measure the degree of
ON THE CUTTING EDGE
Diabetes Care and Education

American Dietetic Association

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MISSION
DCE members are the most valued authorities on nutrition and diabetes prevention, education, and management.

VISION
DCE members lead the future of nutrition and diabetes prevention, education, and management.

STRATEGIC PRIORITY AREAS

GOAL 1: Sustain and grow a high level of satisfaction and retention among members.

Use electronic technology to engage new and existing members.
Promote and support member professional development.
Maintain a high value of membership.

GOAL 2: Advance DCE’s unique position as the authority in nutrition and diabetes prevention, education and management.

Promote and maintain new DCE image.
Develop domestic and global alliance and stakeholder relationships.
Promote and support evidence-based practice and research.

The beneficial effect under “real world” clinical settings. Hence, hypotheses and study designs of an effectiveness trial are formulated based on conditions of routine clinical practice and on outcomes essential for clinical decisions. The Diabetes Prevention Program (DPP) was designed as an efficacy trial; however, many effectiveness trials have been conducted to translate the use of the DPP lifestyle intervention into primary care, work site and community settings (1).

The article by Madelyn Wheeler, MS, RD, CD, CDE, FADA, and David Marrero, PhD, on “Translating the Diabetes Prevention Program Intervention into the Community: the YMCA Experience” is a great illustration of how effectiveness research was designed and implemented to translate the DPP lifestyle intervention to the YMCA community. More importantly, the evidence generated from this effectiveness research, and the potential for nationwide reach using the YMCA setting, has led to some major transformations in health care delivery models: the establishment of the National Diabetes Prevention Program at the Centers for Disease Control and Prevention (CDC) that is providing national training; a recognition program for community-based DPPs; and the potential for third-party payers to provide reimbursement for these programs. These exciting developments, which have emanated from both efficacy and effectiveness research, offer important prevention opportunities for registered dietitians (RDs) and the estimated 79 million people with pre-diabetes in the United States!

The article by Diane Reader, RD, CDE, on “Current Research and Recommendations for Medical Nutrition Therapy in Patients with Gestational Diabetes” is another example of how research can impact practice guidelines by changing diagnostic criteria. If the new recommendations in the diagnostic criteria for gestational diabetes (GDM) are universally accepted, then the number of GDM cases in the United States is likely to double. This will also have an effect on the scope of practice for RDs who provide evidence-based MNT. Knowing the trends in research will help RDs to position themselves for more referral opportunities from primary care providers, obstetricians and nurse practitioners.

Marie-France Hivert, MD, MMSc and I collaborated on the article, “Genetic Testing and Personalized Medicine in Prevention of Type 2 Diabetes: Are We...
Research Toolkit

Are you interested in the latest dietetic research but not sure how to interpret the published data or apply the results to your practice? Do you want to collect outcomes data, but don’t know how to get started? A new online Research Toolkit, developed by ADA’s Research Committee is available free of charge to ADA members at http://ada.portalxm.com/research_toolkit/index.cfm. In addition to providing you with essential information on understanding and conducting research, continuing education credits are available for some topics.

The Toolkit consists of seven content topic areas. Each topic includes text that summarizes important learning points, PowerPoint presentations, practice exercises to reinforce learning, and links to nutrition and dietetics research articles that illustrate content learning objectives. The seven content topics areas will help you to:

- Find research that relates to areas of interest
- Critically appraise an article
- Evaluate whether the study design is suitable to answer the research question and test the hypothesis
- Interpret statistics and determine whether they are appropriately utilized in the study
- Apply research to practice
- Determine the first step in a research project
- Develop a good research question with a testable hypothesis

Additional topic areas for the Research Toolkit are under development. If you are interested in participating by developing or testing content materials, please contact Donna Pertel, MEd, RD at dpertel@eatright.org.

Carol Ireton-Jones, PhD, RD
Research Toolkit Sub-Committee Leader

Ready? Lessons from the Diabetes Prevention Program.” This article addresses the evidence in an emerging area of research – the interface of diabetes, genetic risk and lifestyle. It illustrates a critical concept: the importance of not going beyond what is supported by the evidence when translating research into clinical practice; doing so could negatively impact the credibility of the practitioner. Genetic testing to identify risk for T2DM is not ready for clinical practice at this time because it is a still-growing field. To date, genetic risk scores for T2DM do not add significant predictive value beyond the clinically available risk factors, however there is evidence to support a change in the way we frame our clinical messages to clients. As RDs, we can use this evidence to provide appropriate counsel about the value of genetic testing and to help motivate patients who might feel destined or fated to develop diabetes because of their genetic risk. We can also help them to reframe their thinking so they will feel empowered to prevent diabetes with modest lifestyle changes.

Research is the foundation of cutting-edge clinical practice. Improving your understanding of how to read and interpret research findings and applying research results to your practice can boost your career and yield incredible benefits for your customers, patients and clients. The article by

OTCE Summer 2011

Acknowledgments

THANK YOU!

To the following people for assisting with the development of this issue of On the Cutting Edge:

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Linda Flanagan Vahl
Judith Wylie-Rosett, EdD, RD, “Dissecting Research Articles,” is a step-wise guide for analyzing and interpreting research articles. I encourage you to read this article and use it as a roadmap to critically evaluate research and to help guide your decision making regarding evidence-based communications and practice.

To be credible and respected in our profession, it is critical that the art of MNT is backed by science. As RDs, we must demonstrate the ability to communicate the research evidence supporting diabetes MNT, counseling approaches, and nutrition education strategies and programs to other medical professionals, the media and the public. In addition, we need to help build the evidence to support the effectiveness of MNT. “Getting Started in Research: It Can Be Done,” by Maggie Powers, PhD, RD, CDE, is an excellent guide that outlines the steps on how to get started by collecting data to answer important research questions in your work setting and then publishing your research. For more information on how to analyze research articles and collect outcomes data, check out the new online Research Toolkit, developed by ADA’s Research Committee available free of charge to ADA members at http://ada.portalxm.com/research_toolkit/index.cfm. (Details on page 3)

In clinical practice, your ability to communicate and apply evidence-based research can improve the quality of care and client/patient outcomes, as well as establish the RD as a critical component of cost-effective health care. Outcomes research can increase inpatient consults and outpatient referrals to the RD, which in turn, can help support the need for maintaining or increasing staffing patterns and salaries. Moreover, understanding and using evidence-based research in your communications with other health professionals will increase your credibility and the likelihood of you being included in research collaborations in your practice area. The bottom line is research helps to prove the value of RD services, which can increase the demand for our services and provide job security and new opportunities!

If you are interested in improving your research skills and overall involvement in research, consider the 10 Ways to Build Your Research Skills listed above.

In closing, I would like to thank my wonderful, dynamic and enthusiastic Theme Team of Judith Wylie-Rosett, EdD, RD, Beth Mayer-Davis, PhD, RD, Maggie Powers, PhD, RD, CDE and Wahida Karmally, DrPH, RD, CDE, CLS. Their contributions to the idea-generation process made this issue a reality. My sincere gratitude also goes to the authors for contributing their expertise and efforts and to the expert reviewers for dedicating their time to review the articles and provide excellent feedback and recommendations. Finally, special thanks to Liz Quintana, EdD, RD, LD, CDE, OTCE Editor, and Alyce Thomas, RD, Associate Editor, without whose help this issue would not have been possible.

References

10 Ways to Build Your Research Skills

1. Follow the progress of multicenter clinical trials in diabetes that are forming evidence-based clinical practice. Listen to presentations of the results, read the research publications, carefully study the details of the nutrition interventions in these clinical trials and apply them to your practice. Use evidence-based materials from study websites and the National Diabetes Education Program website.
2. Read meta-analyses and reviews as a way to keep current and to understand the totality of the evidence in a specific area including the strengths and limitations of the research to date.
3. Learn from published research. Pay careful attention to the methods of research articles to see how studies are designed. Read the discussion sections of articles to learn about the strengths and limitations of specific research studies.
4. Use the Evidence Analysis Library (EAL) to stay informed of the research that supports practice and also pay attention to the areas mentioned as research gaps where more or stronger evidence is needed.
5. Apply to become an EAL work group member or evidence analyst. You will participate in a 2-day, evidence-based training workshop and learn to read and analyze articles. Go to the EAL Web site and click on “About” then select “Get Involved” for more information.
6. Join a journal club or start one to discuss research articles with colleagues.
7. Join the Dietetics Practice Based Research Network (DPbRN) by enrolling on the ADA Web site. The DBPRN conducts, supports, promotes and advocates for research in practice-based settings. By joining the DBPRN, you can become a part of research that is meaningful for your dietetics practice and in turn, make your practice part of meaningful dietetic research. As a member, you also have access to the top research experts in the field and network with others who share your passion for dietetics!
8. Approach colleagues conducting research and express interest in contributing your nutrition expertise and collaborating.
9. Find a mentor to guide you in building your research skills.
10. Use the new ADA online research toolkit that was designed to improve the research skills of RDs (see text box) for the highlights of this new resource for all ADA members.
Abstract

Look AHEAD is a randomized controlled clinical trial designed to examine whether intensive lifestyle intervention (ILI) will have better results than diabetes support and education (DSE) in reducing cardiovascular morbidity and mortality in 5,145 people with type 2 diabetes aged 45 to 74 years. After 4 years of follow-up, weight loss was significantly greater with ILI than DSE—4.7% compared with 1.1%, respectively (P<.001)—and fitness levels were 5.1% above and 1.1% below baseline in ILI and DSE, respectively (P<.001). A greater proportion of ILI participants met hemoglobin A1C (A1C), blood pressure and lipid goals compared with the DSE group, and did so with less medication. This article summarizes the 4-year results and discusses implications for evidence-based clinical practice.

Introduction

When completed in 2014, Look AHEAD will be the longest, continuously implemented lifestyle intervention targeting weight loss and increased physical activity. Moreover, it will be the first randomized, controlled clinical trial to examine whether lifestyle intervention reduces cardiovascular morbidity and mortality in people with type 2 diabetes mellitus (T2DM). The results of Look AHEAD’s first 4 years of treatment have been published (1). It is critical that registered dietitians (RDs) understand how these results support the evidence for weight management and physical activity in managing the risk factors related to T2DM and cardiovascular disease (CVD).

It is important to interpret the 4-year results of Look AHEAD in the context of characteristics of the study population, study design and interventions, and to examine the results in terms of adherence to assigned interventions, clinical outcomes and retention of study participants. Participants from 16 centers across the United States were eligible if they met the following criteria: age 45 to 74 years (changed to 55-74 years in year 2) with body mass index (BMI) greater than 25 kg/m² (less than 27 kg/m² if taking insulin), A1C less than 11%, blood pressure less than 160/100 mm Hg and triglycerides less than 600 mg/dL. Recruitment also targeted a goal of more than 33% racial-ethnic minorities as part of the study design. This cohort represents a large and diverse sample of people with T2DM (63.3% white, 15.6% non-Hispanic black, 13.2% Hispanic, 5% American Indian and 1% Asian), and closely parallels the ethnic distribution of people with T2DM in the National Health and Examination Survey 1999-2000 survey (3).

Study Design and Interventions

Participants were randomly assigned to receive intensive lifestyle intervention (ILI) or diabetes support and education (DSE) according to a standardized protocol. The DSE program participants were offered three group sessions per year that focused on diet, activity and social support to enhance retention, however they had no specific clinical goals. The ILI program had two goals: (1) to lose 7% of initial weight at 1 year and maintain that weight loss in subsequent years and (2) to increase activity to at least 175 minutes per week using activities similar in intensity to brisk walking. To enhance the likelihood of achieving an average of 7% weight loss, ILI participants were given individual goals of 10% weight loss and assigned calorie and fat gram goals based on initial weight: 1,200 to 1,500 calories (40 to 50 g fat) for initial weight of 250 pounds or less and 1,500 to 1,800 calories (50 to
60 g fat) for initial weight more than 250 pounds, with dietary goals of less than 30% of calories from fat, less than 10% saturated fat and at least 15% of calories from protein (4).

To meet the nutrition and weight goals, participants were encouraged to use two commercially available liquid meal replacements and two snack replacements per day and structured menus for their main meal for the first 4 to 16 weeks. After that, they were encouraged to make a transition to one meal replacement and one snack replacement per day and to continue with structured menus and meals and a portion-controlled diet for the rest of the day (https://www.lookaheadtrial.org/public/LookAHEADProtocol.pdf). Participants were asked to self-monitor calorie and fat intake, activity, weight and blood glucose levels to assess the effectiveness of the intervention and identify barriers to adherence. Goal setting skills, problem solving, stress management and other behavioral strategies were also emphasized throughout the program (4).

The Look AHEAD ILI was delivered in a group plus individual format. Participants were offered three group sessions and one individual session per month in the first 6 months, two group sessions and one individual session per month during months 7 to 12 and then monthly individual sessions and two to three 4- to 8-week group programs per year for the remainder of the study duration (4,5).

The Look AHEAD ILI curriculum was adapted from the Diabetes Prevention Program (DPP) and tailored to people with T2DM. However, the intervention was designed to be more ambitious than the DPP in its goals for weight loss, activity, calorie and fat gram intake, frequency of contact and use of meal replacements. This is because people with T2DM enrolled in weight loss programs have traditionally lost less weight than their persons without diabetes counterparts and because of the need in this efficacy study to produce weight loss over 12 years to answer the primary study question (5).

**Study Results**

After 1 year of intervention, the ILI group participants had lost 8.6% of initial body weight compared with the DSE group who had lost 0.7% of body weight. In the ILI group, 37.8% and 55.2% of participants met the 10% and 7% weight loss goals, respectively, compared with 3.2% and 7% of DSE participants (2). Fitness levels had increased by 20.4% in ILI participants and 5% in DSE participants. In addition, the percentage of ILI participants who attained the American Diabetes Association (ADbA) goal of A1C less than 7% increased from 46% to 73% despite the fact that these participants decreased their use of glucose-lowering medications. By comparison, the percentage of DSE participants who met A1C goals increased from 45% to 50% at 1 year. Moreover, the percentage of participants who met all three ADbA goals for glycemic control, blood pressure and lipids increased from 10.8% to 23.6% in the ILI group compared with 9.5% to 16% in the DSE group at 1 year (**P** < .001) (2).

After 4 years of intervention, the ILI group maintained significantly greater improvements in weight loss and fitness levels than the DSE group. The ILI participants sustained a mean weight loss of 4.7% compared with a 1.1% weight loss in DSE participants (**P** < .001); fitness levels of ILI participants were still 5.1% over baseline and of DSE participants were 1.1% below baseline (**P** < .001) (1).

### Table. Mean Changes in Weight, Fitness and CVD Risk Factors in ILI and DSE Groups Averaged Across 4 years*

<table>
<thead>
<tr>
<th>Measure</th>
<th>DSE</th>
<th>ILI</th>
<th><strong>P</strong> Value **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight, % initial weight</td>
<td>0.88</td>
<td>-6.15</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Fitness, % METS</td>
<td>1.96</td>
<td>12.74</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>A1C level</td>
<td>-0.09</td>
<td>-0.36</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>SBP, mm Hg</td>
<td>-2.97</td>
<td>-5.33</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>DBP, mm Hg</td>
<td>-2.48</td>
<td>-2.92</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>HDL-c level, mg/dL</td>
<td>1.97</td>
<td>3.67</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Triglycerides level, mg/dL</td>
<td>-19.75</td>
<td>-25.56</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>LDL-c level, mg/dL (without adjustment for med use)</td>
<td>-12.84</td>
<td>-11.27</td>
<td>.009</td>
</tr>
<tr>
<td>LDL-c level, mg/dL (adjusted for med use)</td>
<td>-9.22</td>
<td>-8.75</td>
<td>.42</td>
</tr>
</tbody>
</table>

CVD, cardiovascular disease; ILI, intensive lifestyle intervention group; DSE, diabetes support and education group; METS, metabolic equivalents; A1C, hemoglobin A1C; SBP, systolic blood pressure; DBP, diastolic blood pressure; HDL-c, high-density lipoprotein cholesterol; LDL-c low-density lipoprotein cholesterol.

* Adapted from 4 year results (1).
** **P** value of difference between groups.
As might be expected, for several risk factors, the differences between ILI and DSE participants were most evident in the first year. However, when averaged across 4 years, the sustained differences in weight loss and fitness in ILI and DSE groups led to sustained significant improvements in CVD risk factors in the ILI group compared with the DSE group (Table) (1). Although low-density lipoprotein (LDL) cholesterol was significantly lower in the DSE group than in the ILI group, this difference appears to be related to the fact that the DSE group was taking more lipid-lowering medication; once the results were adjusted for lipid medication use, the difference in LDL cholesterol levels between ILI and DSE was no longer significant.

Also, compared with DSE, a significantly greater proportion of the ILI group met the ADA goals for A1C at each year (P<.001) and for blood pressure at years 1, 2 and 3 (P<.001, P=.003, P<.05, respectively). The significantly better outcomes of A1C and blood pressure were achieved with a smaller proportion of ILI participants who needed medications to achieve these goals. In a population-based survey of people with diabetes, 42% had A1C levels less than 7% compared with 73% and 57% of ILI participants at year 1 and year 4, respectively; 48% met blood pressure goals compared with 69% and 63% of ILI participants at year 1 and year 4, respectively. A comparable proportion of people met the LDL cholesterol goals in the national sample and Look AHEAD (1).

**Implications for Clinical Practice**

The Look AHEAD trial is the first study to examine the effects of ILI through 4 years of follow-up in a large cohort of people with T2DM who are overweight or obese. Study retention has been excellent, with 93% of participants completing outcome assessments at each of 4 years. Therefore, the results of this efficacy trial have important implications for clinical practice.

- The Look AHEAD study provides evidence for the effectiveness of combining a reduced-calorie, low-fat diet with increased physical activity to produce clinically significant weight loss and reduce cardiovascular risk factors (specifically A1C levels, systolic blood pressure and high-density lipoprotein cholesterol) over 4 years.
- Achieving weight loss and increased physical activity improved management of the “ABCs” of diabetes—A1C, blood pressure and cholesterol—in the ILI group compared with DSE and did so with fewer medications.
- Use of meal replacements as part of a structured diet resulted in significantly more weight loss. Those with the highest use of meal replacements (~12/week) had an average weight loss of 11.2% whereas those with the lowest use (~2/week) lost 5.9% of initial weight after the first year of intervention (6).
- Although it is true that participants enrolled in the Look AHEAD trial were screened and selected based on their willingness to participate and commit to the follow-up schedule, the importance of assessing motivation and readiness is relevant in both research and clinical settings (7). Furthermore, the randomization procedure demonstrates the comparative effectiveness of the two study interventions in participants who were motivated, yet willing to accept either the intensive or basic intervention.
- The intervention was effective in a large, diverse group of people with T2DM in terms of age, gender, ethnicity, duration of diabetes and treatment of diabetes which makes the findings more compelling.
- Although insulin users did lose less weight than non–insulin users (7.6% vs.8.7%, P<.002) at 1 year, the program has still been very effective in this subgroup. In fact, about 20% of the ILI participants who were taking insulin at baseline were able to discontinue insulin use by year 1 compared with 8% of DSE participants (P<.001) and this pattern persisted over 4 years of intervention (1).

As we consider the role of a low-calorie, low-fat diet combined with physical activity in the management of T2DM, it is important to consider the constellation of effects on weight, glycemic control, blood pressure, lipids, medications and insulin use that have occurred with this intervention. As we reflect on implications for clinical practice, it is important to bear in mind that the most compelling evidence for use of carbohydrate counting is seen in people who have type 1 diabetes (8). While attention to carbohydrate counting definitely helps manage glycemia in patients with T2DM (8), it is possible that weight loss and increased activity may actually target the underlying causes of T2DM by improving insulin sensitivity as was seen in the DPP (9). Research using a low-fat low-calorie diet in obese patients with T2DM has shown that moderate weight loss normalizes fasting hyperglycemia in patients with poorly controlled T2DM; a relatively small pool of
intrahepatic lipid is mobilized, which reverses hepatic insulin resistance and normalizes rates of basal glucose production, independent of any changes in insulin-stimulated peripheral glucose metabolism (10).

Over the past two decades, data suggest that adipocytes are not just storage depots for excess calories, but are metabolically active and release a number of substances (inflammatory markers and free fatty acids) which are implicated in insulin resistance. Future research in the Look AHEAD trial may better explain the mechanisms by which modest weight losses and moderate increases in activity lead to improvements in CVD risk factors with less medication in people with T2DM, and whether these differences in risk factors translate to reductions in CVD events over time.

Because Look AHEAD is an efficacy trial, it will be up to RDs and other health care providers to translate these findings into clinical practice. Analyses of the cost-effectiveness of the Look AHEAD intervention are under way. If the final results of the Look AHEAD trial continue to demonstrate a benefit of ILI, then it is likely that other less intensive and less costly versions of this intervention will be tested in effectiveness trials as has been done with the DPP lifestyle intervention (11,12). In the meantime, RDs interested in adopting this evidence-based approach can access the counselor manual and materials for the first year of the Look AHEAD lifestyle intervention program (https://www.lookaheadtrial.org/public/dspMaterials.cfm).

References
Abstract
The Diabetes Prevention Program of the National Institutes of Health proved that the risk of developing diabetes could be reduced substantially (58%) through lifestyle intervention in a controlled setting. It was, however, too costly to be translated into a broader public health program. This article describes the program’s lifestyle intervention and the challenges of developing and implementing a translation study, as undertaken by the Indiana University–Young Men’s Christian Association (YMCA) pilot program. In addition, the potential nationwide reach of the YMCA and the community diabetes prevention programs of the Centers for Disease Control and Prevention are discussed.

Introduction
The latest Centers for Disease Control and Prevention (CDC) figures indicate that 25.8 million people in the United States have diabetes, and another 79 million people are estimated to have prediabetes (1). If current trends continue, the CDC projects as many as one in three US adults could have diabetes by 2050 (2). Therefore, reducing the annual number of newly diagnosed cases of diabetes in the U.S. population, with a goal of at least a 10% improvement before 2020, is a major public health objective (3).

Research shows that type 2 diabetes (T2DM) can be prevented or delayed. The Diabetes Prevention Program (DPP) was a multicenter National Institutes of Health–supported controlled clinical trial designed to test the hypothesis that a lifestyle intervention resulting in modest weight loss and increased physical activity or medication (metformin) would prevent or delay the development of diabetes in comparison with a placebo (4).

The goal of the DPP lifestyle intervention was to achieve and maintain a weight reduction of at least 7% of initial body weight and to increase physical activity, such as brisk walking, to 150 minutes per week. The method used to help participants reach these goals was a multifaceted and intensive lifestyle intervention program (5,6) based on a healthy lower calorie, lower fat diet.

Key features (Table 1) included the following:
1) A goal-based behavioral intervention which included an initial structured, individually presented 16-session core-curriculum (lasting 16-24 weeks), a supervised physical activity program, and an ongoing maintenance program with supplemental group classes, motivational campaigns and restart opportunities.
2) Case managers or “lifestyle coaches” who delivered individualized intervention and provided frequent contact with participants. Most of the lifestyle coaches were registered dietitians (RDs), with the remainder typically having master’s degrees in exercise physiology, behavioral psychology or health education.
3) An individualized “toolbox” of adherence/incentive strategies. The toolbox strategies were arranged in a hierarchy from less expensive to more expensive approaches (in terms of staff time as well as money) and contained problem-solving strategies and reinforcements. For example, a participant could be enrolled in a community exercise class or given a cookbook or grocery store vouchers. Approximately $100 per participant per year was available for implementing toolbox strategies.
4) Various materials and strategies that addressed ethnic diversity.
5) An extensive local and national network of staff training, feedback and clinical support provided by the University of Pittsburgh lifestyle-coordinating center.

During the 2.8 years of the DPP, diabetes incidence in high-risk adults was reduced by 58% in the intensive lifestyle intervention group compared with the control group. This risk reduction was associated
with a weight loss of about 5 kg (representing about 5% of initial weight) (7). The biggest predictor of weight loss was a lower percentage of calories from fat and an increase in physical activity (7). The per capita direct medical cost of the lifestyle intervention was $1,399 for the first year, and $2,250 over 3 years (8), with most of the costs (compared with the placebo group) accounted by staff time used for counseling and adherence monitoring. During the 10-year follow-up since randomization, the original lifestyle group lost, then partly regained, weight; however, at 10 years, the diabetes incidence was still (34%) lower than that of the placebo group (9).

Translation to the Community

While the DPP results are significant, the study was an efficacy trial conducted in a controlled situation without regard for translatability to the broader public health arena. In this context, translating the DPP intervention to the community context was cost prohibitive. Given the robust effectiveness of the intervention, the challenge was to design a cost-neutral or cost-effective program, based on the DPP lifestyle concepts, which could be presented in diverse U.S. communities. One solution is presented: the Indiana University (IU)–Young Men’s Christian Association (YMCA) model.

Development of the IU-YMCA Model

Identifying a community partner having the resources, capability, and interest in delivering a modified DPP lifestyle intervention was the first challenge. The YMCA is a nationwide, nonprofit, community-centered service organization focusing on healthy living, well being and fitness. It is accessible to all ages, faiths, backgrounds, abilities and income levels. There are currently almost 2,700 YMCA facilities in the United States, serving over 21 million people (10). The IU-Diabetes Translational Research Center (IU-DTRC) was able to form a partnership with the YMCA of Greater Indianapolis to carry out the pilot study.

Modifying the DPP Curriculum

The DPP curriculum format and content were modified by the IU-DTRC and the Indianapolis YMCA to reduce costs and time requirements while improving long-range sustainability (11). One of the goals was to retain the integrity and philosophy of the DPP lifestyle intervention (11) (Table 1).

- Physical activity and weight loss goals were the same, as was the basic training in diet, exercise and behavior modification skills.
- The emphasis on self-esteem, empowerment and social support was continued.
- A structured protocol (in which all participants received certain common information points) continued to be used, which was tailored to meet individual needs.
- Diet and physical activity interventions were still flexible, culturally sensitive and acceptable in the context of the local communities in which they are implemented.
- Many of the curriculum tools used in the original DPP intervention were retained, including a personalized copy of all core curriculum lesson plans, weekly food and activity tracking logs, guidebooks for fat and calorie content and portion sizes for common restaurant and self-prepared foods, measuring cups and spoons, and food scales and pedometers.

The changes from the original DPP curriculum included the following:
- Shifting the core curriculum from an individual to a group-based delivery format
- Eliminating costly toolbox incentives
- Introducing a formal exercise training system
- Delivering the program using local YMCA staff trained in behavioral counseling rather than specialized lifestyle coaches (11). The YMCA staff members selected as lifestyle coaches were provided a 2½-day group-instructor training to implement the IU-DTRC adaptation of the DPP lifestyle intervention (12).

Following the IU-DPP example, RDs, exercise physiologists, psychologists and physicians were used as resources for the YMCA lifestyle coaches and, in addition, were available for consultations and/or group meeting presentations.

The Clinical Study

The effectiveness of this adaptation was evaluated in a matched-pair, group-randomized intervention trial involving two YMCA facilities in greater Indianapolis (13). Recruiting and identifying individuals with prediabetes (eg, similar to the original DPP participants) included a community marketing approach (mass mailings) and point-of-care biologic testing at the respective YMCA facilities. The study enrolled 92 subjects (46 at the intervention site and 46 at the control site). The result at 4 to 6 months (end of intervention) was an average body weight loss of 6% (~ 5 kg) in intervention participants and only 2% in the control group (P < .001, difference between groups). These differences were sustained after 12 months, and adjustments for differences in
race and gender did not alter these findings. Costs per person were estimated to be $250 to $350 per year.

What’s Next?
1) Partly because of the results of the IU-YMCA study and other translational studies, the National Diabetes Prevention Program (NDPP) at the CDC was initiated by federal statute (a part of the Patient Protection and Affordable Care Act of 2010) (14).
   • The NDPP is in the process of providing national standards and a recognition program for community-based DPPs, quality assurance, applied research and model sites.
   • The NDPP replicated the IU-YMCA findings at the YMCA of Greater Louisville.

2) Training for the YMCA lifestyle coaches is based on a model developed by one of the authors (DGM). All members of the YMCA who become lifestyle coaches are selected by their respective Ys and are trained by either members of the IU-DTRC or by master trainers with the National YMCA office (Y-USA) who were trained by the IU-DTRC. The training follows a structured curriculum and is conducted over 2 days. The training uses a series of coaches’ manuals and patient materials that include review of all course sessions, development of group process technique and methods for collecting and recording data.

3) UnitedHealth Group has initiated a demonstration project to test the business model for reimbursing YMCA offering the Y-DPP. Seven programs were funded in 2010, and the current schedule is to fund an additional 13 during 2011 (Table 2) (14,15).

4) In the future, the Y-DPP should be implemented in the 100 largest metropolitan areas, where an estimated 50 million of the 57 million people with prediabetes reside (15).

Table 1. DPP/Community Lifestyle Intervention Comparisons

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Goals</td>
<td>Overall goals: Loss and maintenance of 7% of baseline body weight; increase of 150 min/wk of physical activity</td>
<td>same</td>
<td>same</td>
</tr>
<tr>
<td>Program duration</td>
<td>16 wk core curriculum (carried out over 16-24 wks). Individual model</td>
<td>16 wk (carried out over 16-20 wks). Group model (8-12 people)</td>
<td>16 wk Group model (up to 15 people)</td>
</tr>
<tr>
<td>Staff/instructors</td>
<td>Case manager/lifestyle coach (RD or master’s level training in exercise physiology, behavioral psychology or health education)</td>
<td>YMCA staff trained as lifestyle coaches</td>
<td>YMCA staff trained as lifestyle coaches</td>
</tr>
<tr>
<td>Maintenance</td>
<td>Maintenance program</td>
<td>4-wk training and refinement. Long-term maintenance phase (monthly large group meetings)</td>
<td>Monthly meetings for a year</td>
</tr>
<tr>
<td>Incentives</td>
<td>Toolbox of incentives</td>
<td>Not used</td>
<td>Not used</td>
</tr>
<tr>
<td>Ethnic diversity addressed</td>
<td>National network of staff training, feedback, and clinical support.</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Support</td>
<td>Provided locally</td>
<td>Provided nationally by the Y-USA and CDC</td>
<td>Provided nationally by the Y-USA and CDC</td>
</tr>
<tr>
<td>Per capita cost/Year One</td>
<td>$1,399</td>
<td>$250-350</td>
<td>Data not yet available</td>
</tr>
</tbody>
</table>

CDC, Centers for Disease Control; DPP, Diabetes Prevention Program; IU, Indiana University; RD, registered dietitian; YMCA, Young Men’s Christian Association.
5) Because of their unique nutrition and behavior expertise, RDs may find unique opportunities to be involved with the Y-DPP at the advisory or consultative level.

Summary
A carefully designed group lifestyle intervention to prevent diabetes can be delivered for $250 to $350 per year in the YMCA environment, which can achieve weight loss results similar to those of the more costly federally-funded DPP research trial. With the assistance of the CDC and insurance providers, the Y-DPP lifestyle program is in the process of a nationwide expansion. To support the long-term sustainability of diabetes prevention programs in the US population, health payer funding and foundation support will be needed to ensure full access.

References

Table 2. YMCA Diabetes Prevention Programs (Y-DPP)
As of April, 2011, Y-DPP programs are currently being offered in these locations (14):

- Birmingham, AL
- Phoenix and Tucson, AZ
- State of Delaware
- Tampa and Jacksonville, FL
- Atlanta, GA
- Fort Wayne, Bloomington and Indianapolis, IN
- Louisville, KY
- Minneapolis, Willmar, Alexandria, and St. Paul, MN
- New York City and Rochester, NY
- Cincinnati, Columbus, and Dayton, OH
- Providence, RI
- Seattle, WA

In addition, the YMCA will be offering the program at these sites by mid-2011 (14):

- New Haven and Wilton, CT
- Washington, DC
- Venice, FL
- Savannah, GA
- Boise, ID
- Marshalltown, IA
- Lexington, KY
- Lawrence, MA
- Livingston and Woodbridge, NJ
- Rye, NY
- Eugene, OR
- Natrona Heights, PA
- Arlington, Dallas, Fort Worth, and Houston, TX
- Spokane, WA
- La Crosse, WI

Table 2. YMCA Diabetes Prevention Programs (Y-DPP)
Abstract
Research on gestational diabetes mellitus has increased dramatically over the last 15 years. Outcomes from a major landmark trial, the Hyperglycemia and Adverse Pregnancy Outcome Trial, have led to recommendations to change the diagnostic criteria for gestational diabetes. In addition, two major intervention trials show that nutrition therapy with glucose monitoring significantly affects maternal and neonatal outcomes. The results of these studies indicate that implementation of medical nutrition therapy by registered dietitians is both primary and essential.

Introduction
Over the last 15 years, research on the topic of gestational diabetes mellitus (GDM) has dramatically increased. The research covers several areas, including diagnostic criteria, incidence, medical nutrition and pharmacologic therapies, monitoring, maternal and fetal complications, postpartum screening, and diabetes prevention for the mother and child. Many topics still need further research. This article will review a major landmark trial that has led to a change in the diagnostic criteria for GDM and two other trials that support the effect of medical nutrition therapy (MNT) and self-monitoring of blood glucose on improved pregnancy outcomes. Registered dietitians (RDs) are also encouraged to access the GDM nutrition practice guidelines available at www.adaevidencelibrary.com, which includes evidence grading of the research articles.

Landmark Trial
For hundreds of years, physicians have observed that some women delivered very large or stillborn infants and had symptoms of polydipsia and polyuria during pregnancy, which disappeared after delivery. A name and definition for this condition was first proposed and accepted in 1980—GDM—which is any degree of carbohydrate intolerance, with onset or first recognition during pregnancy (1).

Dr. John B. O’Sullivan, a physician researcher at Boston General Hospital, was one of the first to recommend that all pregnant women be screened for glucose intolerance using an oral glucose tolerance test (OGTT). Since the implementation of the O’Sullivan and Mahan criteria, adjustments have been made to the diagnostic criteria for GDM (Table 1) (2).

In 1998, the International Association of Diabetes and Pregnancy Study Groups (IADPSG) was formed as an umbrella organization to facilitate collaboration among various regional and national groups that have a primary or significant focus on diabetes and pregnancy (3). The IADPSG identified the need for an international study that would clarify the risks of adverse outcomes associated with various degrees of maternal glucose intolerance less severe than overt diabetes. The result of this collaboration was the design and implementation of the Hyperglycemia Adverse Pregnancy Outcome (HAPO) Trial, which was conducted from 1999 to 2007. A total of 25,505 pregnant women from 15 centers in nine countries participated (United States, UK, Canada, Barbados, Thailand, Israel, Australia, Hong Kong and Singapore). Pregnant women underwent an OGTT using a 75 g of glucose load between 24 and 32 weeks of gestation. If their fasting plasma glucose level was 105 mg/dL or less or their 2-hour value was 200 mg/dL or less, they were included in the study; the researchers were blinded to patients’ glucose data.

The study was designed to measure both maternal and neonatal adverse outcomes. The primary outcomes included (1) a birth weight above the 90th percentile for gestational age, (2) primary cesarean delivery, (3) clinically diagnosed neonatal hypoglycemia and (4) cord-blood serum C-peptide level above the 90th percentile. Secondary outcomes were delivery before 37 weeks of gestation, shoulder dystocia or birth injury, need for intensive neonatal care, hyperbilirubinemia and preeclampsia. In type 1 and type 2 diabetes, the effect of glucose...
control is measured with long-term outcomes such as hemoglobin A1c or the development of diabetes-related complications. In contrast, a pregnancy complicated with diabetes can identify the effect of abnormal glucose control with more immediate outcomes such as infant size and delivery complications.

The study results were published in the *New England Journal of Medicine*, and showed a strong, continuous relationship between all oral glucose tolerance levels and the rate of maternal and fetal outcomes (4). The figure on this page shows this strong continuous relationship with three adverse outcomes: birth weight more than 90%, percentage of body fat more than 90% and cord-blood C-peptide greater than 90%, compared with the fasting OGTT results.

After the study data were published, the IADPSG met again in 2008 to discuss the findings of the HAPO trial and to make clinical recommendations. The planning committee desired universal agreement and therefore representatives from key US and international organizations were invited to participate in this activity, including American Congress of Obstetricians and Gynecologists (ACOG), American Diabetes Association (ADbA), National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Centers for Disease Control and Prevention (CDC), World Health Organization (WHO) and American Association of Diabetes Educators (AADE). Over 225 clinicians and researchers from 40 countries met and reviewed the published and unpublished study findings.

One major problem and difficulty in the approach to GDM diagnosis has been the lack of international unity. Currently, the United States and other countries around the world do not use the same diagnostic criteria. The IADPSG criteria require only one abnormal value.

The IADPSG published their recommendations in the March 2010 issue of *Diabetes Care*, with the hope that every diabetes community around the world will accept the new

### Table 1: History of Glucose Tolerance Testing to Diagnose Gestational Diabetes Mellitus (2; p.213,214)

<table>
<thead>
<tr>
<th>Researcher/Committee (date published or implemented)</th>
<th>Oral Glucose Load</th>
<th>FPG (mg/dL)</th>
<th>1 h (mg/dL)</th>
<th>2 h (mg/dL)</th>
<th>3 h (mg/dL)</th>
<th>Medium Whole</th>
<th>Criteria for Abnormal Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>O’Sullivan and Mahan (1964)</td>
<td>100 g</td>
<td>90</td>
<td>165</td>
<td>143</td>
<td>127</td>
<td>Whole blood</td>
<td>2 values met or exceeded</td>
</tr>
<tr>
<td>National Diabetes Data Group (1985)</td>
<td>100 g</td>
<td>105</td>
<td>190</td>
<td>165</td>
<td>145</td>
<td>Plasma</td>
<td>2 values met or exceeded</td>
</tr>
<tr>
<td>Carpenter/Coustan Criteria (2001)</td>
<td>100 g</td>
<td>95</td>
<td>180</td>
<td>155</td>
<td>140</td>
<td>Plasma</td>
<td>2 values met or exceeded</td>
</tr>
<tr>
<td>IADPSG (2010) and ADbA (2011)</td>
<td>75 g</td>
<td>92 (5.1 mmol)</td>
<td>180 (10.0 mmol)</td>
<td>153 (8.5 mmol)</td>
<td>-----</td>
<td>Plasma</td>
<td>1 value met or exceeded</td>
</tr>
</tbody>
</table>

ADbA, American Diabetes Association; FPG, fasting plasma glucose; IADPSG, International Association of Diabetes and Pregnancy Study Groups.
diagnostic criteria. As of this writing, Japan, Italy and South Korea have adopted these recommendations. In the January supplement of *Diabetes Care*, the ADbA recommended the use of these new criteria. However, AcoG has not yet made a decision to accept the IADPSG criteria. Until AcoG publicly supports the recommendations, the new criteria will likely not be implemented throughout the United States.

**Effect of MNT on Perinatal Outcomes of GDM**

Using the new criteria will increase the number of women diagnosed with GDM. Because the incidence of GDM mirrors the incidence of type 2 diabetes in any geographic area, it is difficult to predict the increase in the number of women with GDM. It is estimated that the incidence will double, at least in the United States. The new criteria require only one abnormal glucose value, which is the primary reason for the increased incidence. This increase is expected to be in the number of women with mild GDM, which is treated with medical nutrition and physical activity therapies. RDs should be alert to this and be prepared for an increase in referrals for GDM.

In the past 5 years, two major trials have clearly shown that MNT with blood glucose monitoring has a significant impact on the outcomes of GDM. The article entitled “Effect of Treatment of Gestational Diabetes Mellitus on Pregnancy Outcome,” was the first large trial to show a reduction in perinatal complications with intervention compared with routine obstetric care (5). “Intervention included individualized dietary advice from a qualified RD, which took into consideration a woman’s pre-pregnancy weight, activity level, dietary intake, and weight gain; instruction on how to self-monitor glucose levels which the woman was then asked to do four times daily until the levels were in the recommended range for 2 weeks [fasting levels between 63 mg/dL and 99 mg/dL and 2-hour postprandial levels that were not greater than 126 mg/dL]” (5). The primary outcomes of the study are reported in Table 2. Note that there was a statistically significant difference between serious perinatal complications in the two groups, with a *P* value of .01.

Women in the intervention group began receiving insulin therapy if their glucose readings were out of the target range. Eighty percent of the women in the intervention group achieved glucose targets using MNT exclusively. The study concludes, “Our results indicate that treatment of GDM in the form of dietary advice, blood glucose monitoring and insulin therapy as required for glycemic control reduces the rate of serious perinatal complications, without increasing the rate of cesarean delivery.”

Similar findings as those of the Crowther et al study described earlier were reported in the October 2009 issue of the *New England Journal of Medicine* entitled, “A Multicenter, Randomized Trial of Treatment for Mild Gestational Diabetes” (6). This study defines ‘mild gestational diabetes’ as an abnormal result on an OGTT but a fasting glucose level below 95 mg/dL. Obstetricians have been skeptical about treating the mildest form of glucose intolerance, doubting that intervention made a difference. The treatment group in this study also used a food plan with glucose monitoring four times per day. Compared with the control group, the treatment group showed significant reductions in mean birth weight, frequency of large-for-gestational-age infants, shoulder dystocia and cesarean delivery. This study, in conjunction with the other two trials addressed herein, clearly answers the skepticism of maternal-fetal health clinicians:

**Table 2: Primary Clinical Outcomes among Infants and Their Mothers (5)**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention Group (No./%)</th>
<th>Routine Care Group (No./%)</th>
<th>Adjusted Relative Risk (95% Confidence Interval)</th>
<th>Adjusted <em>P</em> value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any serious perinatal complications</td>
<td>7 (1)</td>
<td>23 (4)</td>
<td>0.33</td>
<td>.01</td>
</tr>
<tr>
<td>Death (stillbirth or neonatal death)</td>
<td>0 (0)</td>
<td>5 (1)</td>
<td>0.46</td>
<td>.07</td>
</tr>
<tr>
<td>Shoulder dystocia</td>
<td>7 (1)</td>
<td>16 (3)</td>
<td>.08</td>
<td></td>
</tr>
<tr>
<td>Bone fracture</td>
<td>0 (0)</td>
<td>1 (&lt;1)</td>
<td>.38</td>
<td></td>
</tr>
<tr>
<td>Nerve palsy</td>
<td>0 (0)</td>
<td>3 (1)</td>
<td>.11</td>
<td></td>
</tr>
<tr>
<td>Admission to neonatal nursery</td>
<td>357 (71)</td>
<td>321 (61)</td>
<td>1.13</td>
<td>.01</td>
</tr>
<tr>
<td>Jaundice requiring phototherapy</td>
<td>44 (9)</td>
<td>48 (9)</td>
<td>0.93</td>
<td>.72</td>
</tr>
<tr>
<td>Induction of labor</td>
<td>189 (39)</td>
<td>150 (29)</td>
<td>1.36</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Cesarean delivery</td>
<td>152 (31)</td>
<td>164 (32)</td>
<td>0.97</td>
<td>.73</td>
</tr>
</tbody>
</table>
aggressive treatment of mild GDM has significant clinical benefit.

Only three of many research articles published on MNT for GDM are described herein. The American Dietetic Association (ADA) Evidence Analysis Library has many of these research articles graded and sorted by topic. To view the GDM project, go to www.eatright.org/evidence-analysislibrary (7). The library is a valuable resource for RDs who want to provide evidence-based care.

An Opportunity for Dietitians
Medical nutrition therapy is the initial and primary treatment for most women with GDM; therefore RDs play a key role in ensuring good maternal and neonatal outcomes. Research studies clearly show that MNT with glucose monitoring makes a significant difference. As the new criteria for the diagnosis of GDM are implemented and the incidence of mild GDM dramatically increases, RDs are positioned as the most qualified health professionals to educate and care for these patients, including when to initiate pharmacologic therapy. This situation provides an opportunity for RDs to support busy primary care providers, obstetricians and advanced nurse practitioners with excellent care for patients needing intensive nutrition therapy. Lack of reimbursement has not been a common problem. If it is a barrier, RDs (or MNT) can be included in the obstetrics package that is offered to patients, as has been implemented in some institutions. Also insurers can be informed that MNT with monitoring will prevent more costly interventions such as cesarean sections and time in the neonatal intensive care unit. This is clearly a time for RDs to use the evidence to demonstrate their role as therapy providers who can make a significant impact on maternal and neonatal health for the current pregnancy and for the years that follow.

References
Abstract
The concept of personalized genetic profiling has gained in popularity and is a stated research focus at the National Institutes of Health. Because of rapid advances in the field of genetics of type 2 diabetes mellitus (T2DM), we now have 40 “accepted” loci associated with T2DM. Currently, using a genetic risk score to predict T2DM does not add significant predictive value to clinically available information. However, more robust assessments of heritable risk may be available in the future. Evidence from genetic research in the Diabetes Prevention Program (DPP) suggests that lifestyle intervention reduces the risk of T2DM in individuals at high genetic risk, thereby empowering our clinical messages. Registered dietitians can encourage patients to make modest lifestyle changes that can modify or trump expression of high-risk diabetes genes.

Introduction
Recent advances in technology and improved understanding of medical genetics have raised the hope of many health professionals about personalized medicine, especially in the field of complex diseases such as type 2 diabetes mellitus (T2DM). The hope is that with a set of genetic markers we could identify individuals who have a higher risk of developing T2DM, or who are more likely to benefit from a specific intervention to prevent or treat T2DM. Many studies have tried to address these questions but we are still at the infancy of exploration in the field.

In the past few years, research into the genetics of T2DM has exploded. Beginning with a couple of loci discovered using the candidate gene approach, the use of genome-wide association studies has permitted the exponential discovery of T2DM-loci (a definition of terms can be found on the following page). Consequently, we now have 40 “accepted” loci associated with T2DM. Each identified locus is associated with a fairly small effect size: using an additive genetic model, most risk alleles confer an increase in risk of 5% to 20% (i.e., odds ratio [OR] between 1.05 and 1.20 per risk allele for risk of T2DM) and the strongest effect size remains associated with variants located in the gene encoding the transcription factor 7-like 2 (TCF7L2) showing a 40% higher risk of developing T2DM per copy of the allele compared with noncarriers (OR: 1.40 per risk allele) (1). Despite the fact that each locus confers such a small effect individually, it is theorized that it is the additional effect of many risk alleles that leads to an overall increased risk of developing T2DM.

How Can Genetic Information be Used in Diabetes Prevention? The DPP Experience
If the actual knowledge of T2DM genetics is of limited use in predicting T2DM incidence, could it be helpful for other clinical applications? The DPP demonstrated that intensive lifestyle counseling leading to modest weight reduction can prevent T2DM
in patients with impaired glucose tolerance (6). Despite demonstrating the cost-effectiveness of their approach (7), limited human resources and the overall cost of the original program has restricted its application in most clinical settings. One hope is that the genetic investigations in studies such as the DPP may help healthcare professionals direct interventions toward those who are more likely to benefit, especially if the intervention is comprehensive, intensive and requires human resources such as lifestyle counseling supported by a specialized team of health care professionals. Identification of the highest risk individuals most likely to benefit from such an intensive program could help to allocate resources.

Genetics association studies in the DPP have several advantages. First, the DPP was a large-scale randomized controlled trial that enrolled a well-characterized multiethnic group of patients who were at high risk of developing T2DM and who were receiving standardized behavioral and pharmacologic interventions. Second, the extensive in-depth phenotyping and use of behavioral and pharmacologic interventions allow characterization of the effects of genetic risk on diabetes risk and response to therapies (8). The genetic studies within DPP that have the most important implications for lifestyle interventions are described herein.

Soon after the landmark locus TCF7L2 was confirmed to be associated with T2DM in cross-sectional studies, the DPP research group investigated whether the risk alleles at this locus were associated with diabetes incidence in DPP participants (8). They confirmed that individuals carrying both copies of risk allele were at increased risk of developing diabetes. Definitions

**DNA** is a nucleic acid that contains the genetic instructions used in the development and functioning of all known living organisms.

**A chromosome** is an organized structure of DNA containing many genes, regulatory elements and other nucleotide sequences. The human genome is organized in 23 chromosomes.

**A gene** is a unit of heredity in a living organism. It normally resides on some stretches of DNA that code for a type of protein or for an RNA chain that has a function in the organism.

**Locus** (plural loci) is the specific location of a gene or DNA sequence on a chromosome.

**Allele** is one of two or more forms of a gene.

**Risk allele** is the genetic variant that is associated with increased risk of developing the disease of interest (e.g., T2DM) or with more adverse phenotype (higher blood glucose level).

**A single-nucleotide polymorphism (SNP)** is a DNA sequence variation occurring when a single nucleotide — A, T, C, or G — in the genome differs between paired chromosomes in an individual.

**Additive genetic model** is used to estimate the effect of a genetic variant assuming that each copy of a risk allele will increase the risk by a certain size effect: for example at a locus where two alleles are possible (C/T) and the risk allele is T, it was determined that each copy of T allele increases the risk of T2DM by 40% (OR=1.40). Therefore, an individual carrying one risk allele (CT) is 40% more likely to develop T2DM while an individual carrying both risk alleles (homozygous TT) is 80% more likely to develop T2DM.

**A candidate gene approach** is defined as a study conducted on a specific gene based on the assumption that this gene is implicated in pathways leading to the disease of interest.

**A genome-wide association study (GWAS)** is an examination of all or most of the genes (the genome) of different individuals to see how much the genes vary from individual to individual. Different variations are then associated with different traits, such as diseases (T2DM) or quantitative traits (glucose level).

**A genetic risk score (GRS)** is built from a number of known risk alleles associated with a trait or a disease to capture the “global genetic predisposition” to the disease of interest (or adverse phenotype). For example, if 40 loci have been associated with T2DM, we can add the risk at each locus for an individual. At each locus, an individual can carry 0, 1, or 2 copies of the risk allele and so the genetic risk score could putatively range from zero to 80 (40 * 2) if we assume each risk allele has the same weight in the genetic score. The score can also be “weighted" to allow different effect sizes specific to each locus.

**Genotype** is an organism’s full hereditary information, even if not expressed.

**Phenotype** is an organism’s actual observed properties, such as morphology, development or behavior.
T2DM over the 3 years of follow-up (hazard ratio [HR] = 1.55 for TT homozygous compared with CC homozygous at single nucleotide polymorphism [SNP] rs7903146). The results also suggested that the effect of the risk allele was stronger in the placebo group (HR = 1.81) than in the lifestyle intervention group (HR = 1.15). Despite this difference in effect size, the interaction P value was not significant. The overall message that we can draw from this report is that in individuals at high genetic risk conferred by risk alleles at TCF7L2, lifestyle intervention can prevent T2DM with similar (or maybe more) efficacy than in individuals not carrying the risk allele at this locus.

As mentioned earlier, because T2DM is a polygenic disease, a global genetic risk score (GRS) is an appropriate way to assess an individual's overall genetic predisposition to develop T2DM. Consequently, the DPP research group investigated whether a GRS (based on 34 T2DM-loci) was associated with diabetes incidence in DPP participants (9). They found that a high GRS was associated with increased diabetes incidence (HR = 1.02 per risk allele; P = .03) and a lower probability of regression to normal glucose tolerance (HR = 0.95 per risk allele; P < .0001), after adjusting for age, sex, ethnic background, waist circumference, and treatment allocation. Specifically, when examining individuals at the highest genetic risk (4th quartile of GRS), diabetes incidence was significantly lower and regression to normal glucose tolerance was significantly higher in the lifestyle intervention group compared with the placebo arm (P < .0001), whereas the differences between the placebo and metformin arms were not statistically significant. Similar to findings in the TFC7L2 report (8), individuals at higher genetic risk seem to benefit as much (or more) from lifestyle intervention, but the interaction test result was not significant. Other noteworthy findings from this study were as follows:

- More participants in the highest GRS quartile reported a family history of T2DM
- A higher GRS was associated with indices of diminished β-cell function

**Messages We Can Derive From the DPP Genetic Investigations**

Overall, these reports from DPP underscore that individuals at high genetic risk are not “doomed” to develop T2DM: a sustained focus on a low-fat low-calorie diet and regular physical activity leading to modest weight loss and maintenance reduces the risk of developing diabetes at any level of “genetic risk.” Furthermore, the effect seems to be equivalent or even stronger in individuals at high genetic risk than in those at lower genetic risk. Does this mean that patients should be genotyped for T2DM risk loci to target only those at higher genetic risk? This is unlikely to be a logical solution because the DPP demonstrated that lifestyle intervention reduces the risk of T2DM in all individuals, independent of their genetic predisposition.

**Future Directions: Would Knowledge of T2DM Genetic Risk Increase Patients’ Motivation to Adopt Healthier Lifestyles?**

A few studies have started to address the question of how knowledge of genetic risk affects lifestyle choices and motivation. In a survey addressed to primary care patients (without diabetes), 71% of patients believed that being identified as having “a high genetic risk for diabetes” would motivate them to adopt healthier lifestyles (10). By comparison, only 23% of physicians (primary care and endocrinologists, representative U.S. sample) believed that identification of “high genetic risk for diabetes” would motivate their patients (10). One recent qualitative study by Markowitz and colleagues (11) conducted in-depth interviews with 22 overweight participants at high phenotypic risk for T2DM. The study aimed to compare perceptions about diabetes genetic testing with predictions based on risk factors available and no direct genotyping (e.g., family history, abnormal fasting glucose, obesity). Participants were interviewed about their views on diabetes prevention behaviors in response to hypothetical scenarios of learning about both “higher” and “lower” relative genetic risk results. The main findings were as follows (11):

- Many participants ascribed a unique value to personal genetic test results based on perceived scientific certainty and durability of the results, whereas other participants considered the results in the context of an overall risk assessment that included factors such as weight status and fasting blood glucose levels.
- Baseline motivation level was an important mediator of reported subsequent diabetes prevention behavior in response to hypothetical genetic test results. Those described as highly motivated and already making lifestyle changes reported that they would try to intensify their behavior change efforts in response to learning they were at higher genetic risk and would not reduce efforts if they were at lower risk. By contrast, less
motivated patients reported that lower genetic risk results would reinforce their decision not to engage in diabetes prevention behaviors whereas high risk results might lessen their denial and increase their perceived vulnerability and sense of urgency to prioritize action (11).

**Conclusion: Messages for Clinical Practice**

Although the true usefulness of T2DM genetic testing has yet to be determined, evidence supports a change in the way we frame our clinical messaging to our clients. The research to date outlines several clinical practice messages that we can share with our patients.

- The DPP research has demonstrated that modest lifestyle changes can modify or trump the expression of high-risk diabetes genes. Among patients with the highest genetic risk, lifestyle intervention lowers rates of progression to diabetes and results in a higher probability of regressing to normal glucose tolerance compared with receiving no intervention.
- Rather than feeling destined or fated to develop diabetes because of genetic risk, healthcare providers need to help patients reframe their thinking so that they feel empowered to prevent diabetes with modest lifestyle changes. This is especially important for patients with the highest genetic risk, who might benefit from earlier intervention.
- Genetic testing to identify risk for T2DM is not ready for clinical practice at this time because the field is still growing and to date, GRS for T2DM do not add significant predictive value beyond the clinically available risk factors that are used to assess T2DM risk (age, sex, ethnicity, body mass index, fasting blood glucose, systolic blood pressure, high-density lipoprotein cholesterol, and triglycerides).

However, despite the limitations of current diabetes genetic testing, future iterations of diabetes genetic risk testing may provide a more robust assessment of an individual’s heritable risk of T2DM. The concept of personalized genetic profiling has gained popularity and is a stated focus of research at the National Institutes of Health (12); several clinical trials under way are addressing the implementations of diabetes genetic testing. It is important that we keep abreast of the rapid advances in the technology and research related to the clinical application of diabetes genetic testing.

**References**

Introduction

With increasing media interest in diabetes, the public is bombarded with sound bites about nutrition research. Registered dietitians must be able to examine the evidence presented in a research article to address questions and clinical implications (1). Dissecting a research article can be a daunting task especially if under pressure to interpret the study findings on short notice. A quick check of the abstract in Pubmed may not be enough. A growing number of journals require that the authors provide documentation that the study protocol has been submitted to www.clinicaltrial.gov when a manuscript is submitted for review. The published article would then include the clinical trial identification number so that readers can compare the initial study intent and research plan with what the authors reported in the published article. This article provides an overview for dissecting research articles with guidance for examining each section. The format of research articles varies somewhat, but most include the sections addressed herein.

What You Learn From the Abstract

The article abstract provides a quick synopsis of the research study. Abstracts should address the purpose of the study; methods, which include key characteristics of the study participants, overview of the outcomes and analysis approach, and if relevant the intervention; results, which highlight key findings, and conclusions or implications, which address the importance of applying the findings to practice or understanding of a problem. Finding key information is easier to do with a structured abstract that has section headings.

Why Read the Introduction

The introduction of a research article should provide the rationale for the study. The author(s) should identify what gaps in knowledge are being addressed in the research study. After a brief overview of what is known about the issue or statement of the problem, the author(s) should indicate what questions or hypotheses are being addressed.

What You Can Find Out From the Methods Section

The methods section provides valuable information with regard to the study design, enrollment criteria and recruitment strategies for study participants, data collection methods, interventions (if any), and data analysis.

Study Design

The Table provides an overview of common observational and intervention study designs. Observational studies are used to establish associations and can identify predictors of disease. The gold standard for evidence-based practice recommendations usually comes from testing interventions in well-controlled randomized clinical trials (2,3). Randomized controlled trial data can be used to examine predictors of intervention outcomes within one randomization group without including any data from the control group. Such an analysis would be classified as a cohort follow-up study design because the data analysis did not focus on differences on the basis of randomization. For example, the Diabetes Control and Complication Trial (DCCT) used a two-arm trial to maximize the potential effect of multiple strategies to achieve better glycemic control in the intensive intervention to test hypotheses about preventing complications (4). The DCCT evaluation also included post-hoc analyses to address additional research questions after the main results were known. One such analysis examined how much of the improvement in hemoglobin A1C (A1C) levels within the intensive treatment group was related to dietary intervention strategies, but a similar analysis was not performed on the control group participants because their A1C did not change significantly during the trial (5).
Study Participants: Enrollment Criteria

The potential to generalize study findings is largely dependent on the criteria used to determine eligibility and the procedures used for enrollment. The description of study participants and study setting should be compared to the patients in your practice setting to determine if the findings can be extrapolated. For example, a worksite intervention study of middle management personnel from a predominantly white suburban population may not be applicable to low-income minority patients receiving care in a community health center. The National Institutes of Health (NIH) and most other federal agencies require an enrollment plan that addresses the representation of study participants with regard to gender and inclusion of minorities. More recently, the plan must also address the inclusion of children (defined as those younger than 21 years) because dosage recommendations and risk of side effects for children were often extrapolated from studies conducted in adults.

Observational studies, such as the National Health and Nutrition Examination Survey (NHANES) use various strategies to recruit participants who represent the population of the United States; data analysis of such populations can address questions such as, “How many people have undiagnosed diabetes?” (6). Such a generalization could not be made if the recruitment had been a convenience sample, for example, recruiting in a clinical setting where diabetes is likely to be diagnosed. Needs assessment studies may recruit a purposive sample (e.g., members of a church network or patients with diabetes who have missed medical visits) (7).

Table: Overview of Research Designs for Human Research in Diabetes

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Observational Studies</strong></td>
<td></td>
</tr>
<tr>
<td>Cross-Sectional Study:</td>
<td>Data are collected at one point in time to characterize a given group of people or a community. The National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Surveillance System (BRFSS) are designed to assess health status and health behavior of US populations. Data are collected on an ongoing basis to discover trends in the prevalence of obesity and diabetes.</td>
</tr>
<tr>
<td>Case-Control Studies:</td>
<td>Cases are individuals with a condition such as diabetes who are compared with controls who do not have the condition. Usually the controls are matched to the cases with respect to demographic variables.</td>
</tr>
<tr>
<td>Prospective Cohort Studies:</td>
<td>A longitudinal study of the same group of people (the cohort) over time to examine the incidence (new cases) of diabetes or other health condition. The Framingham Study, the Women’s Health Initiative, the Nurses’ Health Study and the Physicians’ Health Study are prospective cohort studies that have been used to identify nutrition-related predictors of adverse health outcomes.</td>
</tr>
<tr>
<td><strong>Intervention Studies</strong></td>
<td></td>
</tr>
<tr>
<td>Quasi-experimental Studies:</td>
<td>Pre-post intervention studies are quasi-experimental in that the recipients of intervention are not randomly determined. Policies regarding obesity are often evaluated using a quasi-experimental design. Evaluation may include a comparison of two communities before and after one community receives an intervention, that is, restaurant calorie labeling in New York City before the national policy was implemented.</td>
</tr>
<tr>
<td>Randomized Controlled Trials:</td>
<td>In randomized controlled trials (RCT), study participants complete a baseline assessment of eligibility and recruitment, and then participants are randomly assigned to receive the experimental or control intervention. An RCT may have two or more arms that are being compared. Random allocation in real trials is complex, but conceptually, the process is like tossing a coin. After randomization, the two (or more) groups of participants are followed up in exactly the same way with regard to evaluation of the chosen outcomes. The most important advantage of proper randomization is that it minimizes allocation bias, balancing both known and unknown prognostic factors, in the assignment of treatments.</td>
</tr>
</tbody>
</table>

Questions to ask include, “How comparable are the clinical and demographic characteristics of study participants to other populations with diabetes or at risk for diabetes?” “What proportion of those randomized completed the study?” If fewer than 80% of participants completed the study, generalizing the findings may be difficult because those who have better results may be more likely to complete the study (8). “Who was excluded from participating in the trial?” Having prospective participants complete a run-in with task assignments similar to study requirements increases the likelihood that study participants will adhere to the study protocol, which is termed internal validity. Studies with high internal validity can provide evidence that improving glycemic control reduces diabetes complications, but extrapolating findings to other patients, who may be less likely to adhere to the treatment used in the study, is termed external validity (9, 10).
Study Measures
Studies should have quality control procedures to help reduce potential bias in the study findings. Methods for obtaining physical measures and laboratory tests should be standardized. Medication trials use double blinding (masking) in which neither the study participants nor staff know who is receiving active medication or placebo. The blinding codes are only revealed at the end of the study or to address potential serious adverse effects of the study medication. For lifestyle intervention studies, only the staff collecting the study outcomes measure can be blinded to the treatment arm. This means that the data collection staff members do NOT know if the participant is in the lifestyle or control group to reduce the likelihood that the participant will report what staff may want to hear regarding food intake or physical activity. If the data collection staff members know a participant is in the lifestyle treatment group, the staff may inadvertently make assumptions such as the serving size was small.

The article should include information and appropriate citations for questionnaires. Look for information about the measurement properties often described as psychometric properties, such as validity and reliability (11). Validity means that the instrument measures what the authors intended it to measure, for example, a dietary questionnaire to assess sodium intake compared with the 24-hour sodium excretion. Often validity assessment is based on another well-established questionnaire. Reliability means that the results are consistently the same. The two major types of reliability are (1) test-retest, which is used to evaluate whether the results are reproducible when the questionnaire is administered twice, usually about 2 weeks apart, and (2) internal consistency, which assesses whether the response to items for the whole instrument or a subscale are similar, for example, questions asking for similar information so that the respondent provides similar responses.

Interventions
Try to use key questions to examine the study intervention. “How is the intervention described?” “What were the intervention goals?” “How was the intervention provided with regard to content, frequency and counseling approach?” “What was included in the control intervention?” Including multiple components in the intervention helps maximize its potential for the desired outcome but does not establish which intervention components achieved the outcome. However, techniques used in observational studies, for example, regression analysis, can determine how intervention variables are related to outcome without assuming causality. Many lifestyle studies use a minimal intervention control because it helps maximize the difference. How feasible is the intervention? For example, the Dietary Study Against Hypertension (DASH), which provided all meals to participants, achieved a dramatic reduction in blood pressure, thereby demonstrating the efficacy of the DASH dietary pattern (12,13). However, translating the DASH dietary pattern into a practical intervention program that could be readily used outside a research unit required an educational intervention study. The PREMIER Study, which evaluated the effects of teaching patients to follow the DASH dietary pattern (14), demonstrated that the DASH educational program was effective in reducing blood pressure though the reduction in blood pressure was less dramatic than that seen when all meals were provided. Thus, the Premier Study provided insights for expected blood pressure reduction and intervention materials that could be used in clinical practice with increased potential for widespread dissemination.

Statistical Analysis
The statistical approach should consider estimates regarding the size of treatment effects or effect size (difference between the experimental intervention and control). Factors that can influence the intervention effects include participant characteristics and selection and quality of the intervention delivery compared with what was planned. Statistical considerations include study design and methods to reduce the influence of confounding variables that could influence study outcomes. The data analysis should include all of the randomized participants (intention-to-treat) so as to evaluate the effectiveness of the intervention. Missing endpoint results are imputed or the last data collected are carried forward and used to replace the missing information. Reporting results only for those who complete the study or adhere to the study protocol (efficacy analysis) examines the results from the best case scenario. Analyzing data from the successful participants can inflate the effects of the intervention because such an analysis does not account for participants who dropped out. Further examining the data set in secondary analyses may show how the intervention or participant characteristics are related to the outcomes.

Questions to ask include, “Did the article indicate how the trial sample size was determined?” “Was statistical power to test the hypotheses addressed?” (15) A larger sample
Discussion

Questions to ask include, “How did the study findings compare with the anticipated results?” “Were the clinical implications of the findings discussed?” “How widely can the study findings be generalized?” Issues such as care setting, participant characteristics and intervention methods need to be considered. “Did the article address study limitations?”

Results

The results section provides the study findings, usually in tables and figures with key findings featured in text. Questions regarding results include, “Are the study findings clearly presented so that the reader can compare the study findings of the treatment arms?” “Is there a table comparing the treatment arms which includes the baseline characteristics?” If there were baseline differences, these should be adjusted for statistically as confounders. “What information about intervention adherence is presented?” If the intervention fails to achieve the hypothesized changes in the outcomes, it may be because of a failure to achieve the intervention goal (dietary change) or it may indicate that dietary change did not result in changing the outcome.
Articles should discuss the limitations of the study while considering variables that could affect the study findings or their generalizability to other settings or populations. The discussion often considers the next steps or recommendation for future research.

Summary
In a research article, the introduction describes the purpose of the study. Information in the methods section includes the study design, enrollment criteria and recruitment strategies for study participants, the study outcomes or variables of interest with regard to the study hypotheses (questionnaires, weight-related information, laboratory tests, etc.), and the statistical methods used to evaluate the study hypotheses. The results section provides the study findings usually with tables and figures, with key findings highlighted in the text. The discussion or conclusion addresses the clinical implications of the study, the limitations of the study and suggestions for potential future research.

References
Abstract
Conducting research is not only for PhDs or those working in an academic setting. It is for anyone who has a question that needs to be answered. This brief article aims to encourage and guide more registered dietitians to get started in research addressing the delivery and value of nutrition therapy. Five steps to research will be reviewed.

The Question or Purpose
The first step in the research process is to identify a specific question. Some researchers keep a list of questions they encounter during their day. Keeping such a list can be useful when selecting a question that is most interesting to the researcher and important to the researcher’s practice. It is helpful if the researcher is curious about the question because that will enhance his or her motivation to follow through on developing the research and finding the answer.

Examples of potential questions:
- Is there a difference in hemoglobin A1C (A1C) levels of patients who see the registered dietitian (RD) for two or four counseling sessions?
- Are the patients who cancel visits experiencing worse glycemic control than those who keep their appointments?

It is critical that the research question be focused, straightforward, simple and answerable. For example, if an A1C level cannot be obtained, one would not be able to research the first question listed above. The initial research question is typically not the final question; it will become more refined as the study is designed and budgeted.

The Study Participants
The second research step is to clearly identify who the study question relates to; the “who” will be the study participants. The study results will be interpreted as relating to the defined study participants. It answers the questions, “what exactly was done, when, where and how?” In research publications this is the methods or design section.

As participants are defined, the researcher develops a list of who will be included and excluded in the study. This information consists of the study’s inclusion and exclusion criteria and provides context to the study results. If a study included only patients with a baseline A1C less than 8%, then the study results should not be interpreted as applying to those with an A1C higher than 8%. Ideas for factors to consider for inclusion and exclusion criteria can be obtained from reading research articles that ask a similar question.

The decisions made about the study participants become part of the research question. However, not all of the inclusion and exclusion criteria need to be in the research question. Make the research question more specific:
- Is there a difference in A1C levels of patients with T2DM who see the RD for two counseling sessions or for four sessions during 2012 at the diabetes center?
- Are the newly referred patients who cancel visits experiencing worse glycemic control than those who keep their appointments?

The Intervention
The third step in the research process is to define the intervention. This is what the researcher will do, or has done, or was previously done by someone else. It answers the questions, “what exactly was done, when, where and how?” In research publications this is the methods or design section.
When defining the intervention, list the questions what, where, when and how and add bullet point responses to each of the questions. As details are added, the intervention becomes very clear. It is described in such detail that someone else could repeat the same study and obtain the same results. For example, the “what” originally may be defined as “usual medical nutrition therapy sessions.” This could be interpreted differently by others and requires further definition so others know exactly what will be done (prospective study) or what was done (retrospective study).

It takes effort to determine the best study design. Expert researchers frequently struggle over the best way to answer a question. Some researchers explore the literature to learn how others have addressed the same or similar question, and may choose to use the same or similar design. Others talk to other researchers to problem-solve and explore different designs.

Data: Identification, Collection and Analysis
Part of research design is identifying what data to collect and when. Data will be needed which describe the study participants and outcomes related to the study question. (See Table for examples of data to collect.)

New researchers often make the mistake of collecting too much data. Extraneous data collection adds cost to the study and detracts from the focus. By continuously revisiting the research question, researchers can more confidently identify the data needed to answer the question.

A recent study addressed the question as to whether a specific quality improvement intervention lowered the mean systolic blood pressure in persons with diabetes at 12 healthcare settings. The researchers wanted to limit the amount of data collection yet wanted to be comprehensive in tracking data that could affect blood pressure. As an RD, the author highlighted the importance of collecting nutrition-related data so that data on nutrition/lifestyle counseling and referral for nutrition/lifestyle counseling were included (1).

Data can be collected in various ways ranging from manual specially designed data collection forms or surveys, to scanable forms, to data downloaded from an existing electronic database (i.e., medical record). Instructions and training are provided to anyone collecting data to ensure that it is obtained in a consistent manner.

Basic data analysis is often easy (for example, mean age of study participants or percentage of total participants with A1C less than 7%). Yet, depending on the type of research undertaken, some extra data analysis support may be needed. This support can guide the RD in how to best analyze the data using software programs such as Microsoft Excel or a statistical analysis program and/or actually have someone do the data analysis for the researcher. It is most valuable to have the data analysis support person engaged early in the development of the project.

Table: Suggestions for Data Collection

<table>
<thead>
<tr>
<th>Basic Demographic Information</th>
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<tbody>
<tr>
<td>• Gender</td>
</tr>
<tr>
<td>• Patient ID (medical record number or your own ID system)</td>
</tr>
<tr>
<td>• Birth date (month/day/year)</td>
</tr>
<tr>
<td>• Height and weight (inches, centimeters, pounds or kilograms; use database to calculate BMI)</td>
</tr>
<tr>
<td>• Type of diabetes (type 1, type 2, GDM, prediabetes)</td>
</tr>
<tr>
<td>• Date of diagnosis (month/year; to calculate duration of diabetes)</td>
</tr>
<tr>
<td>• Location of intervention: Type of clinic-setting, urban/rural</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Data that can be used to evaluate intervention</th>
</tr>
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<tbody>
<tr>
<td>• Hemoglobin A1C and date (before intervention, and at specified times)</td>
</tr>
<tr>
<td>• Systolic and diastolic blood pressure (before intervention, and at specified times)</td>
</tr>
<tr>
<td>• Lipids (total cholesterol, LDL, triglycerides (before intervention and at specified times)</td>
</tr>
<tr>
<td>• Medications (diabetes, hypertensive, lipid; before intervention and at specified times)</td>
</tr>
<tr>
<td>• Prior MNT and/or DSMT (yes/no/unknown)</td>
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<tr>
<td>• Current eating pattern; food frequency</td>
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<table>
<thead>
<tr>
<th>Intervention</th>
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<tbody>
<tr>
<td>• What was done and by whom—could be number of education visits or phone calls</td>
</tr>
<tr>
<td>• You may develop protocols or meals that are followed for the intervention; document whether they were followed</td>
</tr>
</tbody>
</table>

BMI, body mass index; DSMT, diabetes self-management training; GDM, gestational diabetes mellitus; ID, identification; LDL, low-density lipoprotein; MNT, medical nutrition therapy.
of the study because the analysis can help shape the research question and intervention.

Results and Conclusions
The fourth research step is to summarize and draw conclusions from the study results. Researchers write the results in a straightforward manner that does not include any bias. For example, one would write “100% of participants completed the training program” rather than “we were impressed that 100% of participants completed the training program.” Most research papers include a table or figure that presents the results of the data collection and analysis. Some researchers outline proposed tables and figures during the study design process because it guides data collection decisions.

A study’s conclusion offers the opportunity to review why the results are important and how they might be used. At this time, researchers reflect on additional questions that could be researched and limitations of the current study that could potentially be addressed in future research.

The Research Report
The research report includes the information listed before and is the fifth and final step for most research studies. However, it is often omitted for various reasons, including not enough time to complete the report or being uncomfortable with writing. If barriers to writing are known in advance, they are to be addressed upfront in the planning stage. The researcher may need to identify someone who will either perform this task or provide support to get it done.

As expected, research reports are written in a tone and format that fits their audience. For a first study, a researcher may only need to write up a one- or two-page report. If writing a longer report, consider including an executive summary at the beginning and a table or figure that helps present the data. Researchers who want to publish their research in a journal or magazine can check the targeted publication’s specific author guidelines online.

Many journals have sections for original research and research briefs. I recently submitted a research manuscript to the *Journal of the American Dietetic Association* and the reviewers suggested that it be resubmitted as a research brief. Although it is difficult to delete written content on which one has worked hard, the article was tighter and published (2)!

Do Not Forget the Research Budget
It takes time to do research and time, of course, is money. Some find it easiest to examine a research question that is important in their work setting so it can be completed as part of their work and could potentially use other resources from their work setting. Researchers will often develop the budget as part of the design process or work with someone at their institution to put dollars to the study.

To develop a budget, the researcher lists, in some detail, all the steps that need to be performed and the people who will be involved in each step and for how many hours. Some grants allow the inclusion of overhead (space, utilities, equipment) and others allow the purchase of special equipment such as a nutrient analysis software program or laptop computer.

Once the detailed budget is developed, researchers often summarize the budget into broad categories. For example, headings for one research study included study development (protocol and chart audit), intervention (cost of performing study), data analysis (statistician and discussions with project team for interpretation), and dissemination (time to write a paper and present a poster session).

Resources
Those who are involved in recognized diabetes education programs need to conduct a continuous quality improvement (CQI) project each year. If an RD has participated in such an activity, then he or she has already conducted research! The CQI process is a form of research. A handbook published by the American Association of Diabetes Educators (AADE) provides a step-by-step approach to conducting a CQI project (3). The first edition of this handbook was written by AADE’s research committee to encourage a methodical approach to conducting this type of research.

The American Dietetic Association has several terrific research resources (4,5). The article by Sheean et al is the seventh article in a series published in the *Journal of the American Dietetic Association* on the importance of research design, analysis and epidemiology in the conduct, interpretation and publication of nutrition research.

Summary
Research does not need to be daunting. It is basically asking a question and finding the answer in a focused, unbiased manner. The nutrition profession would benefit from more RDs conducting research.
Much can be learned from nutrition-related research about delivering medical nutrition therapy and providing evidence for nutrition therapy and its effectiveness.

References


After reading this issue of *On the Cutting Edge,* “How Research Impacts Clinical Practice and Care in Diabetes,” DCE members can earn 3.0 hours of free continuing professional education units (CPEUs level II) approved by the Commission on Dietetic Registration (CDR). CPE eligibility is based on active DCE membership status from June 1, 2011 to May 31, 2012.

DCE members must complete the post-test on the CPEUs page on the DCE website: [http://www.dce.org/resources/cpeus](http://www.dce.org/resources/cpeus) by August 31, 2012. For each question, select the one best response. After passing the quiz, to view/print your certificate, access your CPEU credit history or view the learning objectives, go to: [http://www.dce.org/account/history](http://www.dce.org/account/history).

Please record 3.0 hours on your Learning Activities log and retain the certificate of completion in the event you are audited by CDR. The certificate of completion is valid when the CPE questionnaire is successfully completed, submitted to, and recorded by DCE/ADA.

### CPE Credit Self-Assessment Questionnaire

1) Study measures that produce results that are reproducible or consistently the same are called:
   a. Double Blind
   b. Life Style Intervention
   c. Reliability
   d. Validity

2) The new criteria to diagnose gestational diabetes mellitus require:
   a. 2 or more values that meet or exceed normal range
   b. 1 hour blood glucose value of 165mg/dL or lower
   c. One value that meets or exceed normal range
   d. A fasting blood glucose of 90 mg/dL or lower

3) A risk allele is:
   a. The specific location of a gene or DNA sequence on a chromosome
   b. Used to estimate the effect of a genetic variant
   c. An organized structure of DNA containing many genes and other nucleotide sequences
   d. The genetic variant that is associated with increased risk of developing a disease

4) The first step in the research process is to:
   a. Define the intervention
   b. Identify a specific question
   c. Select participants
   d. Secure funding

5) The intensive lifestyle intervention program has a goal of:
   a. Losing up to 7% of initial weight
   b. Losing up to 10% of initial weight
   c. Increase activity up to 100 minutes per week
   d. Increase activity up to 175 minutes per week
   e. a & c
   f. a & d

6) In a survey of primary care patients and physicians, _____ percent of patients believed being identified as having a “genetic risk for diabetes” would motivate them to adopt healthier lifestyles and _____ percent of physicians believed patients would be motivated to change.
   a. 71% patients, 23% physicians
   b. 50% patients, 50% physicians
   c. 23% patients, 71% physicians
   d. Both groups believed being identified as having a “genetic risk for diabetes” would have little effect on their lifestyles

7) A study in which data is collected at one point in time to characterize a given group of people or a community is called:
   a. Case-Control Study
   b. Cross-Sectional Study
   c. Prospective Cohort Study
   d. Randomized Controlled Trial

8) A roadblock to the acceptance of the IADPSG criteria in the United States is:
   a. There is a lack of credible studies to support changing the recommendations
   b. The ACOG has not publicly supported the recommendations
   c. The criteria for diagnosis of gestational diabetes mellitus require 3 or more values meeting or exceeding normal range
   d. There is not credible evidence to support the correlation between blood glucose levels and adverse maternal and fetal outcomes

9) Over the past two decades, data suggests:
   a. Adipocytes are storage depots of extra calories
   b. Adipocytes are not just depots of extra calories
   c. Adipocytes release inflammatory markers
   d. Adipocytes release fatty acids
   e. b & c
   f. b, c, d

10) In the Look AHEAD Trial, to ensure the client met the weight loss goal, the diet was set up to be:
    a. 1,200 – 1,500 calories if initial weight was 250 pounds or less
    b. 40-45 grams fat if initial weight was 250 pounds or less
    c. 1,500 – 1,800 kcal calories if initial weight was more than 250 pounds
    d. 50-60 grams fat if initial weight was more than 250 pounds
    e. a, c, d
    f. All of the above
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