Special Article

ASN Position Statement

Waist circumference and cardiometabolic risk: a consensus statement from Shaping America's Health: Association for Weight Management and Obesity Prevention; NAASO, The Obesity Society; the American Society for Nutrition; and the American Diabetes Association[1–4]

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INTRODUCTION

Obesity is an important risk factor for cardiometabolic diseases, including diabetes, hypertension, dyslipidemia, and coronary heart disease (CHD). Several leading national and international institutions, including the World Health Organization and the National Institutes of Health, have provided guidelines for classifying weight status based on body mass index (BMI; in kg/m^2) (1, 2). Data from epidemiologic studies demonstrate a direct correlation between BMI and the risk of medical complications and mortality rate (eg, 3, 4). Men and women who have a BMI $\geq$ 30 are considered obese and are generally at higher risk for adverse health events than are those who are considered overweight (BMI between 25.0 and 29.9) or lean (BMI between 18.5 and 24.9). Therefore, BMI has become the gold standard for identifying patients at increased risk of adiposity-related adverse health outcomes.

Body fat distribution is also an important risk factor for obesity-related diseases. Excess abdominal fat (also known as central or upper-body fat) is associated with an increased risk of cardiometabolic disease. However, precise measurement of abdominal fat content requires the use of expensive radiological imaging techniques. Therefore, waist circumference (WC) is often used as a surrogate marker of abdominal fat mass, because WC correlates with abdominal fat mass (subcutaneous and intraabdominal) (5) and is associated with cardiometabolic disease risk (6). Men and women who have WCs $>$ 40 in (102 cm) and 35 in (88 cm), respectively, are considered to be at increased risk for cardiometabolic disease (7). These cutpoints were derived from a regression curve that identified the WC values associated with a BMI $\geq$ 30 in primarily Caucasian men and women living in north Glasgow, Scotland (8).

An expert panel, organized by the National Heart, Lung, and Blood Institute (NHLBI), has recommended that WC be measured as part of the initial assessment and be used to monitor the efficacy of weight-loss therapy in overweight and obese patients who have a BMI $<$ 35 (7). However, measurement of WC has not been widely adopted in clinical practice, and the anatomical, metabolic, and clinical implications of WC data can be confusing. Therefore, Shaping America's Health: Association for Weight Management and Obesity Prevention; NAASO, The Obesity Society; and the American Diabetes Association convened a panel, composed of members with expertise in obesity management, obesity-related epidemiology, adipose tissue metabolic pathophysiology, statistics, and nutrition science, to review the published scientific literature and hear presentations from other experts in these fields. The Consensus Panel met

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[2] This report represents the proceedings from a conference sponsored by Shaping America's Health: Association for Weight Management and Obesity Prevention; NAASO, The Obesity Society; and the American Diabetes Association and is being published concurrently in the journals *Obesity* and *Diabetes Care*. The report has been endorsed by the American Society for Nutrition (ASN) and is published in *The American Journal of Clinical Nutrition* as an ASN position statement.

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December 17–20, 2006, in Washington, DC, and was charged to provide answers to the following 4 questions:

1. What does waist circumference measure?
2. What are the biological mechanisms responsible for the association between waist circumference and cardiometabolic risk?
3. What is the power of waist circumference to predict adverse cardiometabolic outcomes? How does the predictive power of waist circumference compare with that of BMI? Does measuring waist circumference in addition to BMI improve predictability?
4. Should waist circumference be measured in clinical practice?

QUESTION 1: WHAT DOES WAIST CIRCUMFERENCE MEASURE?

Measurement technique

WC is actually a perimeter, which provides an estimate of body girth at the level of the abdomen. Different anatomic landmarks have been used to determine the exact location for measuring WC in different clinical studies, including *1*) midpoint between the lowest rib and the iliac crest; *2*) the umbilicus; *3*) narrowest (minimum) or widest (maximum) WC; *4*) just below the lowest rib; and *5*) just above the iliac crest. The specific site used to measure WC influences the absolute WC value that is obtained (9). The most commonly used sites reported in studies that evaluated the relation between morbidity or mortality rate and WC were the midpoint between the lowest rib and the iliac crest (29%), the umbilicus (28%), and the narrowest WC (22%). Although sites that use an easily identifiable and reproducible landmark (eg, just above the bony landmark of the lilac crest) might be more precise and easier to use than other sites, we are not aware of data from any studies that demonstrate an advantage of one measurement site over others.

WC measurements should be made around a patient's bare midriff, after the patient exhales while standing without shoes and with both feet touching and arms hanging freely. The measuring tape should be made of a material that is not easily stretched, such as fiberglass. The tape should be placed perpendicular to the long axis of the body and horizontal to the floor and applied with sufficient tension to conform to the measurement surface. In a research setting, WC measurements are typically taken 3 times and recorded to the nearest 0.1 cm. Although specific techniques have been recommended for measuring WC in the clinical setting (2, 10), there is no uniformly accepted approach. Training technicians and even patients to use an appropriate technique for measuring WC is essential to obtaining reliable data; special tape measures, instructional manuals, and videotapes are available for this purpose (11).

The reproducibility of WC measurements at all sites is high for both men and women (eg, iliac crest site, intraclass correlation coefficient, $r = 0.998$ and $r = 0.999$, respectively) (9, 12, 13). The correlation between technician- and self- measured WC after proper training can also be high for men ($r = 0.95$) and women (0.89), respectively (14). However, self-reported measurements are prone to a systematic bias, and there is a nontrivial underestimate of self-measured WC at all anatomic sites (15).

TABLE 1
Distribution of adipose tissue mass in lean and obese men[1]

	Lean men	Obese men
BMI (kg/m^2)	23	37
Body weight (kg)	71	116
Body fat (%)	15	32
Total body fat (kg)	10	37
Total subcutaneous fat (kg)	9	32
Abdominal fat (kg)	4.3	12.3
Subcutaneous (kg)	2.4	7.2
Intraabdominal (kg)	1.9	5.1
Intraperitoneal (kg)	1.1	3.5
Retroperitoneal (kg)	0.8	1.6

[1] Adapted from Reference 16.

Anatomic relations

Adipose tissue consists of adipocytes, inflammatory cells, and vascular, connective, and neural tissues. Adipose tissue is distributed throughout the body as large homogeneous discrete compartments and as small numbers of cells "marbling" or adjacent to other tissues. Most adipose tissue (~85% of total adipose tissue mass) is located under the skin (subcutaneous fat), and a smaller amount (~15%) is located within the abdomen (intra-abdominal fat) in lean and obese persons (**Table 1**) (16). The relative contribution of intra-abdominal fat mass to total body fat is influenced by sex, age, race-ethnicity, physical activity, and total adiposity. The term "visceral fat" is commonly used to describe intra-abdominal fat, and it includes both intraperitoneal fat (mesenteric and omental fat), which drains directly into the portal circulation, and retroperitoneal fat, which drains into the systemic circulation.

Magnetic resonance imaging (MRI) and computed tomography (CT) are considered the gold-standard methods for determining the quantity of subcutaneous abdominal adipose tissue (SAAT) and intra-abdominal adipose tissue (IAAT) (17). Most MRI and CT methods involve acquisition of cross-sectional abdominal images, which are then analyzed for fat content. A single slice is often acquired at the L_4-L_5 inter-vertebral level to estimate SAAT and IAAT volume, expressed as cm^3. However, L_4-L_5 imaging does not provide the best estimate of total IAAT mass, which is more reliably estimated several centimeters cephalad of the L_4-L_5 inter-vertebral space (17, 18). In addition, measurement site influences the relation between IAAT volume and cardiometabolic risk; the association between IAAT volume and the presence of the metabolic syndrome is greater when IAAT volume is determined at the L_1-L_2 than at the L_4-L_5 level (19). Currently, there is no universally accepted site for measuring IAAT and SAAT.

The relation between WC, weight, and BMI can be conceptualized by using simple geometric relations that consider the body as a cylinder; WC is the cylinder's circumference, height is its length, and weight is a measure of mass. Therefore, BMI provides information about body volume and mass, and WC provides information about body shape. In general, BMI and WC are highly correlated, typically with r values in the range of 0.80–0.95 (20), and WC reflects both SAAT and IAAT volumes (21). The relations among WC, BMI, and adipose tissue compartments in primarily Caucasian and African American men and women are shown in **Table 2** (18). These data demonstrate that both BMI

TABLE 2
Relationships among waist circumference, BMI, and adipose tissue compartments in mean and women[1]

	Men		Women	
	BMI	Waist circumference	BMI	Waist circumference
Total adipose tissue	0.82	0.87	0.91	0.87
Percentage body fat	0.70	0.79	0.86	0.82
Total subcutaneous adipose tissue	0.82	0.83	0.91	0.86
Total intraabdominal adipose tissue	0.59	0.79	0.69	0.77

[1] Values are correlation coefficients. Adapted from Reference 18.

and WC are strongly correlated with total-body adipose tissue mass, but that WC is a better predictor of IAAT than is BMI.

Assessment of WC provides a measure of fat distribution that cannot be obtained by measuring BMI. However, there is no standardized approach for measuring WC, and different anatomic landmarks have been used to measure WC in different studies. Moreover, the measurement site that provides the best correlation with disease risk and best reflects changes in abdominal adipose tissue mass has not been established. Nonetheless, the precision of WC measurement is high at any given landmark. Even self-measurement can be highly reproducible when performed by properly trained subjects, although self-measurement results in an underestimation of true WC. Measurement of WC cannot determine the individual contributions of SAAT and IAAT to abdominal girth, which require imaging by MRI or CT. The value of these scanning techniques in clinical practice has not been determined.

QUESTION 2: WHAT ARE THE BIOLOGICAL MECHANISMS RESPONSIBLE FOR THE ASSOCIATION BETWEEN WAIST CIRCUMFERENCE AND METABOLIC AND CARDIOMETABOLIC RISK?

It is not known whether the storage of an absolute or relative excess amount of triacylglycerols in abdominal fat depots is directly responsible for increased disease risk, whether such deposition is simply associated with other processes that cause risk, or both. In addition, WC values provide a measure of both SAAT and IAAT masses. Therefore, the relation between WC and cardiometabolic risk cannot determine whether risk is associated with SAAT, IAAT, or both.

The mechanism(s) responsible for the relation between excess abdominal fat distribution and cardiometabolic disease is not known, but several hypotheses have been proposed. One of the earliest hypotheses that implicated IAAT as a metabolic risk factor suggested that activation of the central nervous system–adrenal axis by environmental stressors caused both the preferential deposition of adipose tissue in the trunk and the cardiovascular and metabolic disorders associated with that deposition (22). More recently, it has been suggested that a limited ability of subcutaneous fat depots to store excess energy results in an "overflow" of chemical energy to IAAT and "ectopic" sites, such as liver and skeletal muscle. Excessive ectopic fat accumulation then causes metabolic dysfunction in those organs. In fact, increased intrahepatic fat is associated with dyslipidemia and hepatic insulin resistance (23), and increased intramyocellular fat is associated with skeletal muscle insulin resistance (24). In this paradigm, IAAT is primarily a marker of the magnitude of overflow of fatty acids from subcutaneous depots. Therefore, increased WC could be a discernible marker of a systemwide impairment in energy storage regulation, in which an increase in IAAT reflects a reduced capacity for energy storage in other adipose tissues. A third hypothesis proposes a direct effect of omental and mesenteric adipose tissue depots on insulin resistance, lipoprotein metabolism, and blood pressure. Metabolic products of omental and mesenteric adipose tissue depots are released into the portal vein, which provides direct delivery to the liver. Lipolysis of omental and mesenteric adipose tissue triacylglycerols releases free fatty acids that can induce hepatic insulin resistance and provide substrate for lipoprotein synthesis and neutral lipid storage in hepatocytes. In addition, specific proteins and hormones produced by omental and mesenteric adipose tissue, such as inflammatory adipokines, angiotensinogen, and cortisol (generated by local activity of 11 β-hydroxysteroid dehydrogenase), can also contribute to cardiometabolic disease. A fourth hypothesis is that genes that predispose to preferential deposition of fat in abdominal depots independently cause cardiometabolic disease.

These hypotheses are not mutually exclusive, and it is possible that all, and other unknown mechanisms, are involved in the association between abdominal fat mass and adverse metabolic consequences.

QUESTION 3: WHAT IS THE POWER OF WAIST CIRCUMFERENCE TO PREDICT ADVERSE CARDIOMETABOLIC OUTCOMES? HOW DOES THE PREDICTIVE POWER OF WAIST CIRCUMFERENCE COMPARE WITH THAT OF BMI? DOES WAIST CIRCUMFERENCE MEASUREMENT IN ADDITION TO BMI IMPROVE PREDICTABILITY?

The importance of WC in predicting cardiometabolic risk factors (eg, elevated blood pressure, dyslipidemia, and hyperglycemia) and adverse outcomes (eg, diabetes, CHD, and death rate) has been examined in many large epidemiologic studies (7, 24–33). Specific relative risks between WC and these outcomes vary, depending on the population sampled and the outcome measured. The relation between WC and clinical outcome is consistently strong for diabetes risk, and WC is a stronger predictor of diabetes than is BMI. The relative risk of developing diabetes between subjects in the highest and lowest categories of reported WC often exceeds 10, and it remains statistically significant after adjustment for BMI. These data demonstrate that WC can identify persons who are at greater cardiometabolic risk than are those

identified by BMI alone. Values for WC are also consistently related to the risk of developing CHD, and the relative risk of developing CHD between subjects in the highest and lowest categories of WC ranges from 1.5 to 2.5 and remains statistically significant after adjustment for BMI. Values for WC are usually strongly associated with all-cause and selected cause-specific mortality rates. Data from several studies support the notion that WC is an important predictor of diabetes, CHD, and mortality rate, independent of traditional clinical tests such as blood pressure, blood glucose, and lipoproteins (7, 26). However, there is not yet a compelling body of evidence demonstrating that WC provides clinically meaningful information that is independent of well-known cardiometabolic risk factors.

The relations between WC and health outcomes are affected by demographic variables, including sex, race-ethnicity, and age. WC is an important predictor of health outcomes in men and women; Caucasians, African Americans, Asians, and Hispanics; and adults of all age groups. In fact, the relation between WC and health outcome changes much less with increasing age than does the relation between BMI and health outcome (31). However, it is not known whether WC can provide a better assessment of health risk in one sex, racial-ethnic group, or age category than another.

The shape of the relation between WC and health outcomes (eg, linear, monotonic, step-function, or U-shaped) influences the WC value that can most efficiently distinguish between "normal" and "abnormal" and serve as a basis for considering clinical action. Data from most studies suggest that the shape of the relation between WC and health outcome lends itself to identifying clinically meaningful cutpoint values, because risk often accelerates monotonically above, and can be relatively flat below, a specific WC value. Optimum WC cutpoints will likely vary according to the population studied, the health outcome of interest, and demographic factors.

Data from most clinical weight-loss and exercise training trials have shown that reductions in WC occur concomitantly with reductions in obesity-related cardiometabolic risk factors and disease. However, these results do not prove that the reduction in WC was responsible for the beneficial effect on health outcome. Additional studies are needed to evaluate the effect of decreasing WC on cardiometabolic outcomes.

QUESTION 4: SHOULD WAIST CIRCUMFERENCE BE MEASURED IN CLINICAL PRACTICE?

The panel concluded that determining whether WC should be measured in clinical practice depends on the responses to the following 4 key questions:

1. Can waist circumference be reliably measured? Answer: **Yes**.

Health care personnel and even patients themselves, who are given appropriate training in technique, can provide highly reproducible measurements of WC in men and women. However, it is not known whether measurement at one anatomical site is a better indicator of cardiometabolic risk than is measurement at other sites.

2. Does waist circumference provide *a*) good prediction of diabetes, CHD, and mortality rate? Answer: **Yes**; *b*) incremental value in predicting diabetes, CHD, and mortality rate above and beyond that provided by BMI? Answer: **Yes**; and *c*) sufficient incremental value in these predictions above and beyond that offered by BMI and commonly evaluated cardiometabolic risk factors, such as blood glucose concentration, lipid profile, and blood pressure? Answer: **Uncertain**.

Data from many large population studies have found WC to be a strong correlate of clinical outcome, particularly diabetes, and to be independent of BMI. In addition, data from a limited number of studies demonstrate that WC remains a predictor of diabetes, CHD, and mortality rate, even after adjustment for BMI and several other cardiometabolic risk factors. Additional studies are needed to confirm that WC remains an independent predictor of risk.

3. Do the current definitions used to determine a high WC identify a nontrivial number of patients who are at increased cardiometabolic risk, but who would not otherwise be identified by having a BMI $\geq$ 25 and an assessment of commonly evaluated cardiometabolic risk factors? Answer: **Yes**.

The recommended WC thresholds for increased cardiometabolic risk in men [>40 in (102 cm)] and women [>35 in (88 cm)] were derived from WC values that correlated with a BMI $\geq$ 30 (2). The National Health and Nutrition Examination Survey III (NHANES III) found that about 14% of women and about 1% of men had a "high" WC but a normal BMI (18.5–24.9) (36). In addition, $\approx$70% of women who were overweight (BMI 25.0–29.9) had a WC > 35 in and $\approx$25% of men who were overweight had a WC > 40 in. An estimate based on data available from the World Health Organization's Monica Project, conducted in >32 000 men and women from Europe, Australia, and New Zealand, suggest that about 10% of participants who had a BMI < 30 had a WC above the recommended cutpoints for increased risk (36). It is not known what portion of subjects who had a large WC would have been identified as having increased cardiometabolic risk based on findings from a standard medical evaluation. Therefore, the optimal WC criteria needed to identify patients at increased risk of metabolic disease, who would otherwise not be identified by evaluating BMI and/or other standard cardiometabolic risk factors, is not known and will likely require adjustments based on BMI, sex, age, and race-ethnicity.

4. Would assessment of WC in patients who have a BMI $\geq$ 25 affect clinical management if NHLBI obesity treatment guidelines are followed? Answer: **Probably not**.

Measurement of WC in clinical practice is not trivial, because providing this assessment competes for the limited time available in a busy office practice and requires specific training to ensure that reliable data are obtained. Therefore, WC should only be measured if it can provide additional information that influences patient management. Based on NHANES III data, 99.9% of men and 98.49% of women would have received the same treatment recommendations proposed by the NHLBI Expert Panel by evaluating BMI and other cardiovascular risk factors, without an assessment of WC (37). However, it is likely that different WC cutpoint values could provide more useful clinical information. For example, an analysis of data obtained from the NHANES III and the Canadian Heart Health Surveys found that BMI-specific WC cutpoints provided a better indicator of cardiometabolic risk than did the recommended WC thresholds (35). For normal-weight (BMI 18.5–24.9), overweight (BMI 25.0–29.9), class I obesity (BMI 30.0–34.9) and class II/class III obesity (BMI $\geq$ 35.0), the optimal WC cutpoints were 87, 98, 109, and 124 cm in men and 79, 92, 103, and 115 cm in women, respectively. Therefore, it is possible that WC measurement could be an effective clinical tool for identifying "metabolically obese, lean" patients,

who might benefit from lifestyle therapy but would not have been considered for treatment because of a normal BMI. WC could also identify "metabolically normal, obese" subjects, who do not require aggressive obesity therapy because they do not have a marked increase in cardiometabolic risk.

CONCLUSIONS

WC provides a unique indicator of body fat distribution, which can identify patients who are at increased risk of obesity-related cardiometabolic disease, above and beyond the measurement of BMI. However, the current WC cutpoints recommended to determine health risk (2) were derived by regression from an "obese" BMI and are unlikely to affect clinical management when BMI and other obesity-related cardiometabolic risk factors are already being determined. Therefore, the clinical usefulness of measuring WC, when risk is based on the currently accepted guidelines, is limited. However, WC measurement can sometimes provide additional information to help the clinician determine which patients should be evaluated for the presence of cardiometabolic risk factors, such as dyslipidemia, and hyperglycemia. In addition, measuring WC can be useful in monitoring a patient's response to diet and exercise treatment, because regular aerobic exercise can cause a reduction in both WC and cardiometabolic risk, without a change in BMI (38). Further studies are needed to establish WC cutpoints that can assess cardiometabolic risk that is not adequately captured by BMI and routine clinical assessments. Selection of the most appropriate WC values will be complex, because they are likely influenced by sex, race-ethnicity, age, BMI, and other factors. Nonetheless, it should be possible to determine more useful WC cutpoints than are currently recommended, by carefully reviewing published data and re-evaluating datasets available from existing population studies. These additional analyses will define the future role of WC measurement in clinical practice.

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Current Research

Continuing Education Questionnaire, page 1381
Meets Learning Need Codes 1000, 4000, 5000, and 7000

Effects of Lifestyle Intervention on Health Care Costs: Improving Control with Activity and Nutrition (ICAN)

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ABSTRACT

Objective To evaluate program and health care costs of a lifestyle intervention in a high-risk obese population.

Design Twelve-month randomized controlled trial comparing lifestyle case management to usual care.

Subjects/setting Health plan members (n=147) with obesity (body mass index ≥27) and type 2 diabetes.

Intervention Lifestyle case management entailed individual and group education, support, and referrals by registered dietitians. Those in the usual-care group received educational material.

Main outcome measures Medical and pharmaceutical health care costs reimbursed by the participant's primary insurance company.

Statistical analysis Total costs were modeled using the four-equation model using previous year cost as a predictor.

Results Net cost of the intervention was $328 per person per year. After incorporating program costs, mean health plan costs were $3,586 (95% confidence interval [CI]: −$8,036, −$25, $P<0.05$) lower in case management compared to usual care. The difference was driven by group differences in medical (−$3,316, 95% CI: −$7,829 to −$320, $P<0.05$) but not pharmaceutical costs (−$239, 95% CI: −$870 to $280, not statistically significant), with fewer inpatient admissions and costs among case management compared with usual care (admission prevalence: 2.8% vs 22.5% respectively, $P<0.001$).

Conclusion Addition of a modest-cost, registered dietitian–led lifestyle case-management intervention to usual medical care did not increase health care costs and suggested modest cost savings among obese patients with type 2 diabetes. Larger trials are needed to determine whether these results can be replicated in a broader population. The findings can be judiciously applied to support that the addition of a registered dietitian–led lifestyle case-management program to medical care does not increase health care costs.

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The direct cost of diabetes in the United States was $91.8 billion in 2002 (1). The cost of overweight and obesity was equally high (2). As prevalence of both diabetes and obesity in the United States increases (3), so does the human and financial burden of these conditions. An estimated 38% of the increase in the cost of diabetes between 1987 and 2001 was due to increases in the prevalence of obesity as well as increased medical spending on care of obese individuals (4). This suggests that treating obesity in the context of diabetes management may improve both health and economic outcomes.

Lifestyle treatment (diet and physical activity) is the cornerstone of treatment for both type 2 diabetes and obesity. Modest weight loss improves insulin sensitivity (5) and improves glycemic control, blood pressure, and lipid profiles in people with existing type 2 diabetes (6-9). Independent of weight loss, lifestyle treatment is an effective means of improving glycemic control (10), blood pressure (11,12), and lipid levels (13-18). Moreover, lifestyle treatment with modest weight loss has been shown to be an effective (19-21) and a more cost-effective means

to prevent diabetes than metformin or usual care in patients at high risk of developing diabetes (22,23). Registered dietitians (RDs) could play a vital role in the delivery of lifestyle treatment considering their training in food and nutritional sciences, health, and behavior change. In addition, many RDs have advanced certification in diabetes and weight management.

Despite this, health systems have generally not integrated lifestyle treatment into clinical practice or systematically reimbursed for nutrition services. The resource burden of some lifestyle treatments demonstrated in efficacy trials may be too great for patients, clinicians, and health care systems to sustain. During the 3 years of the Diabetes Prevention Project, the cost for lifestyle treatment, from a health system's perspective, was $2,780 per person (24). Translation of lifestyle efficacy trials into lower-intensity, cost effective interventions is one approach to maximize their applicability and long-term maintenance for obese individuals with type 2 diabetes (25,26).

We have previously reported that a modestly priced, RD-led case management approach to lifestyle modification was more effective than usual medical care for improving clinical and health-related quality of life outcomes and decreasing self-reported prescription medication use of patients with obesity and type 2 diabetes (27). The purpose of this analysis is to evaluate the within-trial program costs and economic outcomes associated with a 1-year lifestyle intervention led by an RD lifestyle case manager.

METHODS AND PROCEDURES

The Improving Control with Activity and Nutrition (ICAN) study was a randomized controlled trial (RCT) conducted from 2001 to 2003. The University of Virginia Institutional Review Board approved the study. It is in compliance with Health Insurance Portability and Accountability Act of 1996, and all patients gave written informed consent.

Study Design

The purpose of the ICAN pilot project was to evaluate the differences in clinical, humanistic, and economic outcomes of a nutrition intervention involving lifestyle case management and medical nutrition therapy by an RD compared with usual medical care for obese individuals with type 2 diabetes. The intervention is aimed at moderate weight loss (5% to 10%), improvement in diet quality, and an increase in physical activity. In addition, we wanted to obtain effect sizes of the intervention and gather necessary data critical to planning a larger randomized trial.

Eligibility criteria were: type 2 diabetes (ICD-9 [International Classification of Diseases-9th edition] code 250.XX, 357.2 362.0, 362.02, or 366.41, and confirmed by physician), diabetes medication use, body mass index (calculated as kg/m^2) of 27 or more, age 20 years or older, ability to comprehend English, and membership in Southern Health Services health plan as primary health insurance. Exclusion criteria were: pregnancy, cognitive limitations, or medical reasons precluding dietary and physical activity modifications.

Eligible participants were randomly assigned to either case management or usual care using random permuted blocks with randomly chosen block sizes of 2 or 4. Study personnel were blinded to allocation schedule until assignment.

Intervention—Lifestyle Case Management by a Registered Dietitian

One RD case manager met with participants individually, in groups, and by phone for assessment, goal setting, education, and referrals to community resources. The RD measured weight and waist circumference, reviewed laboratory results, and discussed patient-care issues with physicians when appropriate. Individual sessions occurred six times throughout the year, totaling 4 hours. Individual sessions were similar to an outpatient nutrition visit during which the participant's lifestyle was assessed and patient-centered goals were developed. Goals were tailored but based on national dietary recommendations for people with type 2 diabetes and obesity (28,29). Follow-up visits reassessed whether participants met their goals and, if not, discussed ways to overcome barriers; goals were reset to more achievable levels. Participants also attended six, 1-hour small group (10 or more people per group) sessions developed to provide the majority of education regarding diet and physical activity for improved glucose control and weight loss. Brief monthly phone contacts provided support. Participants were given the LEARN (Lifestyle, Exercise, Attitudes, Relationships, Nutrition) manual (30).

Control Group—Usual Care

Usual care participants received written educational material including the LEARN manual (30). Usual care patients were seen by a research associate every 3 months for weight measurements and to complete questionnaires. The research associate was allowed to answer questions but did not assess, set goals, or have an ongoing dialogue about a participant's diet or physical activity level.

Outcome Measures

The primary outcome measures were health care utilization and health plan costs during the year of the trial. Utilization is defined as the number of claims during the year, except for inpatient and pharmaceutical use. Utilization within the inpatient analysis represents the number of unique hospital admissions. Length of stay was defined by Southern Health Services and represents the number of nights in the hospital. Utilization in the pharmacy analysis represents the 12-month change in self-reported number of prescription medications taken daily. Cost is defined as the dollar amount paid by the health insurance company. We also explored other perspectives of health care cost, including costs to patients (medical costs+copay) and charges, but focused on costs paid by the insurer. Direct nonmedical costs (out-of-pocket costs for exercise equipment and diet food) were not included in this analysis.

The health plan variable "place of service" was aggregated from 11 potential place of service categories. *Inpa-*

tient services included all paid claims for care in hospitals. *Outpatient* included all paid claims for services occurring in physician offices and other clinical practices, outpatient hospital services, and independent laboratories outside physician offices. *Emergency room* included all paid claims originating from emergency departments and ambulance use. *Procedures* included all paid claims generated by ambulatory surgical centers. *Pharmaceutical* was generated from the pharmacy database and represents claims and payment for insurance-covered prescription medications. Other types of services (ie, nursing home and rehabilitative facilities) were not included due to low occurrence. The outcomes were defined as the sum of claims and cost for a person from the initial visit to 365 days after that visit. There were 23 participants who completed the trial whose pharmaceutical claims did not cover a full 365 days (three with fewer than 3 months of data; six with fewer than 6 months; five with fewer than 9 months; and nine with fewer than 12 months). All available data within that timeframe were used.

Program Costs

Program costs were calculated by applying standard unit costs to the resources used. Resource use included educational materials and patient care unit time. Unit costs were actual costs of educational material. Salary and overhead were based on published costs from the Diabetes Prevention Project (24). All costs were adjusted to 2002 US dollars using the medical component of the consumer price index (in accordance with the intervention year and the direct medical costs). Net program costs subtract usual-care program costs from the case management intervention program costs. Although both groups were allowed to join other weight management or diabetes care programs outside the ICAN program, these program costs were minimal and are not included in the analysis. We excluded the costs of the research component including resources used for recruitment, data collection and surveillance of complications and outcomes. Laboratory costs incurred as part of the study were not included in the cost of the intervention. Clinical lab tests ordered by participants' physicians as part of their usual medical care are included as part of their direct medical expenses. This avoids double-counting laboratory costs.

Direct Medical Costs

Direct medical costs typically represent expenditures for medical services and products that are usually paid for by health systems and include costs of hospitalization, urgent care, outpatient care, laboratory tests, and procedures. The cost variables within this analysis represent the dollar amount that the health insurance plans paid the practice or provider (physician, pharmacy, hospital). Health plan administrative data were linked to research databases by participant number. The health plans used two internal databases to document payments: the pharmaceutical and the medical care databases. The pharmaceutical database included outpatient prescription pharmaceutical claims and costs. The medical care database included all medical claims (except outpatient pharmaceuticals): inpatient pharmaceuticals, procedures and care; outpatient visits; ambulatory procedures and diagnostic testing; and urgent care. Claim and cost data were carefully evaluated for validity. Absolute cost differences between groups are reported for the year of the trial because participants were all members of Southern Health Services. Relative cost differences between groups are reported when comparing the year preceding the year of the trial due to an administrative change in insurance companies between these years.

Study and Analysis Group

One hundred forty-seven participants were randomly assigned to usual care (n=74) or case management (n=73). Three patients withdrew before baseline assessment, so the intention-to-treat analysis population was comprised of 72 usual-care participants and 72 case-management participants.

For health care cost data in the year preceding the trial, there were five participants without medical claims data (ie, they were not health plan members before the study) and 14 participants without pharmaceutical claims data (non–health plan members or lack of pharmaceutical benefits within their Southern Health Services medical care coverage). For health care cost data during the intervention (primary analysis), there were 11 people with missing pharmaceutical claims data (8 people without pharmacy benefits and 3 people who: [a] didn't have pharmacy benefits, [b] had no claims data during the intervention period, or [c] changed health insurance companies at the beginning of the trial). The final sample size for pharmaceutical cost was 133 (65 in usual care and 68 in case management). For medical claims data, there were two participants with missing claims data for the entire year due to changing health insurance companies during the trial. Hence, the final sample size for medical claims cost was 142 (71 in usual care and 71 in case management).

Statistical Analysis

Administrative data were extracted and transferred by Microsoft Access (version 5.0, 2002, Microsoft, Redmond, WA). Data preparation and quality assurance was implemented in SPSS (version 11, 2001, SPSS, Chicago, IL) (31). Estimation of descriptive statistics, significance tests, and fitting of models has been done in both R (R version 2.0, 2004, Vienna, Austria) (32) and SPSS.

The "four equation model" of Duan and colleagues (33) was used to model total costs. This approach was developed by authors of the RAND Health Insurance Experiment (34) to account for the wide variability observed due to inpatient health care costs and is now commonly applied to medical cost data. This method was applied only to medical costs and cannot be applied to the pharmaceutical database or to categories of health care (ie, outpatient care) that do not include inpatient hospitalizations. Previous year cost was a predictor in the equations. Logit link and bias corrected and accelerated nonparametric bootstrap (35) was used for obtaining standard errors.

RESULTS

Baseline Characteristics

Groups were similar in all demographic and clinical measures at baseline (Table 1). Study participants, on aver-

Table 1. Baseline characteristics of ICAN[a] participants by study group

	Usual-Care Group (n=72)		Case-Management Group (n=72)	
	n	%	n	%
Categorical variables				
Female	42	58	45	62
White	53	74	61	85
Smoking status				
Never	40	56	41	57
Former	30	42	27	38
Current	2	3	4	6
Continuous variables	← *mean± SD*[b] →			
Age (y)	53.4±8.0		53.3±8.6	
Years with diabetes diagnosis	7.7±7.3		6.9±5.7	
Body mass index[c]	37.5±6.4		37.6±7.7	
Waist circumference (cm)	118.1±16.5		116.8±15.5	
Glycosylated hemoglobin (%)	7.5±1.5		7.9±1.6	
Cholesterol (mg/dL)[d]				
Total	181±37.2		183±43.4	
LDL[e]	105±33.3		105±33.7	
HDL[f]	44.6±12.3		45.4±12.8	
Triglyceride (mg/dL)[g]	167±77.2		193±76.7	
Number of medical conditions other than diabetes	2.4±1.6		2.8±1.7	
Number of prescription medications/day	5.8±2.6		6.3±2.9	
Number of diabetes medications/day	1.8±0.85		1.8±0.92	
Annual medical care cost year prior to intervention ($)	3,984±8,413		3,328±8,967	
Annual pharmaceutical cost year prior to intervention ($)	2,221±2,411		1,990±2,180	

[a]ICAN=Improving Control with Activity and Nutrition study.
[b]SD=standard deviation.
[c]Body mass index calculated as kg/m^2.
[d]To convert mg/dL cholesterol to mmoL/L, multiply mg/dL by 0.026. To convert mmol/L cholesterol to mg/dL, multiply mmol/L by 38.7. Cholesterol of 193 mg/dL=5.00 mmol/L.
[e]LDL=low-density lipoprotein.
[f]HDL=high-density lipoprotein.
[g]To convert mg/dL triglycerides to mmol/L, multiply mg/dL by 0.0113. To convert mmol/L triglycerides to mg/dL, multiply mmol/L by 88.6. Triglycerides of 159 mg/dL=1.80 mmol/L.

age, were in class 2 (body mass index=35 to 39.9) obesity and had a high-risk waist circumference, suggesting very high-risk obesity (36). Participants reported a mean (±standard deviation) of 2.6±1.6 "health problems" (eg, hypertension) in addition to diabetes; this was similar between groups. For the year preceding the trial, there were no significant differences between usual-care and case-management participants in medical (P=0.65) or pharmaceutical costs (P=0.39).

Program Costs

The direct cost of the intervention and usual care (per person per year) are presented in Table 2. Net program costs were approximately $325 per person per year.

Mean Annual Health Care Costs During Intervention

There were 5,329 pharmaceutical and 6,921 medical claims for all participants during the 1-year intervention period. Total health care costs (sum of medical and pharmaceutical costs) paid by the health plan during the 1 year of intervention were $3,911 per person per year less among those receiving lifestyle case management compared with usual care (95% confidence interval [CI]): $−8,374 to $−353, $P<0.05$) (Table 3). There was a significant difference in medical care costs (eg, inpatient, outpatient, procedures) (95% CI for the mean difference in cost: $−7,829 to $−320, $P<0.05$). Mean and median costs and utilization for prescription medications was not statistically significant (95% CI for the mean difference in cost: $−870 to $280, P=0.28). Evaluating "cost" from the perspectives such as *medical charges* or adding patient co-pay onto medical costs were not statistically significant (95% CI charges: $−14,391 to $640, not significant); medical costs+co-pay: $−7,617 to $69, not significant). Comparing health care costs from the year preceding to the year of the trial, there was a relative increase in health care costs among both groups; 84% in usual care and 41% in case management.

Health Care Costs by Place of Service

Mean and median cost and mean utilization data by place of service are presented in Table 3. Group differences by place of service are provided for descriptive purposes only because the Duan and colleagues method is applied only

Table 2. ICAN[a] within-trial direct program costs by study group

Item	Provider	Units	Time (h)	Unit cost ($)	Total cost ($)
Lifestyle group					
Curriculum	RD[b]		0.55	25.39	13.96
Materials	LEARN[c]	1		16.17	16.17
In-person visits	RD	4	1	25.39	101.55
Group sessions	RD	0.10	9	25.39	26.36
Phone calls	RD	12	0.25	25.39	76.16
Reminder phone calls	RD	6	0.16	25.39	24.37
Overhead (48% of personnel)					116
Annual cost: case management					374.57
Usual-care group					
Materials	LEARN	1		16.17	16.17
Reminder phone calls	RN[d]	5	0.16	25.39	20.31
Overhead					9.75
Annual cost: usual care					46.23

[a]ICAN=Improving Control with Activity and Nutrition study.
[b]RD=registered dietitian.
[c]LEARN=Lifestyle, Exercise, Attitudes, Relationships, Nutrition.
[d]RN=registered nurse.

to services that include inpatient utilization. Overall, across all places of services, there were no significant differences in mean and median costs by types of service by groups.

Inpatient Admissions

Post hoc analyses indicated that there were 18 inpatient admissions during the intervention. The usual-care group had significantly more admissions during the intervention period (n=16, 22.5% of usual-care group) compared with the case-management group (n=2, 2.8% of case-management group) ($P<0.001$). Among the usual-care group, one person had five admissions and another had two admissions during the intervention. The remaining admissions were person-specific. There was a significant difference between the groups for the number of people with at least one hospital admission (usual care: n=11, 15.5% of usual-care group vs case management: n=2, 2.8% of case-management group, $P=0.008$).

Table 4 provides detailed information about the cost and diagnoses of the inpatient admissions during the trial. The mean (±standard deviation) length of stay among the usual-care group was 4.7±5.0 days compared with 1.0±0 day in the case-management group. All but four hospitalizations were for conditions often related to obesity and diabetes (ie, heart disease, stroke, osteoarthritis), and nine admissions in usual care and two admissions in case management were related to cardiovascular disease. The four admissions unrelated to obesity/diabetes/cardiovascular disease cost less than most of the cardiovascular- and diabetes-related admissions. Two admissions in usual care (C and I) had less-than-expected costs considering the number and type of claims. Further inquiry revealed that these claims were denied for a variety of reasons; this underreporting of total inpatient costs was observed only in the usual-care group.

Total Health Care Costs Including Intervention Program Costs

Including the cost of the lifestyle program (Table 2) in the direct cost of health care during the year of intervention (Table 3), mean net total costs were $3,586 per person per year less among case management compared with usual care (95% CI: −$8,046, −$25, $P<0.05$).

DISCUSSION

Our analysis found that the addition of a clinically feasible, modest-cost lifestyle intervention, involving an RD as a lifestyle case management for a high-risk obese population at best saved $8,046 per person per year and at worst did not increase health care costs (saved $25 per person per year) compared with usual medical care ($P<0.05$). We remain cautious in declaring a cost saving within this pilot project because of the relatively small sample size for an economic evaluation coupled with large confidence intervals. Larger trials are needed to verify our results.

There is growing evidence from large efficacy trials that lifestyle interventions among higher risk populations are cost-effective (22,23,37). Larger health systems are beginning to offer lifestyle treatment options for their patient populations. There is less evidence that translating findings from efficacy trials to more typical clinical settings will demonstrate cost effectiveness. In a health care environment in which spending outpaces inflation and wage growth (38), payers of health care are looking for cost-effective programs (39).

In 2000, the Institute of Medicine recommended coverage of nutrition services for the Medicare population based on "limited but consistent" evidence supporting the medical efficacy of nutrition services in improving outcomes and increasing quality of life, but stopped short of saying there was enough evidence to support the cost effectiveness of such treatment (40). A recent systematic review of the cost effectiveness of outpatient nutrition

Table 3. Mean and median health care costs and health care utilization[a] by study group during the time period of the ICAN[b] intervention

Type of service	Usual-care group	Case-management group	95% CI[c] or *P* value for absolute cost difference
	← mean ± SD[d] →		
Medical care			
Mean costs ± SD ($)	8,536 ± 13,538	5,220 ± 5784	−7,829 to −320 ($P<0.05$)
Median costs ($)	3,627	3,604	
Inpatient			
Mean ± SD cost ($)	13,491 ± 13,241	8,477 ± 10,098	($P=0.35$, NS[e])
Median cost ($)	9,873	3,693	($P=0.37$, NS)
Utilization[f]	16	2	($P<0.001$)
Outpatient			
Mean ± SD cost ($)	3,811 ± 4,612	3,402 ± 2,481	($P=0.51$, NS)
Median cost ($)	2,453	2,683	($P=0.50$, NS)
Utilization	1,333	1,334	
Emergency room			
Mean ± SD cost ($)	862 ± 1,488	849 ± 662	($P=0.97$, NS)
Median cost ($)	408	739	($P=0.17$, NS)
Utilization	47	65	
Procedures			
Mean ± SD cost ($)	2,880 ± 4,646	1,409 ± 1,097	($P=0.15$, NS)
Median cost ($)	791	1,064	($P=0.75$, NS)
Utilization	17	14	
Pharmaceutical care			
Mean costs ($)	2,832 ± 1,589	2,593 ± 1,846	−870 to $280 (NS)
Median costs ($)	2,933	2213	($P=0.28$, NS)
Change in no. of medicines[g]	−0.3 meds/day	−0.9 meds/day	($P<0.01$)
Total health care			
Mean costs ($)	11,406 ± 13,892	7,495 ± 5,763	−8,374 to −353 ($P<0.05$)
Median costs ($)	7,392	6,152	(NS)

[a]Number of unique claims.
[b]ICAN = Improving Control with Activity and Nutrition study.
[c]CI = confidence interval.
[d]SD = standard deviation.
[e]NS = not statistically significant.
[f]Number of unique hospital admissions.
[g]Evaluated from self-reported prescription medication database (reference 27).

services supports the Institute of Medicine findings (41). Five RCTs evaluated the cost effectiveness of nutrition services for patients with obesity and/or diabetes and supported the medical efficacy of these services (42-46). However, all of these studies took the provider perspective (evaluating only program costs) and therefore did not report medical utilization and cost during the intervention. In general, program cost without medical expense data offers limited information to health plan decision makers. On the other hand, medical care expenses among Kaiser Permanente Northwest members, who attended a behavioral weight-loss program and lost 5% or more of their initial weight, were significantly less the year after attending the program compared with age- and sex-matched control subjects ($2,935 vs $3,354, $P=0.026$); however, program costs were not included in the cost evaluation (47). Both program costs and direct medical expenses are important components when establishing the case for a new program or benefit.

The inclusion criteria combining obesity with diabetes and taking diabetes medication purposely yielded a population that was at high risk for cardiovascular events (48), so we could evaluate economic outcomes. Baseline lipid levels indicated that many participants had not reached the Third National Cholesterol Education Program's Adult Treatment Panel targets (49) for high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglycerides; 64% of participants were on cardiovascular medications; 76% were on anti-hypertensive agents. Baseline body mass index and waist circumference placed them at very high risk (36). Eisenstein and colleagues reported that among patients with acute coronary syndrome, obesity was related to more inpatient utilization and costs (50). In general, obesity is associated with greater inpatient utilization in the US population (51) and in US managed care population (52). We did not evaluate diabetes-specific costs only because the study's population had both diabetes and obesity. Because obesity is related to many comorbid conditions, and both obesity and diabetes influence outcomes in many other conditions, evaluating hospitalizations based on obesity or diabetes-specific diagnoses has the potential to introduce bias. Table 4 provides the diagnoses related to hospitalizations.

Table 4. Inpatient utilization and costs during ICAN[a] intervention year

Participant	Primary diagnosis for hospitalization	Primary procedures	Length of stay (days)	Cost of hospitalization ($)
Usual-care group hospitalizations				
A	Osteoarthritis of the hip	Total hip joint replacement	5	24,441
B	Congestive heart failure	Cardiac diagnosis and treatment: Cardiac catherization, ECHO,[b] stress test	5	8,078
B	CVA[c]	Cerebral vascular diagnosis and treatment: ECHO, stress test	2	5,450
B	CVA-related	Cerebral vascular diagnosis and treatment	2	3,707
B	CVA-related	MRI[d]-brain, other diagnosis tests and treatment	4	7,242
B	CVA-related	CVA diagnosis and treatment: MRI, angiography	21	16,793
C	Intestinal vascular insufficiency Vascular insufficiency with stump complication	Diagnosis tests and treatment: Colonoscopy, abdominal operation, management of complications	4	1,664[e]
C	Ischemic heart disease	Stress test	1	136
E	Bacterial pneumonia	Diagnosis and treatment of pneumonia	2	4522
F	ACS[f]	Diagnosis and treatment of ACS	2	3,990
G	ACS with septicemia	Cardiac cauterization, CT[g] scan, ECHO	10	14,279
H	Lumbar spinal stenosis	Pro laminectomy	5	14,597
I	Severe myositis	Diagnosis and treatment of myositis	6	6,341
I	Chest pain	Diagnostic services (stress test, CT scan) and intermediate ICU[h]	3	4,039[e]
J	Malignant neoplasm of brain	Brain biopsy	1	100
K	Trimalleolar fracture	Diagnosis and treatment	2	7,029
Mean±SD[i]			4.7±5.0	7,716±6,707
Case-managed group hospitalizations				
L	COPD[j] with exacerbation	Observation	1	500
M	Congestive heart failure	Diagnostic tests (nuclear stress test, CT scan)	1	7814
Mean±SD[i]			1.0±0	4,157±5,172

[a]ICAN=Improving Control with Activity and Nutrition study.
[b]ECHO=echocardiogram.
[c]CVA=cerebral vascular accident.
[d]MRI=magnetic resonance imaging.
[e]Admission had many denied paid claims.
[f]ACS=acute coronary syndrome.
[g]CT=computed tomography.
[h]ICU=intensive care unit.
[i]SD=standard deviation.
[j]COPD=chronic obstructive pulmonary disease.

The main limitations of ICAN include its small sample size for economic evaluation, restriction to insured participants, the short follow-up, and the inherent limitations of administrative claims data. As with all studies, there is a possibility that our significant findings were due to chance. Because inpatient visits are rare but often expensive, there is wide variation in cost data, and in a study the size of ours typically results in broad confidence intervals. Despite this, the results using costs are consistent with the data for the number of hospitalizations by group. Furthermore, the control and treatment groups did not differ in their pretrial economic outcomes or the duration of being diagnosed with diabetes.

Regarding the study population, most participants (80%) were white and employed. Although we saw no substantial differences by race, study results may not be generalizable to multiethnic or uninsured populations. As with all clinical trials, volunteer participants may be healthier and more motivated to change behavior compared with eligible nonvolunteers. On the other hand, lifestyle interventions are always voluntary in practice, and likely to be attractive to more motivated patients. Our findings of decreased health care costs should also not be generalized across different types of lifestyle interventions, settings, or conditions.

Although use of administrative data is essential to

capture costs from a payer's perspective, there can be imprecision and change. A major administrative change in Southern Health Services is one example of this and underlies the importance of including longitudinal comparison groups (eg, in RCT or cohorts) when working with commercial health plans. Throughout the trial, the ICAN research team collaborated with health plan counterparts to minimize the imprecision and bridge the data gap between clinical research, clinical care, and business. The finding that inpatient costs among usual care were underreported due to our definition of cost being limited to costs *reimbursed by the primary insurer* is one such example. In addition, the increase in health care costs from the year previous to the year of the trial is another example. Brown and colleagues report that health care costs for people with diabetes varies little over time, but that costs, especially inpatient costs begin to increase in the seventh and eight year after diagnosis (53). The ICAN participants were a mean of 7.3 years from the time of diagnosis. The annual increase in health care cost as diabetes progresses, however, cannot explain the large increase we observed. A further explanation may be the accounting practice differences between Southern Health Services and Qual Choice, the health system acquired by Southern Health Services; hence, we report relative changes over time. The strength of the RCT design was critical to distribute inaccuracies randomly, resulting in groups with data of comparable accuracy.

CONCLUSIONS

In 1999-2000, only 52% of third-party payers (54) and 45% of Fortune 100 firms (55) covered outpatient nutrition services. Health plans, insurers, and employers may need business cases to support the decision to provide lifestyle behavior modification by an RD. The ICAN project provides preliminary evidence that moderate-intensity lifestyle intervention using an RD as a lifestyle case management reduces risk, improves quality of life (27), and does so without increasing health care costs. Given the growing prevalence of both diabetes and obesity and the substantial burden of health care costs to patients, employers, and society, effective interventions that are at least cost-neutral should be welcome additions to comprehensive medical care. Food and nutrition professionals can use these results to judiciously support the cost neutrality and effectiveness (27) of their services as an integral component of medical care.

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