tinuous rather than distinctive entities or the cost-benefit ratio reaches an unfordable level. Answers to these questions depend greatly on the values of the population concerned and resources available.[2-4]

Our recent study[5] showed that the changes in the cutoffs for diagnosing hypertension, hypercholesterolemia, and diabetes mellitus around the year 2000 resulted in doubling the prevalence of all the 3 conditions in China.[5] If the new patients were all treated with drugs, the annual drug costs alone would consume 56% of the government's total health expenditure in 2010.[5] Regardless of the benefit of treating these conditions, which is bound to be small, it is unlikely affordable for China. Indeed, most uninsured patients with hypertension in the country were unwilling to take drugs as guidelines recommended.

This implies importantly that populations with different values and resources available for health care should consider different cutoff values; for example, the World Health Organization recommended 3 different cutoff values for cardiovascular risk above which drug interventions are recommended.[3,4] Opposed to how the disease was originally defined, this approach adds a subjective, value-laden component that entails further discussions.

Much of the above discussions equally apply to new definitions of diseases. Finally, do risk, benefit, and harm make a complete list of necessary criteria? If not, what other factors should be considered? Methods and procedures for modifying disease definitions should also be elaborated. Changes should be based on current best evidence, and strong evidence must be provided.

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In Reply We thank Dr Yang and colleagues for raising important points regarding our Special Communication[1] on modifying disease definitions, many of which we alluded to in our article but that we agree need further discussion.

We agree with Dr Yang and colleagues that when modifying a disease definition, it is essential to consider whether the additional patients classified with the expanded definition warrant clinical intervention, as well as whether this net benefit should be paid for. Such decisions should include consideration of the regional variations in the values of the population concerned and their available resources. In our checklist, we recommended that the definition should reflect the values and preferences of patients and the wider community and include the impact on resource usage.[1]

Dr Yang and colleagues have highlighted an important consequence of this recommendation: that different disease definitions for clinical care may then be appropriate in different countries. The World Health Organization has recognized this problem with the recommendation that different countries use different levels of risk for the primary prevention of cardiovascular disease.[2]

Our article[1] outlines a checklist of issues that we recommend should be considered and reviewed prior to making a recommendation to modify a disease definition. The checklist is not a set of criteria. We hope that the checklist will improve the transparency of the methods and processes used when disease definitions are being modified. We agree that the current checklist[1] is just the beginning of work in this important area of research and that the checklist requires testing and extension in a variety of conditions and settings.

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Concerns About Conclusions of Self-monitoring of Blood Glucose

To the Editor In a recent issue of *JAMA Internal Medicine*, an Original Investigation by Young et al[1] reports the results of a randomized clinical study wherein use of daily self-monitoring of blood glucose failed to improve glycated hemoglobin (HbA_{1c}) levels compared with the study's control participants. Young et al[1] conclude that glucose monitoring in patients with non–insulin-treated type 2 diabetes should not be routine, and Figure 1 shows a reduction of HbA_{1c} by 0.35% in patients using self-monitoring of blood glucose after 6 months. Glycated hemoglobin levels gradually returned to baseline levels by 1 year, but 33% of study participants had stopped monitoring after 6 months while 40% to 60% stopped monitoring after 1 year.[1] If half the participants did not adhere to the intervention, a sustained response should

not have been expected, especially with the well-known progression of glucose intolerance in type 2 diabetes.

Concerning limitations of experimental design and implementation of the study,[1] there was no contact between the study group and patients between the study initiation and termination. Young et al[1] presented no evidence that either the patients or the primary care physicians were trained and/or competent in the interpretation and usage of glucose data. It is unknown how often physicians adjusted therapy or whether participants adjusted diet, activity, or medication usage. The average baseline HbA_{1c} level (7.5%) was not markedly elevated, and it is unspecified whether individualized goals for improvement were set for HbA_{1c} or fasting plasma glucose.

We are concerned about a long-term controversy because there is a vast literature on benefits of self-monitoring of blood glucose in type 2 diabetes.[2] There is a consensus that self-monitoring of blood glucose, when used properly, can improve HbA_{1c} in patients with type 2 diabetes not receiving insulin[2] alongside glucose data being used by patients and physicians to adjust therapy and lifestyle. Structured testing (ie, multiple glucose values per day [premeal, postmeal, bedtime, overnight] to define the ambulatory glucose profile) can provide superior, actionable information[3] that promotes interaction with health care clinicians, enables adjustment of therapy, and significantly improves HbA_{1c}.[4]

The current generation of mobile applications automatically collect data regarding glucose, diet (ie, carbohydrates and calories), medications, and physical activity, and provide real-time reminders for monitoring glucose and taking medications,[5] interpretation of results, insights, motivational messages, alerts and warnings, online access to certified diabetes educator coaches, educational materials, news items, recipes, and support from the online diabetes community. Several of these applications have been demonstrated to provide major reductions in HbA_{1c} and improved self-care in well-motivated patients.[5]

Numerous studies have shown that self-monitoring of blood glucose, properly implemented, can improve HbA_{1c} in patients with non-insulin-treated type 2 diabetes.[2-5]

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Conflict of Interest Disclosures: None reported.

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In Reply We thank Pimazoni-Netto et al for their letter and include our response to their concerns. In considering our published results,[1] it is of tantamount importance that readers understand the tenets of comparative effectiveness research (CER). Comparative effectiveness research studies are pragmatic in nature, and they are designed to: (1) inform health care decisions and/or policy; (2) evaluate 2 or more interventions that have the potential to represent best practice; and (3) be executed in real-world, clinical settings.[2] The MONITOR trial[1] was designed as a comparative effectiveness trial. For those steeped in the traditions of efficacy trials, fully embracing the tenets of CER can be challenging.

We selected high-quality, primary care practices in an academic health care organization. The primary care providers were experienced, high-performing clinicians. This is evidenced in part by the mean glycated hemoglobin (HbA_{1c}) of 7.5% across the practices at baseline. Throughout the trial[1] we delivered additional trainings to the practices both on the implementation of the study and general management of diabetes. In keeping with the spirit of CER, we intentionally designed the study such that our interactions with the patients were minimized. It is not unusual for patients not enrolled in a clinical trial to tire of self-monitoring of blood glucose (SMBG). This is regularly seen in routine clinical practice. Thus, we feel our results reflect primary care effectiveness, arguably in a better-than-average practice setting. Frankly, we hoped and expected to demonstrate benefits, particularly of the enhanced use of SMBG-tailored messaging. Nevertheless, our study[1] demonstrated that SMBG had no effect on participant HbA_{1c} levels over the course of a year. We remain hopeful that new technology and better implementation strategies can be developed and validated in a future CER study to improve outcomes that are important to patients.

The bottom line remains that previous trials of SMBG in patients with non–insulin-treated type 2 diabetes have not uniformly demonstrated a benefit. Our pragmatic trial adds to the base of literature. Glucose monitoring is a multi-billion-dollar business. If we can relieve society of its cost, patients of their burden, and health care providers of prescribing and reviewing the results, we can encourage each to embrace more fruitful avenues of therapy, including lifestyle intervention and drug adherence. Based upon the results of our trial,[1] we suggest that comprehensive lifestyle intervention and modern drug therapies in the preinsulin phase of diabetes management without routine SMBG can be effective in controlling HbA_{1c} and other parameters of glycemic control at least in patients who are well informed and on the fence with regards to the value of SMBG.

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Conflict of Interest Disclosures: Drs Young, Donahue, and Buse report that the University of North Carolina at Chapel Hill has licensed its interest in copyright works to Telcare of a glucose messaging and treatment algorithm for the purposes of commercialization. No other conflicts are reported.

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Selection Does Not Equate Consumption

To the Editor We applaud Turnwald et al[1] for their experimental design to test inexpensive interventions to increase healthy food consumption within the Stanford University dining hall. In a Research Letter published in a recent issue of *JAMA Internal Medicine*, Turnwald et al[1] reported that indulgent descriptors of healthy vegetables dramatically increased "consumption" compared with alternatively labeling the same food. The assumption that measuring the quantity of a vegetable selected equates to consumption is flawed and may misrepresent the results and overstate the conclusions. The authors cited a review by Wansink and Johnson[2] that found that on average 92% of foods selected are consumed.

However, many of the studies reviewed were in a food laboratory and were single experiments without the context of a free-living population on a college campus with repeated exposures to the same food. Additionally, consumption was much lower in studies of individual food items. There is also not adequate literature specifically on vegetable consumption, which traditionally is consumed less than other "healthy" foods, such as fruits, whole grains, lean meats, and dairy[2]; in our studies,[3-5] we observed substantially greater consumption of these healthier items compared with vegetables.

For example, in our plate waste study in a cafeteria setting measuring thousands of participants over time, we found that while similar marketing techniques can result in increased selection of vegetables, students consumed on average as little as 18% of these items.[3] We found that upgrading the taste through a chef intervention had the best long-term impact on real consumption. While our research was conducted among a younger population, it is still relevant in highlighting the need to measure actual consumption among study participants.

While we believe that research that furthers our understanding of effective promotion strategies for healthier foods is critically important, it is equally important for researchers to move beyond measuring just selection and to focus on taste and actual consumption.

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In Reply We agree with Dr Cohen and colleagues about the importance of measuring taste and consumption. We also agree that work should be done to upgrade the preparation of healthy foods. The ultimate taste and experience of any food is a synergy of quality ingredients, their preparation, and one's mindset about those foods.[1,2] Thus, improving consumption is best achieved by changing both our negative mindsets about healthy foods and the preparation of the foods themselves.

In our study,[1] we counted every diner who chose vegetables and weighed each serving dish as it was placed on and removed from the serving line on each of 46 days. While measuring plate waste would help approximate consumption, collecting and measuring waste is difficult and prone to error. The few studies that have taken to the arduous task of weighing waste understandably do so only on a handful of days,[3,4] therefore introducing error with respect to representativeness and generalization across a variety of vegetables. Given these tradeoffs, we elected to concentrate on robustly measuring selection on all 46 days of our intervention.

Several reasons lead us to believe that consumption was indeed affected. First, if the indulgently labeled vegetables led people to select them but ultimately dislike them, any differences in selection observed early in the study would disappear or reverse over time. This is not what we observed. Second, contrary to their statement, the review[5] cited by Cohen does contain field studies and reports no difference in consumption rates between field and laboratory studies. The same review reports that self-served food consumption is greater in adults compared with children (92% vs 59%),[5] which may explain the low consumption rates observed by Cohen and colleagues in their own studies of children.[3,4] Third, Cohen and colleagues correctly state that vegetables are consumed at lower rates than other healthy foods; however, low base rates of consumption bear no relevance on how consumption rates may change in response to intervention. In fact, Cohen and colleagues themselves observed that vegetable consumption rates increased as much as or more than other healthy foods after intervention.[3,4] Finally, we did actually measure taste among more than 200 diners on 2 days during the intervention and