Medicare's Search for Effective Obesity Treatments

Diets Are Not the Answer

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The prevalence of obesity and its associated health problems have increased sharply in the past 2 decades. New revisions to Medicare policy will allow funding for obesity treatments of proven efficacy. The authors review studies of the long-term outcomes of calorie-restricting diets to assess whether dieting is an effective treatment for obesity. These studies show that one third to two thirds of dieters regain more weight than they lost on their diets, and these studies likely underestimate the extent to which dieting is counterproductive because of several methodological problems, all of which bias the studies toward showing successful weight loss maintenance. In addition, the studies do not provide consistent evidence that dieting results in significant health improvements, regardless of weight change. In sum, there is little support for the notion that diets lead to lasting weight loss or health benefits.

Keywords: diets, weight loss maintenance, interventions, obesity, Medicare

Levels of obesity are increasing throughout the world, and in the United States, health problems associated with obesity are a leading cause of mortality, second only to health problems associated with smoking (Mokdad, Marks, Stroup, & Gerberding, 2005). About 15% of the American population was obese[1] in 1980. Over the next 20 years, the percentage of obese individuals increased dramatically, and 34% of the population is now considered obese (2003–2004; National Center for Health Statistics, 2006).

In light of the rapid increase in the prevalence of obesity, it is not surprising that Medicare has recently altered its policy on covering obesity treatments. In July 2004, the Centers for Medicare and Medicaid Services (CMS) deleted the phrase "obesity is not considered an illness" from its coverage manual. This six-word deletion opened the door for Medicare to cover treatments for obesity itself, rather than just treatments for specific conditions thought to be caused by obesity, such as diabetes and hypertension. However, CMS did not go so far as to classify obesity as a disease, and according to CMS, diseases and illnesses are distinct entities with different coverage rules. Treatments for diseases must be included in coverage, whereas treatments for obesity—classified as an illness rather than a disease—will have to meet higher standards of effectiveness[2] to be covered (Higgins, 2004).

Medicare uses a formal process to make policy decisions to grant coverage for specific treatments. When an official request for coverage of a particular treatment is made, a compilation of currently available medical and scientific information regarding the treatment is submitted to CMS. CMS then reviews the submitted data and scientific literature as well as all other relevant evidence. The staff may make a decision based on this information, or they may determine that an external review is necessary. After all external reviews have been conducted, CMS makes a final decision and then provides formal written instruction to claims processors about what claims will be covered under particular circumstances ("Medicare Program," 2003).

Throughout this decision process, scientific evidence must be evaluated and its strength must be assessed. A recent effort has been made to create a single system for grading the quality of evidence and strength of recommendations for all types of medical procedures (GRADE Working Group, 2004). According to that system, called the GRADE system, four main assessments must be made. First, judgments are made about the quality of evidence for each distinct outcome examined, across all available studies. These judgments are based on study design, study quality (i.e., the methods and execution of the study), consistency of results across studies, and directness or generalizability of the studied samples, treatments and measures. Second, if there are many outcome measures evaluated, judgments are made about which outcomes are

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[1] Obesity is defined as having a body mass index (BMI; kg/m^2) of 30 or greater. Overweight is a BMI of 25–30.

[2] Although we are aware of the distinction between the terms *efficacy* and *effectiveness* used in the clinical intervention literature, we use the terms interchangeably.

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critical. Third, the overall quality of evidence across these critical outcomes is assessed. Fourth, the balance of benefits and harms is considered.

In assessing whether Medicare should fund calorie-restricting diets for the treatment of obesity, we shall attempt to answer the questions posed by the GRADE system. We begin by evaluating the quality of evidence for the most common obesity treatment—the severe restriction of calorie intake (which we will refer to as *dieting*[3])—according to one primary outcome measure: sustained weight loss. We focus on long-term weight loss because short-term weight loss is not a cure for obesity. Population-level changes in obesity (and presumably its concomitant health problems) will only occur if losses are maintained. Direct indicators of health, such as blood pressure, cholesterol levels, disease incidence, and even mortality, are also important outcomes of obesity treatments, and we discuss these outcomes in the few long-term studies that include them. Finally, we briefly discuss the balance of benefits and harms associated with using diets as a treatment for obesity.

According to the GRADE system, the first factor to consider in evaluating the quality of scientific evidence is the study design. The system assigns a higher starting grade to randomized trials and a lower starting grade to observational studies (GRADE Working Group, 2004). The starting grade is then adjusted on the basis of the quality of the study methods and execution. We first discuss long-term randomized trials of diets (higher starting grade) and then two different types of observational studies of diets (lower starting grades). In each section, we assess the quality of the study methods and execution as well as the consistency and directness of the findings.

Long-Term Effects of Dieting

Reviews of the scientific literature on dieting (e.g., Garner & Wooley, 1991; Jeffery et al., 2000; Perri & Fuller, 1995) generally draw two conclusions about diets. First, diets do lead to short-term weight loss. One summary of diet studies from the 1970s to the mid-1990s found that these weight loss programs consistently resulted in participants losing an average of 5%–10% of their weight (Perri & Fuller, 1995). Second, these losses are not maintained. As noted in one review, "It is only the rate of weight regain, not the fact of weight regain, that appears open to debate" (Garner & Wooley, 1991, p. 740).

The more time that elapses between the end of a diet and the follow-up, the more weight is regained. For example, in a study in which obese patients were starved in the hospital for an average of 38 days, patients were followed for varying lengths of time after the starvation period. Among patients who were followed for under two years, 23% gained back more weight than they had lost. Among patients who were followed for two or more years, 83% gained back more weight than they lost (Swanson & Dinello, 1970). Even in the studies with the longest follow-up times (of four or five years postdiet), the weight regain trajectories did not typically appear to level off (e.g., Hensrud, Weinsier, Darnell, & Hunter, 1994; Kramer, Jeffery, Forster, & Snell, 1989), suggesting that if participants were followed for even longer, their weight would continue to increase. It is important for policymakers to remember that weight regain does not necessarily end when researchers stop following study participants.

Long-Term Randomized Studies

The most rigorous designs in studies of long-term weight loss maintenance are those that randomly assign individuals to a diet condition or to a no-diet condition and then follow them over time. Such studies allow causal conclusions to be drawn about the effects of the diet on weight, and they are particularly useful because individuals who do not go on diets are often found to slowly gain weight over time (e.g., Burke et al., 1996; Shah, Hannan, & Jeffery, 1991). Very few such studies include long-term follow-ups that allow for clear comparisons between the weight of dieters and the weight of control participants, presumably because it is difficult to require obese individuals with an interest in dieting to remain in wait-list control groups for extended periods of time.

By conducting searches of online databases, inspecting studies listed in the reference sections of several large reviews of diet outcome studies (Astrup & Rossner, 2000; Black, Gleser, & Kooyers, 1990; Foreyt, Goodrick, & Gotto, 1981; Jeffery et al., 2000; Leon, 1976; Perri, 1998; Perri & Fuller, 1995; Saris, 2001), and examining the reference sections of the diet outcome studies themselves,

[3] The term *dieting* has been used to refer to a wide range of behaviors, but we use it solely to refer to the specific behavior of severely restricting one's calorie intake in order to lose weight.

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we were only able to locate seven studies[4] that randomly assigned participants to a diet or a wait-list control group, follow them for at least two years, and then report on weight outcomes. The diets in several of these studies are combined with other lifestyle interventions, including exercise, but we include these studies because they are the most rigorous type of diet studies and because they have control groups that allow for useful comparisons. In fact, only one of these seven studies is a formal diet study without additional interventions. One is an obesity prevention program, and five are clinical trials of large-scale interventions designed to reduce risk for heart disease or diabetes or to prevent or control hypertension.

The formal diet study followed participants for 2.5 years (Jeffery & Wing, 1995). Participants were randomly assigned to one of four types of diets or to a wait-list control group. At the end of the 2.5-year follow-up, participants assigned to the wait-list control group did not show a statistically significant weight gain, and their weight change was only marginally different than that of the dieters. The dieters had kept off an average of only 1.7 kg (3.7 lb). This methodologically rigorous study shows that in the long term, dieters do not fare notably better than nondieters.

Another study compared individuals assigned to either of two obesity prevention programs with those assigned to a wait-list control group (Jeffery & French, 1999). The focus of the obesity prevention programs was to encourage participants to pay attention to their weight and to make small changes to their diet and exercise habits. After three years, there were no significant differences in the weight change between prevention participants and wait-list participants. Participants gained an average of 1.6 kg (3.5 lb), and the researchers concluded that the obesity prevention program had not succeeded.

Five different large-scale clinical trials randomly assigned individuals[5] to interventions with many components, in which one component was a focus on losing weight through dieting. These interventions were aimed at large groups of participants, and they tended to last several years, so there were not always rigorous controls on whether particular individuals actually participated in the intervention (and whether control participants truly did not diet). Still, these studies provide information on the long-term weight trajectories of dieters compared with nondieters.

The study with the most promising results in terms of health outcomes randomly assigned overweight or obese individuals at risk for diabetes to a lifestyle intervention involving diet and exercise or to one of two control groups (Diabetes Prevention Program Research Group, 2002). At a three-year follow-up, participants in the lifestyle intervention lost an average of about 4 kg (8.8 lb), while participants in the placebo control group had gained about 0.5 kg (1.1 lb).[6] In this same time frame, however, the lifestyle intervention reduced the incidence of diabetes by 58% compared with the placebo control group. These results may not directly be due to the diet part of the intervention, and in fact participants in the lifestyle intervention engaged in large amounts of physical activity (averaging 227 minutes per week), and this may be the potent factor. As we discuss in detail below, exercise seems to be an important factor in weight and health outcomes. In addition, the findings may not apply to all obese people, but rather just to the specially chosen subset of obese people included in the study—obese people (and overweight people) with elevated plasma glucose concentrations, a risk factor for diabetes.

The largest weight loss occurred, not surprisingly, in the study with the shortest follow-up time. In that study of a nonpharmacologic intervention for older individuals with hypertension, participants in the diet conditions maintained an average weight loss of 4.7 kg (10.4 lb) at the 2.5-year follow-up, whereas control participants maintained a loss of 0.9 kg (1.9 lb; Whelton et al., 1998). This study also included health outcomes and found no significant difference between participants in the diet condition compared with the control condition in systolic or diastolic blood pressure or in the number of cardiovascular events (e.g., strokes, myocardial infarction) experienced. However, participants in the diet condition did appear to have a reduced need for antihypertensive drugs.

[4] Several studies that are often cited as support for the long-term success of diets followed individuals for less than one year (Foreyt & Kennedy, 1971), six months (e.g., Klem, Wing, Simkin-Silverman, & Kuller, 1997), or even less time (Dahlkoetter, Callahan, & Linton, 1979; Presnell & Stice, 2003).

[5] Studies that randomly assigned entire communities to interventions and control groups are not included here because of the low power inherent in such designs (Fortmann, Williams, Hulley, Haskell, & Farquhar, 1981; Jeffery et al., 1995; Taylor et al., 1991).

[6] These numbers were not reported in the article but were estimated from a graph depicted in it.

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A study designed to prevent hypertension (Hypertension Prevention Trial Research Group, 1990) and a study designed to control hypertension (Stamler et al., 1987) followed participants for three and four years, respectively, and found similar results in terms of weight loss but differed on the health outcomes. In both studies, participants in the diet-type interventions maintained an average weight loss of 1.8 kg (3.9 lb), whereas corresponding control participants gained an average of 1.8 kg. In the hypertension prevention study (Hypertension Prevention Trial Research Group, 1990), participants on the diet did show significantly greater reductions in diastolic and systolic blood pressure over the three years of the study than did control participants, though these differences were clinically small (1.8 millimeters of mercury and 2.4 millimeters of mercury, respectively). Diet and control participants did not differ in whether they needed drug treatment for hypertension, nor did they differ in periods of hospitalization or deaths. In the hypertension control study (Stamler et al., 1987), hypertensive participants were assigned to a control group or to an intervention that combined a diet, sodium restriction, and alcohol reduction. They were then removed from their hypertension medication. The most important outcome of the study was whether participants were able to keep their blood pressure low enough to remain off their hypertension medication. On this outcome, 39% of participants in the diet intervention succeeded after four years, whereas only 5% of control participants succeeded. Although an important and clinically significant finding, it likely fails the test of directness recommended by the GRADE system. First, the intervention was not solely a diet but also required sodium and alcohol reduction, and the beneficial effects of it may be due to those components. Second, the intervention is an effective treatment for hypertension, not obesity. As such, Medicare might fund it for individuals with hypertension, regardless of whether they are obese, and the new policy on treating obesity per se is not necessary for this to occur.

Participants in the remaining study were individuals at risk for cardiovascular disease, according to their diastolic blood pressure, cholesterol level, and cigarette use. About two thirds of the participants were hypertensive. Participants were assigned to an intervention designed to lower cardiovascular risk factors or to a usual-care control group and then were followed for six years (Grimm, Cohen, Smith, Falvo-Gerard, & Neaton, 1985). The intervention included a low-cholesterol diet and instruction in smoking cessation, among other components. At the 6-year follow-up, the average weight loss maintained for individuals in the intervention condition was about 0.5 kg (1.1 lb), whereas control participants gained an average of 0.5 kg. Blood pressure levels decreased for participants in both conditions, but the decreases were significantly larger for participants in the intervention than for participants in the control group. However, this difference is likely attributable to the fact that significantly more intervention participants were taking antihypertensive medication than control participants throughout the study. Mortality rates did not differ between participants in the two groups at the 6-year follow-up, but mortality rates were lower for intervention participants at a 10.5-year follow-up (Multiple Risk Factor Intervention Trial Research Group, 1990). These mortality changes may have been due to smoking changes rather than dietary ones (or to the use of the antihypertensive medications). The directness of this study to obesity treatment must be questioned as well, as the participants were not necessarily obese, and in fact participants who weighed more than 50% over their ideal weight (according to height and weight charts) were excluded.

In sum, across these studies, there is not strong evidence for the efficacy of diets in leading to long-term weight loss. In two of the studies, there was not a significant difference between the amount of weight loss maintained by participants assigned to the diet conditions and those assigned to the control conditions. In the three studies that did find significant differences, the differences were quite small.[7] The amount of weight loss maintained in the diet conditions of these studies averaged 1.1 kg (2.4 lb), ranging from a 4.7-kg (10.4-lb) loss to a 1.6-kg (3.5-lb) gain. Participants in the control groups averaged weight gains of 0.6 kg (1.3 lb; ranging from losses of 0.9 kg [1.9 lb] to gains of up to 1.8 kg [3.9 lb]). The most positive conclusion is that dieting slows the slight weight gain that occurs with age among the average nondieter, and even this slight weight gain was not seen in all of the no-diet control groups. It is hard to call these obesity treatments effective when participants maintain such a small weight loss. Clearly, these participants remain obese.

[7] Two studies did not report sufficient information to assess whether differences were significant.

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There is some evidence for the effectiveness of diets in leading to other beneficial health outcomes, particularly in helping people stay off antihypertensive drugs and preventing diabetes, but this evidence is not consistent across the studies. In addition, it is not possible to detect whether the diet components of these interventions were potent, as the interventions all contained other components that may have reduced hypertension or prevented diabetes (e.g., increases in physical activity, reductions in smoking, alcohol use, and sodium). In addition, the effects on blood pressure seem to be specific to individuals who have hypertension, rather than to individuals who are overweight, and hence those interventions are more aptly labeled *hypertension treatments*—not *obesity treatments*—and might be offered to hypertensive individuals regardless of their weight. Similarly, only individuals with a specific risk factor for diabetes were included in the diabetes prevention study, so its generalizability to obese individuals in general is not known. Finally, although all of the studies in this section used strong research designs, in studies that tracked participants for such long periods of time, it is difficult to retain all participants in follow-up assessments. It is not entirely clear from the research reports exactly which participants were included at each assessment point, a problem that we discuss in more detail below.

Observational Studies: Type 1. Long-Term Follow-Ups Without Control Groups

Most conclusions in the literature on the long-term outcomes of dieting come from studies in which participants in structured weight loss programs are recontacted from two to five years after the diet ends. These studies do not include control groups of nondieting comparison participants, so no causal conclusions about the effects of the diets can be drawn from them. Despite this problem, these studies do give a useful sense of the weight trajectories of individuals who go on diets.

By searching online databases and reviews of diet studies (Anderson, Konz, Frederich, & Wood, 2001; Astrup & Rossner, 2000; Black, Gleser, & Kooyers, 1990; Foreyt et al., 1981; Jeffery et al., 2000; Leon, 1976; Perri, 1998; Perri & Fuller, 1995; Saris, 2001), we were able to locate 14 studies that followed participants for at least four years after a diet (see Table 1 for the features of these studies). The average weight loss on these diets was 14 kg (30.8 lb), and by the long-term follow-up, participants had gained back all but 3 of those kilograms (6.6 lb).

Eight of the studies reported (or made it possible to compute) the percentage of participants who weighed more at follow-up than before they went on the diet. These rates averaged 41% and ranged from 29% (Pekkarinen & Mustajoki, 1997) to 64% (Wadden, Sternberg, Letizia, Stunkard, & Foster, 1989), including one study that found that 50% of the participants weighed more than 5 kg (11 lb) above their starting weight by five years after the diet (Foster, Kendall, Wadden, Stunkard, & Vogt, 1996). Of note, studies always report the percentage of participants who manage to keep off some percentage of the lost weight, but only a subset reported on participants for whom the diet was counterproductive, even though this percentage is typically larger than the percentage who kept off substantial weight.

Although the findings reported so far give a bleak picture of the outcomes of diets, there are four reasons why the actual effectiveness of diets is even worse. First, the studies have very low follow-up rates, and this is especially true for the longer term follow-ups. Second, many of the participants in these studies self-reported their weight over the phone or by mail. Third, most of the studies confound effects of the diet with effects of exercise. Fourth, a substantial percentage of participants in these studies have been on other diets since the studied diet ended. Each of these methodological problems biases the studies toward showing more effective maintenance of the lost weight. We will briefly consider each of these problems for the 14 studies in which individuals were followed for four or more years after the diet ended.

Follow-up rates. The follow-up rates in these studies were quite low (see Table 1). Overall, 33% of the original participants in these diet studies returned for their long-term follow-up. Not surprisingly, the four studies with the highest follow-up rates (from 81% to 88%) were among the five studies with the smallest sample sizes (≤36 participants). Eight of the studies had follow-up rates lower than 50%.

It is generally believed that low follow-up rates bias the results of diet studies, making the diets appear to be more effective than they were, because individuals who gain back large amounts of their weight are particularly unlikely to show up for follow-up tests. In one study, researchers examined the weight trajectories of participants on the basis of how many follow-up appointments they attended (Hovell et al., 1988). The initial amount of weight

Table 1
Features of Diet Studies With Long-Term Follow-Ups (and No Control Groups)

Study	Years of follow-up	*N*	% of *N* in follow-up	% self-reporting weight	% on additional diets (or mean number of diets)	% reporting regular exercise	Mean change from baseline to end of diet (kg)	Mean change from baseline to follow-up (kg)	% regain all lost weight (or more)
Anderson et al. (1999)	5–7	52	12	30	20[a]	—	−29.7	−5.2	—
Foster et al. (1996)	5	55	47	0	65 (*M* = 1 diet)	—	−21.1	+3.6	50% were > 5 kg above baseline
Graham et al. (1983)	4.5	60	43	0	(*M* = 3 types of treatments)	35	−4.5	−3.3	—
Hensrud et al. (1994)	4	21	88	0	>50[b]	22	−12.5	−1.6	37
Jordan et al. (1985)	5	111	25	100	—	—	−8.4	−5.2	—
Kramer et al. (1989)	4	152	77	7	(*M* = 1.3 diets/year)	—	−11.9	−3.1	38
Lantz et al. (2003)	4	54	48	0	—	—	−7.0	−3.3	—
Murphy et al. (1985)	4	25	33	0	38 (*M* = 1.6 programs)	46	−7.7	−0.5	—
Pekkarinen and Mustajoki (1997)	5.5	24	88	13	12% lost > 10 kg on other diets[c]	—	−22.9[d]	−5.8	29
Stalonas et al. (1984)	5	36	81	22	(*M* = 2 diets)	—[e]	−4.7	+0.7	46
Stunkard and Penick (1979)	5	26	81	63	—	—	−8.8	−5.4	31
Wadden and Frey (1997)	5	281	22	100	43	—	−25.6	−6.6	32
Wadden et al. (1989)	5	55	72	47	55	—	−14.6	−0.6	64
Walsh and Flynn (1995)	4.5	143	47	100	36	—[f]	−21.4	−5.1	—

Note. Dashes indicate that data were not reported. 1 kg = 2.21 lb.
[a] 20% of larger sample entered special "restart" classes for former participants who failed to maintain their weight or desired further weight loss. [b] >50% engaged in informal diet attempts. [c] It is unclear how many of these participants were in the restrictive diet being evaluated here versus in another study condition. The authors do not report how many participants were on additional diets but lost less than 10 kg on them. [d] This mean only includes the 50% of participants who showed up for more than half of the meetings. [e] Participants exercised a mean of 15.6 months (of 60). [f] Percentage not given, but authors stated that regular exercisers maintained significantly greater weight loss than nonexercisers.

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lost did not differ among these participants, but participants who showed up for only one follow-up appointment had the steepest rate of weight regain over the next 30 months, regaining 82% of the weight they had lost. Participants who showed up for two to four follow-up appointments regained 59% of the lost weight. In addition, a survey of individuals who had participated in a commercial weight loss program found that individuals who responded to the survey had lost significantly more weight than those who did not respond (Grodstein, Levine, Spencer, Colditz, & Stampfer, 1996).

One study with a high follow-up rate enticed participants back to the study by offering further diet services (Graham, Taylor, Hovell, & Siegel, 1983). Only 23% of participants responded to requests to return for further assessments when those requests were made with a standard letter and phone call. But when researchers offered an inexpensive follow-up class, an additional 60% of participants agreed to return, and 17% more agreed to return after being offered home weights and a free class. This pattern of return suggests that the recruitment practices used by nearly all other studies (a letter and a phone call) may inadvertently lose participants who feel that they still need further weight loss services. Giving participants the sense that it is fine to return for additional follow-ups even if they regained significant amounts of weight may help to increase follow-up rates and reduce bias.

It is difficult to compare studies based on their follow-up rates, because studies reported and computed these rates in different ways. Ideally, these rates would be computed by dividing the number of participants in the follow-up by the total number of participants in the original diet (as reported in Table 1). Few, if any, studies, however, compute their follow-up rate that way. Most studies subtract various subgroups of participants from the total number of participants in the original study, thereby reducing the denominator of this equation and increasing the reported follow-up rate.

The subset of participants typically subtracted from the overall total includes participants who have died since the study ended and participants for whom researchers could not locate a valid phone number or address. Attrition for those reasons is considered random by most researchers, but it may not be. Because being obese is linked to health outcomes, participants who have died may have been more likely than other participants to have regained their lost weight. In studies in which participants know there are long-term follow-ups, being difficult to locate is not necessarily a random event. Participants with poor outcomes may not bother continuing to update study personnel on their whereabouts.

Even more problematic is that most researchers also subtract additional categories of participants from their original study totals (and their data analyses), and excluding these categories does not just make the follow-up rate appear higher than it actually was, but it also typically makes the diet appear more successful than it was. These additional categories of exclusions include participants who did not lose sufficient amounts of weight during the study, participants who left substantial portions of questionnaires blank, participants who had participated in a similar diet before, participants who refused to participate in earlier follow-ups for the study, participants who did not return calls, and participants who had gastric bypass surgeries (or other types of surgery) to induce weight loss subsequent to the study. One study reported excluding two participants from analyses because "inclusion of the two patients strongly skewed the results against weight loss maintenance" (Walsh & Flynn, 1995, p. 232).

These types of exclusions can lead to follow-up reports on fractured samples. For example, one study enrolled 426 participants in a diet program (Anderson, Vichitbandra, Qian, & Kryscio, 1999) and then excluded all but 154 participants from analysis for a variety of the reasons reported above. Researchers obtained follow-up weights for 112 of those 154 participants at their first time point and therefore reported a follow-up rate of 73%, even though only 26% of the original participants were included in the follow-up. In addition, the article is a long-term follow-up study, but the final four follow-up points only include from 15 to 42 participants each, a tiny fraction of the original sample size.

Which categories of participants it is appropriate to exclude from study totals is, of course, a judgment call, but it is important to remember that all of these exclusions likely make weight loss maintenance appear more successful than it is. It is worth noting that although studies find numerous reasons to exclude participants who might make the diet look ineffective, it does not appear that any studies exclude participants who might inappropriately make the diet look effective. For example, we could not locate any studies that excluded participants who had a history of stable weight before a single recent episode of weight gain, perhaps after a pregnancy or an episode of clinical depres-

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sion. These individuals, whose weights are higher than their long-standing typical weight, are thought to have an easier time maintaining weight loss after a diet.

Self-reports of weight. Another reason why the results from the 14 long-term diet studies are likely biased toward overestimating the effectiveness of the diets is that a substantial percentage of the participants in these studies self-reported their weight (by mail or phone) instead of being weighed at the lab (see Table 1). Researchers generally acknowledge that the most accurate way to assess individuals' weight is to measure it with a scale in the laboratory. Because many participants are unable or unwilling to come back to the lab, it is not usually possible for researchers to measure each participant's weight.

In these studies, 56% of participants self-reported their weight. The percentage of self-reported weights varies significantly across the studies, with the larger studies tending to have higher self-report rates than the smaller studies. In three of the studies, including three of the four largest studies, 100% of the participants self-reported their weight. Self-report rates for the remaining 10 studies ranged from 0% (in 5 studies with small sample sizes) to 63%. For some of these studies, researchers tried to correct for self-reporting bias by adding 2.3 kg (5 lb) to each participant's weight. It is not clear if this is an adequate correction.

There has been a considerable amount of research comparing individuals' self-reported weights to their scale-measured weight, but most of that work was not conducted with obese individuals or with individuals who were participating in weight loss programs. A meta-analysis of 15 studies comparing individuals' self-reported weight with their scale-measured weight located only two studies of participants in weight loss programs that reported sufficient information to be included in the meta-analysis (Bowman & DeLucia, 1992). Participants in the 15 studies significantly underestimated their weight by approximately 2.1 kg (4.6 lb). More extreme bias (underestimates of 3.7 kg [8.2 lb]) was found when considering just the studies of individuals in weight loss programs, although these conclusions should be considered tentative as there were only two such studies. Nevertheless, it is important for researchers to use scale-measured weights as often as possible and to be aware that the use of self-reported weights will bias studies toward making diets look more effective than they are.

Confounding diet and exercise. Effects of dieting are confounded with effects of exercising in many long-term follow-ups of diet studies. Individuals on diets should exercise, but if the goal is to evaluate the effects of restricting calorie intake—not the effects of exercise—on subsequent weight patterns, the occurrence of exercise becomes a methodological problem. This confound is particularly significant because correlational studies consistently find that individuals who reported the most exercise also had the best weight loss maintenance (reviewed in Fogelholm & Kukkonen-Harjula, 2000; Wing, 1999).

Exercise has also been shown to improve the maintenance of weight loss in two meta-analyses of controlled trials in which participants were randomly assigned to diet and exercise or just to diet (Fogelholm & Kukkonen-Harjula, 2000; Wing, 1999).

In one study, for example, participants were randomly assigned to a diet-only, exercise-only, or diet-plus-exercise intervention for one year (Skender et al., 1996). All participants lost similar amounts of weight during the first year. When participants were reassessed during the second year, the diet-only participants averaged a follow-up weight that was about 0.9 kg (1.9 lb) heavier than baseline, whereas the groups that included exercise remained 2.5 kg (5.5 lb) below baseline.

According to the National Weight Control Registry, a longitudinal study of individuals who maintained a weight loss of 13.6 kg (29.9 lb) for at least one year, 90% of its participants used regular physical activity as a strategy to maintain the loss (Klem, Wing, McGuire, Seagle, & Hill, 1997). Similar results were found in another sample of individuals who maintained a substantial weight loss (Kayman, Bruvold, & Stern, 1990) and in a survey of subscribers to *Consumer Reports* ("The Truth About Dieting," 2002). In fact, a survey of participants in a commercial diet program found that exercise frequency was the strongest predictor of weight loss maintenance (Grodstein et al., 1996). If substantial percentages of participants in diet studies are exercising, the diet will appear more effective than it actually is.

Nine of the 14 studies with long-term follow-ups did not report information on the exercise habits of participants (see Table 1). Of the 5 studies that did report on exercise, 3 found that participants who exercised regularly maintained significantly greater weight loss than participants who did not exercise. One study did not find a correlation between a yes–no question about exercise and weight loss maintenance, but it had a small sample size ($N = 26$) that may have precluded finding such a correlation (Murphy, Bruce, & Williamson, 1985). The remaining study assigned participants to weight loss programs that either included or did not include an exercise component (Stalonas, Perri, & Kerzner, 1984). No differences in the amount of lost weight maintained were found between participants assigned to the two types of programs, but it is important to note that researchers did not compare the weight loss maintenance of participants who actually engaged in exercise with participants who did not. Overall, it seems likely that long-term follow-ups of diet studies give overly optimistic views of the success of such diets because participants who exercise tend to show greater weight loss maintenance than participants who simply diet.

Participation in additional diets. Another factor that obscures the results of long-term diet studies is that study participants often participate in additional diets after the diet being assessed in the study ends but before the long-term follow-up data are collected. Eleven of the 14 studies with long-term follow-ups reported some information on additional dieting (see Table 1). Seven of these studies reported the percentage of participants who said they had been on additional diets, and these rates ranged from 20% to 65% of participants. Three additional studies asked participants how many other diets they had been on since the original one and reported means of one to three other diets. Finally, one study reported that 12% of the participants lost more than 10 kg (22 lb) on other diets (but did not report the prevalence of simply participating in other diets; Pekkarinen & Mustajoki, 1997).

Participating in additional diets can make the original diet look more effective than it was, because a consistent outcome of diets is significant weight loss in the short term (which—as we have shown—will later be regained).[8] In one study, participants were asked to report what they weighed when they started an additional diet, and after taking this weight into account, the researchers concluded that "failure to correct for the effects of additional therapy would have resulted in significant overestimation of the long term efficacy of this therapy" (Wadden et al., 1989, p. 42). Another study found that participants had lost an average of 11.8 more kg (26 lb) on additional diets and noted that participants did not diet during follow-up until their weight exceeded their baseline weight (Foster et al., 1996). A survey of participants in a commercial diet program asked participants to report their maximum weight since completing the diet. It found that 60% of participants weighed more than their starting weight at some point in the three years since the diet ended, even though only 40% currently weighed more than their starting weight (Grodstein et al., 1996).

In sum, long-term diet studies without control groups find little support for the effectiveness of dieting in leading to sustained weight loss. From one third to two thirds of participants in diets will weigh more four to five years after the diet ends than they did before the diet began. This conclusion comes from studies that are biased toward showing successful weight loss maintenance by the four factors described above and must be considered a conservative estimate of the percentage of individuals for whom dieting is counterproductive. The true number may well be significantly higher.

Observational Studies: Type 2. Prospective Studies Without Randomization

At any particular time, individuals are gaining, maintaining, or losing weight (Klesges, Isbell, & Klesges, 1992). Prospective nonrandomized studies can help determine the effects of dieting on weight by tracking weight trajectories over time for both dieters and nondieters. In these studies, individuals' weight and diet statuses are assessed at baseline and then their weight is measured at certain follow-up points. These studies do not randomly assign individuals to diet or not diet, so causal statements cannot be made from them, but they do allow for useful comparisons between people who choose to diet and people who choose not to diet. To date, however, few studies have used such designs and controlled for potential confounding variables.

Of the 10 prospective studies we located, only 1 found that dieting at baseline led to weight loss over time, 2 found no relation between dieting and weight change, and 7 found that dieting led to weight gain. In the 1 study that showed dieting to be effective, 1,120 adults were weighed at baseline and again 4 years later (French, Jeffery, & Murray, 1999). During the ensuing years, participants reported the number of weeks during which they engaged in 17 different weight loss behaviors. Although the majority of the behaviors (including participating in weight loss groups, eating low-calorie diet foods, and eating fewer carbohydrates) did not significantly predict weight change over the 4-year period, reducing calories did. Cumulative duration of calorie reduction (in weeks) predicted weight loss 4 years later, after controlling for baseline weight.

Two studies found no relationship between dieting and weight. One weighed a group of 24 dieters and nondieters daily for six weeks and then again six months later (Heatherton, Polivy, & Herman, 1991). Although neither group showed significant weight gain or loss at six months, dieting status was a significantly better predictor of weight variability over the six weeks of daily weight recordings than was initial body weight. The short duration of the study may have prevented significant weight changes from occurring, and the small sample size may have made any changes difficult to detect. A similar study used a larger sample size (N = 305) and a longer follow-up time (2.5 years), however, and showed no relationship between restraint status and weight change (Klesges, Klem, Epkins, & Klesges, 1991), although self-reports of weight were used.

The remaining seven prospective studies each found that dieting was related to weight gain over time, after controlling for baseline weight. In one methodologically rigorous study, researchers attempted to explore the long-term effects of dieting on weight gain over 6 and 15 years in a large cohort (N = 7,729) of adult Finnish twins

[8] Repeatedly losing and then regaining weight, called *weight cycling*, is not recommended as a weight loss strategy.

(Korkeila, Rissanen, Kapro, Sorensen, & Koskenvuo, 1999). Overall, the authors found that attempts to lose weight were related to future risk of major weight gain, even after controlling for several potential confounding variables. Specifically, dieting at baseline was a consistent predictor of subsequent weight gain (of over 10 kg [22 lb]) at both follow-ups after adjusting for age, BMI, smoking, alcohol use, education level, social class, marital status, and energy expenditure at baseline.

The findings of Korkeila et al. (1999) are consistent with several other prospective studies indicating that dieting history is related to risk for future weight gain. For example, French et al. (1994) examined the relationship between dieting and exercise behaviors and changes in body weight. They found that both men and women who had participated in formal weight loss programs gained significantly more weight over a two-year period than those individuals who had not participated in such a program. Among the 3,552 participants, this history of formal weight loss attempts predicted weight gain, even after controlling for baseline weight, dietary intake, physical activity, age, education level, occupation, marital status, and smoking status. Another prospective study examined a variety of lifestyle factors and their relationship to changes in weight over a four-year period in over 19,000 healthy older men (Coakley, Rimm, Colditz, Kawachi, & Willett, 1998). One of the two best predictors of weight gain over the four years was having lost weight on a diet at some point during the years prior to baseline, and this predictor remained significant even after controlling for baseline height and weight, physical activity, television viewing, and eating habits.

Two studies prospectively examined the relationship between dieting and weight change in large samples ($N =$ 14,972 and $N = 692$, respectively) of adolescents (Field et al., 2003; Stice, Cameron, Killen, Hayward, & Taylor, 1999). In the larger study, participants were followed for three years, and dieters gained more weight during this time than nondieters, controlling for an exhaustive set of variables, including age, gender, BMI, calorie intake, and physical activity. This weight gain was not explained by increases in calorie or fat intake. In the smaller study of adolescents (Stice et al., 1999), participants were followed annually for four years and had an average increase in weight of about 1.4 kg (3 lb). Participants who were initially overweight were no more susceptible to weight gain than those who were underweight or normal weight at baseline. There was a significantly higher increase in weight and onset of obesity in participants who had prior weight loss attempts, and participants who were dieting at baseline showed increases in weight, controlling for their baseline weight. Of the 589 female adolescents who were not obese at baseline, 63 had become obese by the end of the study. The occurrence of obesity, like weight gain in general, was strongly associated with prior weight control efforts. Among female adolescents who dieted, the risk for obesity onset over the four years was over three times that for nondieters.

The final two studies found suggestive evidence that dieting leads to more weight gain over time than not dieting. A study of 287 Caucasian adults found that baseline restraint status (as measured with the Restraint Scale) significantly predicted weight gain in women (but not men) a year later, controlling for baseline weight, age, energy intake, and physical activity levels (Klesges et al., 1992). A small study of college students over the week surrounding the Thanksgiving holiday found that dietary restraint predicted increased weight gain over the eight-day period, despite predicting decreased calorie consumption (Klesges, Klem, & Bene, 1989).

In sum, prospective nonrandomized studies do not provide support for the effectiveness of diets in leading to sustained weight loss. In only 1 of these 10 studies did dieting prospectively predict weight loss, and in the majority of studies dieting predicted weight gain.

Balancing Benefits and Harms

The final step of the GRADE system of evaluating evidence involves an analysis of the benefits of the treatment in relation to potential harms from the treatment. As we have reviewed above, the benefits of dieting are minimal. Sustained weight loss was only found in a small minority of participants, whereas complete weight regain was found in the majority. Beneficial health outcomes have not been consistently or frequently demonstrated in the long term, and very few studies were able to show clinically significant health benefits that persisted after weight regain.

Health benefits from even small weight losses are widely touted as reasons to diet (Institute of Medicine, 1995), and indeed many short-term randomized trials demonstrate such benefits. For example, short-term weight loss appears to be effective in improving glycemic control for people with (or at risk for) Type 2 diabetes (Torgerson, Hauptman, Boldrin, & Sjostrom, 2004; Williams & Kelley, 2000), for relief of osteoarthritis symptoms (Felson, Zhang, Anthony, Naimark, & Anderson, 1992), and for reducing hypertension (Schotte & Stunkard, 1990).

However, short-term studies of health benefits of weight loss do not address the question of what happens when the weight is regained. Three of the long-term randomized studies that we reviewed found that some health benefits persisted despite participants regaining much of their lost weight (Diabetes Prevention Program Research Group, 2002; Multiple Risk Factor Intervention Trial Research Group, 1990; Stamler et al., 1987), but it is not clear from these trials whether the potent effects of the interventions were from dieting or from exercise, sodium/alcohol reduction, or even increased antihypertensive medication use. The other trials we reviewed did not find sustained health benefits when weight was regained. It may be the case, as has been suggested by others, that dieting may be beneficial primarily for certain subgroups of obese individuals with comorbid conditions (Lissner, Steen, & Brownell, 1992).

It is also possible that weight regain leads to health problems of its own. An analysis of the benefits and harms of dieting must consider the potential harms of weight cycling. Weight cycling, the repeated loss and regain of weight, is commonly observed in dieters (Brownell &

Rodin, 1994; National Task Force on the Prevention and Treatment of Obesity, 1994). There is evidence from large-scale observational studies that weight cycling is linked to increased all-cause mortality (Blair, Shaten, Brownell, Collins, & Lissner, 1993; Lee & Paffenbarger, 1992) and to increased mortality from cardiovascular disease (Hamm, Shekelle, & Stamler, 1989). In addition, weight cycling is associated with increased risk for myocardial infarction, stroke, and diabetes (French et al., 1997), increased high-density lipoprotein cholesterol (Olson et al., 2000), increased systolic and diastolic blood pressure (Kajioka, Tsuzuku, Shimokata, & Sato, 2002), and even suppressed immune function (Shade et al., 2004).

It has often been suggested that the harmful effects of weight cycling result from unintentional weight loss (i.e., from smoking or illness) rather than from intentional dieting (French & Jeffery, 1994; National Task Force on the Prevention and Treatment of Obesity, 1994). However, at least two large-scale studies that controlled for unintentional weight loss still found that intentional weight loss is linked to mortality risk (Andres, Muller, & Sorkin, 1993; Pamuk, Williamson, Serdula, Madans, & Byers, 1993), and the balance of evidence does seem to implicate intentional weight loss in adverse health outcomes.

In sum, the potential benefits of dieting on long-term weight outcomes are minimal, the potential benefits of dieting on long-term health outcomes are not clearly or consistently demonstrated, and the potential harms of weight cycling, although not definitively demonstrated, are a clear source of concern. The benefits of dieting are simply too small and the potential harms of dieting are too large for it to be recommended as a safe and effective treatment for obesity.

Research Agenda

Further study is needed in three primary areas to address the health problems associated with obesity. It is clear that dieting does not lead to sustained weight loss in the majority of individuals, and additional studies of the effects of dieting on weight are not needed. A call for more rigorous diet studies seems unwarranted as it has been noted that among diet studies, “greater methodological rigor seems to be associated with poorer results” (Kramer et al., 1989, p. 126). We do not think further study of existing diets will lead to a different assessment, nor do we think a new diet formulation will appear that leads to more favorable outcomes. Instead, we recommend that researchers conduct long-term randomized studies on the effects of dieting on health outcomes, with a specific focus on whether the short-term health benefits of weight loss persist after the weight is regained. Such studies should measure health indicators, such as cholesterol levels, blood pressure, and blood glucose, as well as illness outcomes, and should make an effort to assess whether obese people in general will benefit or whether only people with risk factors for particular illnesses will benefit. These studies must make every effort to minimize the biases that led to overly optimistic reports of the success of diets (i.e., low follow-up rates, self-reported weights, participation in additional diets, and confounds with exercise).

Second, although we do not recommend further study of the effects of dieting on weight loss, it is still necessary to explore the health consequences of weight regain. Because the majority of individuals who engage in diets tend to regain most of their lost weight, no diet can be recommended without considering the potential harms of weight cycling. Research must continue to examine the effects of weight cycling, and in particular this work must make a focused effort to distinguish effects of intentional weight loss from those of unintentional weight loss. In addition, research on weight cycling must attempt to locate mechanisms that link weight cycling to health outcomes. So far, such efforts have had mixed success (Brownell & Rodin, 1994; National Task Force on the Prevention and Treatment of Obesity, 1994).

Finally, as noted earlier, exercise may very well be the potent factor leading to sustained weight loss, particularly among participants in the National Weight Control Registry (Klem, Wing, McGuire, Seagle, & Hill, 1997). A comprehensive review of the effects of exercise on health stated that in addition to its effects on weight, exercise also has been linked to positive health outcomes, including decreased mortality, decreased cardiovascular disease, decreased Type 2 diabetes, decreased hypertension, and increased mental health (U.S. Department of Health and Human Services, 1996). We therefore suggest that future research focus on exercise as a treatment for obesity. Especially recommended are randomized, controlled trials that compare exercise-only interventions to both diet-only interventions and combined interventions so that the effects of exercise can be distinguished from the effects of dieting. Studies typically confound the effects of diet and exercise by comparing diet-only interventions with combined diet-plus-exercise interventions (for a review, see Avenell et al., 2004). These studies cannot assess whether exercise alone is as beneficial, or even more beneficial, than diet plus exercise. In one study that was able to assess the unique contribution of exercise by comparing participants assigned to diet-only, exercise-only, or a combined intervention, the exercise-only group showed better long-term weight loss maintenance than the combined group (Skender et al., 1996). More studies with this type of design are needed.

In the studies reviewed here, dieters were not able to maintain their weight losses in the long term, and there was not consistent evidence that the diets resulted in significant improvements in their health. In the few cases in which health benefits were shown, it could not be demonstrated that they resulted from dieting, rather than exercise, medication use, or other lifestyle changes. It appears that dieters who manage to sustain a weight loss are the rare exception, rather than the rule. Dieters who gain back more weight than they lost may very well be the norm, rather than an unlucky minority. If Medicare is to fund an obesity treatment, it must lead to sustained improvements in weight and health for the majority of individuals. It seems clear to us that dieting does not.

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