Examining the economic costs related to lifestyle and pharmacological interventions in youth with Type 2 diabetes

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The best treatment option for children with Type 2 diabetes has not yet been established. The Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study is currently testing the efficacy of three therapies: metformin, metformin plus rosiglitazone and metformin plus an intensive lifestyle intervention. The relative cost–effectiveness of these therapies is also being examined. This review discusses the rationale for the design and methods applied in the economic analysis. The design of the economic analysis in the TODAY study was influenced by the existing literature and two primary study parameters: the nature of the interventions and the participants' age. The lifestyle intervention is an intensive behavioral intervention comprising diet and physical activity. Since economic factors influence both diet and physical activity, the analytical plan includes measurement of food and exercise-related purchases. Due to the young age of the participants, the impact of the intervention on adult caregivers is also included in the analysis. This analysis focuses on the time spent by the caregivers in both medical treatment and nutrition- and activity-related activities, and the value of this time relative to usual activities. Important methodological questions include how and when to collect information, not only on medical costs, but also on the impact of caregiver time, travel, food and equipment purchases. In the TODAY study, these latter resources are being measured by regularly administered surveys completed by the caregivers. The approach to the cost–effectiveness assessment undertaken by the TODAY study is one of the first in diabetes research to focus on youth and to include a societal perspective, regular and prospective assessment of clinician and caregiver time, and a comprehensive assessment of the costs associated with lifestyle behaviors. It can serve as a model for future studies of diabetes treatments.

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Diabetes mellitus (DM) is now recognized as an important global public health issue. Diabetes has garnered great attention owing to the dramatic increase in the prevalence of diabetes observed over the last 20 years, and because models predict a continued increase in the prevalence of the disease in the future. In addition, diabetes is associated with excess death, disability and use of healthcare resources. This translates to a sizeable total economic burden [1]. One illustration of this phenomenon is the finding that diabetes patients consume a disproportionately high percentage of all medical expenditures [2]. Per capita, healthcare expenditures for patients with diabetes are two- to five-times that of similar patients without diabetes [3–6].

DM consists of a heterogeneous group of disorders characterized by persistently high blood glucose levels [7]. The most common forms of diabetes include Type 1 and Type 2

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diabetes. Type 1 DM is generally distinguished by an abrupt onset of the symptoms of the disease, a dependence on exogenous insulin to sustain life and a greater prevalence among children and young adults [8]. The development of Type 2 diabetes typically occurs in adulthood, although, as reported here, increased prevalence of this form of diabetes in children and adolescents has been observed. Type 2 DM is often related to obesity, insulin resistance and a progressive β cell dysfunction in the pancreas, such that the body cannot properly utilize available insulin and cannot produce sufficient insulin to maintain normal levels of blood glucose. The majority of individuals with diabetes have Type 2 diabetes (90–95%).

The link between Type 2 diabetes and obesity is well established. Of particular concern, however, is the emergence of significant obesity amongst youth [102–104], and the specter of an increasing rate of Type 2 diabetes in youth. For many years, Type 2 diabetes was considered to be extremely rare in children. While the numbers of youth with Type 2 diabetes is debated, several reports now document notable levels of Type 2 diabetes in children and adolescents in the USA [9–12] and globally [13].

Current therapeutic approaches to Type 2 diabetes in children & adolescents

Several treatment options exist for Type 2 diabetes in adults and children. These strategies are diverse and encompass medication, diabetes education programs, behavioral strategies for decreasing insulin resistance by reducing body weight via healthier dietary and physical activity habits, pharmacological interventions and the use of insulin. However, the evidence regarding best practices for the treatment of Type 2 diabetes is mixed. The effectiveness of treatment practices in Type 2 diabetes is best understood among adults. A number of studies, for example, have demonstrated that weight loss associated with lifestyle changes in eating behavior, diet and physical activity, can result in significant improvements in short-term health outcomes [14–16]. Also, the Diabetes Prevention Program (DPP) has demonstrated that lifestyle interventions to affect weight loss can prevent diabetes in high-risk adults [17].

Optimal treatment strategies for youth have not yet been established. There is little evidence of the effectiveness of either pharmacological or lifestyle modification programs among youth with Type 2 diabetes. Effective strategies are required to optimize long-term health for youth with Type 2 diabetes. Without effective treatment, many professionals fear that the public health burden will escalate as individuals age and develop late-stage eye, kidney and heart complications in young adulthood. Thus, the goal of the Treatment Options for Type 2 Diabetes in Adolescents and Youth (TODAY) study is to identify the best treatment option(s) for this population.

TODAY study

The TODAY study is a multicenter clinical trial designed to evaluate the safety and efficacy of three treatment regimens in maintaining glycemic control for Type 2 DM in children and youth. The treatment regimens are:

- Metformin alone
- Metformin plus rosiglitazone
- Metformin plus an intensive lifestyle intervention focused on behavioral change in diet and exercise (FIGURE 1)

Eligible participants must be between the ages of 10 and 17 years of age and are randomized into the study within 2 years of the diagnosis of Type 2 diabetes. The study is currently in the recruitment phase. When complete, the study will be based upon 750 total participants across 13 clinical centers, representing 250 subjects in each treatment arm. These subjects will be followed for a minimum of 2 years to assess treatment outcome. The primary outcome measure is time to treatment failure, defined as HbA1c levels greater than or equal to 8% over a 6-month period, or the inability to wean from temporary (<3 months) insulin therapy.

At the end of the study, a cost–effectiveness analysis (CEA) will be conducted as one of several secondary aims in the trial. In this article, the authors review the background and current understanding regarding the economic issues underlying obesity and diabetes, and discuss the methodological approaches being taken in the economic analysis of the TODAY study in this context.

Expert commentary

Economic analysis in the TODAY study

A CEA is planned for the TODAY study in order to provide an objective, structured method for relating treatment costs to study outcomes, with the goal of providing information for improved decision-making about the future allocation of limited resources for the treatment of Type 2 diabetes in youth. In addition to a CEA, an analysis of the total costs of each intervention will also be performed to inform future providers about the resources required for implementation of the treatment strategies.

The CEA will measure the resources used for each treatment arm relative to the health benefits obtained. The authors have chosen to consider two outcome measures in the analysis; a

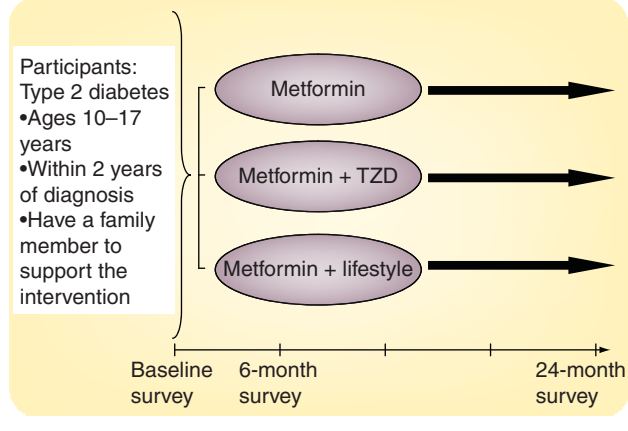

Figure 1. Treatment interventions in the TODAY study and the frequency of survey assessment.
TZD: Thiazolidinedione.

disease-specific measure focused on blood glucose control and a general measure, the quality-adjusted life year (QALY). In the TODAY study, QALYs will be determined using information obtained from responses of participants in the three treatment arms to the Health Utilities Index survey instrument [18]. The Health Utilities Index is the only preference-based quality-of-life instrument that has been validated in a pediatric population.

Perspective

The perspective of a CEA is an important step for determining which resources to include and evaluate in the assessment. A CEA conducted from the health system's perspective, for instance, will measure a more limited set of costs than an analysis conducted from the point of view of society as a whole. A societal perspective accounts for the costs to all sectors and populations affected by an intervention. In the case of the TODAY study, in the intensive lifestyle arm in particular, participants and family members must make a significant time commitment to treatment – a commitment that is much greater than that for the other two interventions. Since this level of commitment is a meaningful component of the intervention, the CEA in the TODAY study has been designed to take a societal perspective, so that issues, such as the cost of caregiver involvement, can be included in the assessment.

Taking a societal perspective is unusual in the diabetes cost–effectiveness study literature. Most prior studies, including those based on clinical trials, have focused only on the costs and consequences to healthcare payers or healthcare systems [19–25]. Only the reports originating from the DPP have taken the societal perspective. In its long-term evaluation [26], the societal perspective was taken to include factors related to the behavioral intervention; a treatment strategy that has not been widely examined in prior evaluations. However, the focus of the DPP is on the prevention of diabetes in adults. To the authors' knowledge, no economic analyses of treatment strategies for Type 2 diabetes in youth have been performed.

Identifying intervention-related resource use

In the authors' discussions about the study design for the evaluation, many of the debates centered on the questions of which resources to focus on, how to measure them and how these resources should be valued. The decisions that were ultimately made and the thinking that shaped the design were largely influenced by the types of interventions being implemented in the TODAY study, the characteristics of the study participants, the prior literature on cost–effectiveness studies, and the literature on the economic factors in obesity.

TODAY study interventions

Pharmacological interventions

Two intervention arms in the TODAY study consist of the provision and management of pharmacological agents (FIGURE 1). In one arm, randomized participants will be administered metformin alone. Metformin is a pharmacological agent commonly used in patients with diabetes to reduce hepatic glucose production, and increase the body's sensitivity to insulin. In the second arm, participants will receive metformin and rosiglitazone (a thiazolidinedione [TZD]). TZDs are designed to increase insulin sensitivity through different mechanisms from metformin.

Many prior cost–effectiveness analyses have been conducted within clinical trials to examine the impact of pharmacological agents. Thus, there is extensive literature available to identify which types of resources should be assessed. As a result, many resources included in the economic analysis in the TODAY study follow this pattern, or standard model, applied in earlier cost–effectiveness reports. Related resources include, for example, the frequency and amount of agent use, activities related to nonadherence, and activities associated with the side effects of the agent.

Lifestyle modification

The third intervention in the clinical trial is a combination of metformin and an intensive lifestyle program. The comparison of this arm with the metformin-only arm will permit an assessment of the impact of the behavior modification program on the control of blood glucose values in children and adolescents with Type 2 diabetes. The lifestyle program is designed to promote moderate weight loss, and, given that the study population is young and growing, maintain adequate nutrition through pubertal development. The goals of the intervention include modification of eating and physical activity behaviors so that new, healthier behaviors develop and replace less healthy ones [27]. Specific behaviors targeted include:

- Reducing caloric intake overall
- Reducing the intake of foods with low nutritional value
- Increasing physical activity
- Decreasing sedentary behaviors

The lifestyle intervention is modeled on the family-based weight control program developed by Epstein and colleagues [28]. Past studies have shown that sustained weight loss in children typically requires parental or caregiver participation as an integral component [29–32]. Therefore, the TODAY lifestyle program requires the participation of the youth and at least one adult who is closely involved with the daily activities of the youth. Caregiver involvement is also required in the other two treatment arms in the trial, however, the intensity of involvement is lower.

The focus of the lifestyle modification program suggests that costs related to diet and physical activity may be important components in an economic evaluation. This notion is reinforced by the research literature outlining the economic factors that contribute to obesity in the USA. Several reports note temporal trends that suggest a possible link between economic factors and obesity. These trends include the decline in food prices over time, particularly for energy-dense foods (sugars and fats) [33–35]. Increased time spent eating outside of the home, and larger portion sizes in restaurants also have been observed over time. Both of these trends have

been driven by economic incentives [34,36,37]. The result is a continuing increase in energy intake from high fat, high calorie, and low nutrient diets [38–40].

The relationship of the physical environment and technological change to physical activity levels and sedentary behaviors is being increasingly noted. New homes and communities are now increasingly built in a manner such that driving is essential for all daily activities [41]. Americans spend more time in motor vehicle transportation than ever before [42]. Technological changes have also replaced the need for many forms of manual labor and occupational physical activity [33,36]. Again, economic factors are among the many influences underlying these changes.

Measuring & valuing intervention resources in the TODAY study

The specific resources being examined in the economic analysis in the TODAY study are detailed in TABLE 1. These resources will be assessed for all three interventions. They include direct healthcare costs, such as clinical care and adherence activities. Medical care visits have been set by the trial protocol to be equal in number between the three treatment arms. The lifestyle intervention arm, however, does include additional resources related to assessments by the lifestyle program leader and psychologists. Nonmedical costs, including food costs, physical activity costs and participant and caregiver time are also being assessed. Out-of-pocket costs to study participants will be assessed as well as costs related to the time spent in treatment for providers, staff and study participants. Underlying the measurement of time costs is the concept of opportunity cost – the notion that time spent in one activity, since it precludes spending time in a different activity, has a cost. This is the cost associated with the next best alternative use of time. The approach for collecting cost information as well as the authors' method of valuing time is described below.

Direct healthcare costs

Medical resources related to the interventions will be assessed and valued using a microcosting approach, rather than gross costing. For instance, for within-trial medical care, the authors will identify the costs associated with the provision of services by each member of the study team, cost of drugs, cost of supplies, and so on. Direct medical care resources of interest include those related to study visits, provider and staff time spent in care-related activities, drugs, laboratory tests, testing strips and other supplies, and out-of-trial healthcare use for intervention-related side effects.

Measuring resources used to provide clinical care & assure adherence to the intervention

The microcosting approach to estimating healthcare costs entails a focus on healthcare resource use, the most important of which is provider time. Measuring provider time has the salutary effect of avoiding the problems associated with using physician or hospital charges. Hospital charges are subject to the vagaries of different cost accounting systems and different cross-subsidization structures among institutions and may or may not bear a direct and consistent relationship to costs. They almost certainly vary from hospital to hospital and area to area, an important issue in a multicenter clinical trial. Physician charges, when they are not included in hospital charges, vary according to the practice's contracts with insurers and managed care organizations.

The healthcare resource data required for the economic evaluation are available largely through the case report forms in the study. These forms detail, for example, the frequency of visits, type of visits and diabetes management issues. However, some resource data are not available from the case report forms, including the time spent in clinical care by physicians, other providers and staff. Thus, the time spent by all providers and staff (physicians, certified educators, project coordinators, dietitians, supervising psychologists and physical activity leaders) in clinical care-related activities will be assessed on a regular basis in the TODAY study using a time diary. This type of instrument and methodological approach to measuring time was the most acceptable method of assessment to the study staff. The diaries will be completed over a 1-week period once every 4 months by each clinical center in the trial. Each staff member in each center is asked to record the time spent in care-related activities for each participant that they are involved with in the 1-week window.

Prior to implementation, the time diary was pilot tested to identify face and content validity. In addition, everyone completing the diaries have been provided detailed instructions regarding the activities that should be recorded on the diary. The instructions emphasize the importance of distinguishing care-related activities from research activities, so that the costs of conducting the research project are not included in the assessment. Training on the completion of the diaries has also been provided to clinic coordinators, who in turn, will relay training to the study staff in the clinic. A future effort will also involve validation of the diaries with external time assessment in a sample of the clinics.

Assigning values to provider & staff time

Valuing time for study personnel is straightforward. Information on the average/median salary and level of benefits will be collected for each category of staff in the study. There are several sources for these data. The US Bureau of Labor Statistics provides average and median salaries for detailed Standard Occupational Codes, including numerous health professions. Such data are also available commercially. The value of employee benefits for specific professions is also available commercially. This approach to valuing provider time, based upon nationwide average or median data, is generic, however, it avoids the problem of adjusting for labor market conditions specific to all of the different study sites.

Nonmedical costs

Having adopted a societal perspective for the cost analyses, it is also important to collect data on the care-related costs incurred by participants and their families. The most substantial cost incurred by most participants is time, although there are also

Table 1. Economic resources in the TODAY study and their method of assessment.

Direct costs	Method of assessment
Medical resources	
Study personnel:	
Physician	Frequency of contact by case report form Time spent in activity from CPT code for every visit and time log completed by study personnel
Nurse educator	Frequency of contact by case report form Time spent in activity from CPT code for every visit and time log completed by study personnel
Lifestyle program leader	Frequency of contact by case report form Time spent in activity from time log completed by study personnel
Psychologist	Time spent in activity from time log completed by study personnel
Dietitian	Time spent in activity from time log completed by study personnel
Drug	Frequency of use by case report form
Glucose monitoring	Frequency of use by case report form
Nonmedical resources	
Subject centered:	
Exercise equipment	Amount purchased as documented in questionnaire
Time exercising	Time in exercise from case report forms/logs completed by participants
Time spent in clinic visits and travel to clinic	Amount as documented in questionnaire
Family centered:	
Foods	Amount purchased as documented in questionnaire
Caregiver centered:	
Time exercising with child	Amount as documented in questionnaire
Time spent in clinic visits and travel to clinic	Amount as documented in questionnaire
Time spent preparing foods	Amount as documented in questionnaire
Time spent shopping for food	Amount as documented in questionnaire

CPT: Current procedure terminology.

meaningful out-of-pocket costs related to travel to the clinics, food and exercise. The microcosting approach will also be followed for the measurement of participant and caregiver costs. The focus will be on identifying the amount of time spent by participants and caregivers on various aspects of the treatment, as well as treatment-related out-of-pocket costs.

To assess these nonmedical resources, a questionnaire has been developed that will be administered regularly to the primary family-support person identified for each participant. The survey focuses on intervention-related out-of-pocket costs for food and exercise equipment, clothing, services and travel, as well as time spent in exercise, buying and preparing food, assuring adherence to treatment, and traveling to clinic and sports/exercise activities. The survey is administered by study staff to the family-support person through a personal interview conducted at baseline, 6 months, 24 months and annually thereafter (FIGURE 1). These time intervals coincide with the major data collection points set by the protocol of the trial. The following paragraphs describe in detail the participant and family costs that are being measured in addition to the analytical methods.

Food costs

Economic influences on consumer behavior in the marketplace may have indirect implications for the lifestyle modification program in the TODAY study. For example, ecological data suggest that changing dietary behavior to diminish consumption of energy-dense foods and to enhance the consumption of fresh meats, fruits and vegetables may increase food costs for the lifestyle program families. Some individuals, particularly those with low incomes, may forego foods prescribed by dietary guidelines due to higher food prices. Whether the diets recommended under a lifestyle intervention cost more than the subjects' current diets, however, is open for debate. Dietary

interventions in obese individuals, including those in the lifestyle intervention, also promote reductions in energy intake. This may lead to lower food costs, as highlighted in one report [43], as food consumption decreases overall.

Measuring food costs among individuals or families can be accomplished through a variety of approaches, including the use of scanners, diaries and food intake surveys. The most accurate approach is the use of handheld scanners, where the participant scans food items as they are selected and purchased in a grocery or food store [44]. These devices can distinguish not just price, but types of food and nonfood items. However, scanners are expensive to use as a measurement tool in large samples and pose a time burden for research staff in distributing them to families. Thus, scanners are not widely used for assessments in clinical trials.

An alternative approach to measuring food costs includes participant surveys. Such assessments include the use of detailed diaries of food purchases, questions on recent food purchases or food frequency questionnaires (in which nutrient levels are identified and assigned a corresponding cost). The US Census Bureau uses both a food purchase diary and a validated survey of food purchases in the Consumer Expenditure Survey (CES). The CES is conducted annually in order to track the buying habits of American consumers [45,105]. Finally, food costs have also been estimated using survey instruments to identify foods conusmed and the nutrient composition of these foods [46]. Nutrient level data are then assigned a corresponding cost and applied to the amount of nutrients consumed to estimate costs.

In the TODAY study, recent food purchases (last week or last month) are being queried from the family support person to identify food costs related to the interventions. The food purchase questions being used are the same as those from the CES. The questions ask for total cost of food purchased at grocery stores, convenience stores, markets and other food stores. The cost of food purchased at restaurants (fast-food and other types) and at school is also being assessed. In addition, the use of reduced price meal plans in school is recorded. This approach measures food costs for the participant's whole household. It was decided to focus on household-based cost rather than participant-specific cost as the lifestyle modification program encourages family participation and thus may influence family behaviors. Information on family size is also being obtained to allow for the adjustment of food costs depending on the number of people in the household.

Physical activity costs

Declines in physical activity levels are another common feature mentioned in the discussion of economic influences on obesity. Finkelstein [33] and others [36,42] noted a decline in occupational physical activity occurring with recent technological change. Shifts of population from urban to suburban settings are also linked to lower activity levels [41], in part because many suburban areas do not provide environments promoting physical activity. Commute times to work, shopping and recreation are longer than before. Time spent in productive activities at home (housework, cooking, etc.) has also declined [42]. While leisure-time exercise has increased slightly, it has been more than compensated for by the increase in time spent viewing television [42].

These observations suggest that interventions to increase household physical activity may change the manner in which individuals allocate their time. This change will involve an opportunity cost. Whether it carries an economic cost of interest to this study will depend on what the individuals would do had they not changed how they allocate their time.

Exercise costs include the equipment and/or clothing involved in the activity, in addition to the value of the time spent exercising. Equipment and clothing could pose substantial out-of-pocket costs to the families, for example, expenses related to running or basketball shoes, exercise videos, sports uniforms, health club memberships, and so forth. Such exercise-related costs are most often identified through surveys that identify recent purchases and assign associated retail prices. However, few validated instruments for this currently exist. In the TODAY study, questions for estimating these expenses were developed and field tested with nonstudy volunteers prior to the beginning of the study to assess face validity. The instrument is administered by an interview with the caregiver.

Travel costs

The other direct cost borne by families is travel cost. This primarily includes travel to clinics and to exercise venues. As with exercise-related costs, questions regarding these costs were developed by the authors and field tested with volunteers prior to the beginning of the study.

Effect of participant characteristics on the cost analysis

An important influence on the design of the economic analysis was the young age of the study participants as well as the inclusion of family members in the lifestyle intervention. Studies involving children and adolescents generally include parents or caregivers, directly or indirectly. In the TODAY study, at least one caregiver/parent (the family support person) is actively included in the treatment interventions and is asked to be involved in the oversight of diabetes management or in oversight and assistance in diet and exercise. Caregiver burden may therefore pose an economic cost of interest in the study.

Caregiver burden is not widely assessed in cost–effectiveness studies. However, the research literature does note meaningful caregiver time spent in the treatment of chronic diseases, for example, Alzheimer's disease, by family members [47]. Time spent in intervention activities may be the most important of participant/caregiver costs. Thus, in the TODAY study, it was decided to include an assessment of the time that participants and caregivers spend in intervention activities. This includes the time spent in monitoring and supervising diabetes treatment and blood glucose monitoring, time spent shopping and preparing food, time spent exercising, and time spent in traveling to exercise activities and clinic visits.

In considering how to collect caregiver and participant time information, it was judged that the likelihood that busy families would complete a time diary was low. The authors determined that there was really no practical method other than a personal interview survey to determine the time spent by patients and caregivers in treatment activities. Therefore questions about time spent in intervention-related activities were added to the expense questionnaire. These questions generally take the form of asking about time spent in the particular activity, for example, exercising, during a typical week.

The survey instrument also asks the caregiver what they would be doing were they not involved in these activities. This question will be used to value the caregiver's time by establishing each individual's opportunity cost (or the cost associated with the next best alternative use of their time). The value assigned to this time will be determined by the response provided by the caregiver among three types of alternative activities: time spent in outside employment, time spent performing household activities and leisure time. Each of these activities will be valued differently in order to estimate the value of caregiver time. In the case of work loss, national average mean or median wages (US Bureau of Labor Statistics) and benefits for all workers will be assigned. For time that would otherwise be spent on household activities, or household production, a national average value of household production will be applied. After much discussion, the authors decided not to value lost leisure time. While it is recognized that leisure time has value, it is difficult to assign it a monetary valuation, in part because its value varies greatly among individuals.

Current study instrument performance

The TODAY study is currently in progress and preliminary information is available on the performance of the study measures described here. The short-term experience is that the measures are performing appropriately. Compliance by clinicians on the time diary has been excellent. A short review has found that confusion exists among a few random study staff on distinguishing research activities from clinical care activities. This required another training reminder for the affected individuals. The instrument detailing food and exercise expenses, and caregiver time has also been well accepted, with little missing data. Anecdotal observations suggest that the instrument does not carry a large time burden to the respondents.

Five-year view

Looking to the future, one should expect to see a better understanding of several issues affecting Type 2 diabetes in youth. The findings of the TODAY study will be available in approximately 5 years. These results will very likely influence treatment guidelines for Type 2 diabetes in adolescents and children. Treatment guidelines will be an integral component of secondary prevention efforts in the future. We have already seen the emergence of Type 2 diabetes in youth. In the coming years, we will undoubtedly see the emergence of the late-stage and disabling complications of diabetes in this group. A heavy emphasis will be placed on reducing the burden of complications. While further evidence on the importance of treatment with metformin and rosiglitazone will be available, Type 2 diabetes in youth will also likely be influenced by the development of new pharmacological approaches to dealing with β cell loss.

Intensive behavioral approaches to diabetes will likely be considered an integral, if not necessary, component of diabetes treatment in children and adults. At present, the impact of a lifestyle treatment program has not been demonstrated for children and adolescents with Type 2 diabetes. The TODAY study will provide some of the first evidence of this effect. Given the evidence of the value of lifestyle programs in adults (with and without diabetes), one could speculate that a behavioral program will be beneficial in children as well. However, strategies to achieve behavioral change in persons with diabetes may be difficult to implement. The affected child and the family must buy into and act upon the goals of the program. In addition, societal acceptance and passive environmental changes at the family, school and community levels will also be important for widespread implementation to succeed. Of course, questions of who will pay for behavioral interventions and environmental change will be a recurrent theme in many discussions.

There will be further explanatory information available on the role of economic factors on dietary and physical activity patterns. For example, we should have a better understanding of how personal and family choices in diet and exercise are influenced by price. Further information on the relationship between food costs and diets will be available, and we should have more compelling information to add to the debate concerning whether diets will increase or decrease food costs for individuals.

Implicit in the arguments regarding the link between economic factors and obesity is the notion that economic barriers to behavioral change exist. Barriers may include not only the price of food or exercise equipment, but also the time commitments involved in changing diet and exercise activities. In the future, the barriers that affect leisure time activities will be better understood, in addition to the role of environmental incentives on physical activities [48]. Clinically, new pharmacological approaches and surgical interventions will influence the treatment of obesity.

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USA), University of Colorado Health Sciences Center (CO, USA), University of Oklahoma Health Sciences Center (OK, USA), University of Texas Health Sciences Center at San Antonio (TX, USA), Washington University in St Louis (MO, USA)/St Louis University (MO, USA), and Yale University (CT, USA), with support from the coordinating center (George Washington University Biostatistics Center [MD, USA]).

Information resources

To find out more about this topic, interested individuals should consider the following sources of information:

- TODAY study website: www.bsc.gwu.edu/stopp-t2d, which provides details on the clinical sites and goals of the TODAY study;
- Bloomgarden ZT. Type 2 diabetes in the young: the evolving epidemic. *Diabetes Care* 27(4), 998–1010 (2004), which highlights the primary issues in Type 2 diabetes in youth;
- Gold MR, Siegel JE, Russell LB, Weinstein MC. Cost–effectiveness in health and medicine. Oxford University Press, NY, USA (1996). The standard reference tool for the conduct of cost–effectiveness studies in medicine.

Key issues

- Obesity is increasing among all ages in most areas of the world. Changes in the environment, technology, food consumption and exercise patterns have been implicated in this rise. Concomitant with the increase in obesity, the prevalence of Type 2 diabetes mellitus (DM) is increasing. Recent evidence suggests a marked rise in Type 2 DM in youth and adolescents.
- There is debate about the most appropriate method of treatment for adolescents and youth with Type 2 DM for their long-term health benefit. Most individuals are currently treated with either metformin or insulin. Lifestyle interventions focused on behavioral changes in diet and exercise have been effective in reducing obesity in adults and in young persons without diabetes. No evidence exists to demonstrate the efficacy of existing treatment strategies. The Treatment Options for Type 2 diabetes in Adolescents and Youth (TODAY) study is currently testing the efficacy of three therapies in Type 2 diabetes; metformin, metformin plus rosiglitazone, and metformin plus an intensive lifestyle intervention.
- The economic analysis in the TODAY study has been shaped by available reports on the economic factors in obesity, the age of the participants and the intensity of the lifestyle modification intervention involved. The young age of the participants requires that adults be involved in the treatment strategies. This implies an economic cost related to caregiver burden.
- An important issue in assessing the economic costs of lifestyle interventions in children with diabetes is the impact of the intervention on food costs, exercise costs, family work and home productivity, and the value of time related to these activities. These economic elements may be influenced by the intervention and may also serve as a barrier to intervention success in some participants.
- The involvement of the family of the participant in the supervision of the treatment strategies and in modifying the nutrition and physical activity environments in the lifestyle modification arm requires that the economic analysis take a societal perspective. Few prior studies on cost–effectiveness in diabetes have taken this perspective.
- Future diabetes care will benefit from science-based information on the best practices for treatment of Type 2 diabetes in children and the costs associated with it.

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