

# Use of Chromium Picolinate and Biotin in the Management of Type 2 Diabetes: An Economic Analysis

JOSEPH P. FUHR, Jr., Ph.D.,<sup>1,2</sup> HOPE HE, M.A. M.P.A.,<sup>2</sup> NEIL GOLDFARB, B.A.,<sup>2</sup>  
and DAVID B. NASH, M.D., M.B.A.<sup>2</sup>

## ABSTRACT

This paper addresses the potential economic benefits of chromium picolinate plus biotin (Diachrome<sup>®</sup>) use in people with Type 2 diabetes (T2DM). The economic model was developed to estimate the impact on health care systems' costs by improved HbA<sub>1C</sub> levels with chromium picolinate plus biotin (Diachrome). Lifetimes cost savings were estimated by adjusting a benchmark from the literature, using a price index to adjust for inflation. The cost of diabetes is highly dependent on the HbA<sub>1C</sub> level with higher initial levels and higher annual increments increasing the cost. Improvement in glycemic control has proven to be cost-effective in delaying the onset and progression of T2DM, reducing the risk for diabetes-associated complications and lowering utilization and cost of care. Chromium picolinate plus biotin (Diachrome) showed greater improvement of glycemic control in poorly controlled T2DM patients (HbA<sub>1C</sub>  $\geq$ 10%) compared to their better controlled counterparts (HbA<sub>1C</sub> < 10%). This improvement was additive to that achieved by oral hypoglycemic medications and correlates to calculated levels of cost savings. Average 3-year cost savings for chromium picolinate plus biotin (Diachrome) use could range from \$1,636 for a poorly controlled patient with diabetes without heart diseases or hypertension, to \$5,435 for a poorly controlled patient with diabetes, heart disease, and hypertension. Average 3-year cost savings was estimated to be between \$3.9 billion and \$52.9 billion for the 16.3 million existing patients with diabetes. Chromium picolinate plus biotin (Diachrome) use among the 1.17 million newly diagnosed patients with T2DM each year could deliver lifetime cost savings of \$42 billion, or \$36,000 per T2DM patient. Affordable, safe, and convenient, chromium picolinate plus biotin (Diachrome) could prove to be a cost-effective complement to existing pharmacological therapies for controlling T2DM. (Disease Management 2005;8:265–275)

## INTRODUCTION

**D**IABETES is a serious, costly metabolism disorder affecting 6.3% of the US population, or approximately 18.2 million people.<sup>1</sup> Type 2 diabetes (T2DM) accounts for 90%–95% of all di-

abetes and affects more than 16.3 million adult Americans, incurring substantial economic burden to the individual and the society.<sup>2</sup> The risk and prevalence of T2DM increases steadily with age, and nearly half of all people with T2DM are older than 65 years.<sup>1,3</sup> By age 60, approximately

<sup>1</sup>Widener University, Department of Economics, Chester, Pennsylvania.

<sup>2</sup>Department of Health Policy, Thomas Jefferson University, Philadelphia, Pennsylvania.

10% of the population is estimated to have T2DM.<sup>3</sup> Moreover, approximately 9% of patients with T2DM develop microvascular disease, and 20% have a macrovascular complication within 9 years of diagnosis.<sup>4</sup>

T2DM is characterized by insulin deficiency, insulin resistance, and impaired insulin secretion. Insulin resistance and abnormally elevated blood sugar levels are its first signs and the underlying causes of the diabetes-associated complications.<sup>5,6</sup> The risk of diabetes rises relative to the degree of insulin resistance.<sup>6</sup> As a result, many T2DM medications such as sulfonylureas, non-sulfonylurea secretagogues, biguanides (eg, metformin), and the carbohydrate blockers (acarbose and miglitol) directly target insulin resistance by increasing insulin production in the pancreas, or by decreasing glucose output through the liver, while the insulin-sensitizing thiazolidinediones (TZDs) target different key organs to decrease insulin resistance and improve blood glucose uptake into the cells.<sup>7,8</sup> Some nonprescription agents (nutritional supplements), such as the essential nutrient chromium, improve insulin sensitivity, while other nutrients, such as biotin, help to improve liver and pancreatic function.<sup>9</sup> The nutrient combination of chromium picolinate plus biotin (as Diachrome) affects both glucose and lipid pathways and has shown benefits such as improving insulin sensitivity by increasing the number of cellular insulin receptors and activating these receptors, improving glucokinase activity in the liver, and improving pancreatic  $\beta$ -islet cell function.<sup>10</sup>

The treatment goal for T2DM essentially is to improve glycemic control and to adapt to medical regimens and lifestyle changes, which has proved cost-effective.<sup>11-13</sup> Good glycemic control has proved to be cost-effective in delaying the onset and progression of the disease, reducing the risk for complications, and thus lowering medical utilization and costs of care.<sup>14-16</sup> Glycosylated hemoglobin (HbA<sub>1c</sub>) is the accepted standard measure of glycemic control, while fasting plasma glucose (FPG) indicates immediate diagnosis of diabetes. Individuals with T2DM are more prone to cardiovascular disease (CVD) risk; hence, they also must closely monitor cardiovascular risk factors. The high incidence of CVD among people

with T2DM further increases medical utilization and costs of care for these individuals.<sup>4,17,19,72</sup>

The UKPDS (United Kingdom Prospective Diabetes Study) study<sup>17</sup> results indicated "that for every percentage point decrease in HbA<sub>1c</sub> (eg, from 9% to 8%), there was a 25% reduction in diabetes-related deaths, a 7% reduction in all-cause mortality, and an 18% reduction in combined fatal and nonfatal myocardial infarction."<sup>18</sup> However, the cost of improving glycemic control can be substantial. For example, in the 1997 UKPDS study,<sup>19</sup> the costs of intensive and control therapy were \$8,020 and \$6,740, respectively. The annual cost in the 1993 Diabetes Control and Complications Trial (DCCT) study<sup>19</sup> was \$4,000 for Multiple Daily Injections (MDI), \$5,800 for Continuous Subcutaneous Insulin Injections (CSII), and \$1,700 for conventional therapy.

Pharmacological therapy has been effective in glucose control and usually is initiated when other methods, such as diet and exercise, fail to manage blood glucose levels within target ranges. The UKPDS study showed that the rigorous treatment of diabetes using blood glucose-lowering agents can decrease the morbidity and mortality of T2DM. Patients who use blood glucose-lowering agents have shown fewer physical symptoms and enhanced well being,<sup>12</sup> and have had a significantly reduced risk of cardiovascular and microvascular complications.<sup>17,20</sup> Available oral hypoglycemic agents such as sulphonylureas, non-sulfonylurea secretagogues, metformin, thiazolidinediones, and acarbose have glucose-lowering efficacy<sup>21</sup> but enhance adverse side effects and other complications related to CVD. These agents have been clinically shown to reduce HbA<sub>1c</sub> levels an average of 0.5%–2.0%. Some of the adverse side effects are gastrointestinal distress, edema, weight gain, hypoglycemic episodes, hepatotoxicity, and congestive heart failure (Table 1). These adverse effects can lead to patient intolerance and cessation of therapy, resulting in poor glycemic control and substantial costs.<sup>8,21,19</sup> As a result, pharmacological treatments are not considered the most cost-effective and safe measures for managing T2DM, and helping prevent those at high risk for developing T2DM.<sup>2,10</sup>

TABLE 1. ORAL ANTIDIABETES THERAPIES: AVERAGE HbA<sub>1c</sub> REDUCTION AND SIDE EFFECTS

<i>Class</i>	<i>Oral agent</i>	<i>Average HbA<sub>1c</sub> reduction</i>	<i>Common side effects</i>
Sulfonylureas	Glipizide (Glucotrol, Metaglip), glipizide extended release (Glucotrol XL), glyburide (Diabeta), micronized glyburide (Glucovance), glimepiride (Amaryl), chlorpropamide (Diabinese), tolbutamide, tolazamide	0.8%–2.0%	Weight gain, hypoglycemia
Non-sulfonylurea secretagogues	Meglitinides—repaglinide (Prandin); nateglinide (Starlix)	0.5%–2.0%	Weight gain, hypoglycemia
$\alpha$ -Glucosidase inhibitors	Acarbose (Precose), miglitol (Glyset)	0.7%–1.0%	Flatulence, abdominal pain, diarrhea
Biguanides	Metformin (Avandamet, Fortamet, Glucophage), metformin extended release (Glucophage XR)	1.5%–2.0%	Diarrhea, flatulence, nausea and vomiting, abdominal pain, lactic acidosis, vitamin B12 malabsorption
Thiazolidinediones (TZDs)	Rosiglitazone (Avandia), pioglitazone (Actos)	0.5%–1.5%	Congestive heart failure, hepatotoxicity, peripheral edema, anemia, weight gain
Nutritional supplement	Chromium picolinate and biotin (Diachrome)	0.5%–1.94%	None

As the disease progresses, to maintain the optimum HbA<sub>1c</sub> levels, it is often necessary and cost-effective to treat the patient not only with more than one pharmacological agent (including using insulin), but also to complement the pharmacological treatments with other adjunctive therapies such as nutritional measures.<sup>22</sup> Chromium picolinate, when administered in combination with biotin (Diachrome), has shown to be a cost-effective, safe adjunctive treatment.<sup>23</sup> Like other nutritional therapies for patients with T2DM, chromium picolinate plus biotin (Diachrome) is aimed at helping patients achieve glycemic control, improve serum lipids, and ultimately reduce risk of associated complications.<sup>24</sup>

#### *Economic and health impact of glycemic control*

The economic burden of diabetes alone has grown to \$132 billion in 2002, including direct medical expenditures and the costs of foregone productivity.<sup>1,25</sup> From 1997 to 2002, the per capita costs of diabetes rose 30%.<sup>1,25</sup> The majority of these costs can be attributed to various

diabetes-associated complications, such as CVD, which accounts for 52% of costs.<sup>26–31</sup> One study showed patients with diabetes cost an excess of \$3,494 per person, which was 2.4 times more for diabetic members than for matched control subjects. In addition, 37.6% of total direct excess costs per patient per year were attributable to long-term complications, and an additional 4% were due to short-term complications.<sup>26</sup> Moreover, the average direct cost of managing complications over 30 years was shown to be \$47,240 per patient for those who had been treated for 5 years and with a mean HbA<sub>1c</sub> of 8.4, assuming HbA<sub>1c</sub> would increase by 0.15 percentage points annually, other things being equal.<sup>32</sup>

Furthermore, the economic burden from impending diabetes is apparent at least 8 years before diagnosis, with the average diabetes-associated incremental direct cost of \$1,205 per type 2 diabetic patient per year during the first 8 prediagnostic years.<sup>31</sup> A related study found that the average incremental cost of diabetes was \$2,257 per year during the first 8 postdiagnostic years.<sup>30</sup> In addition, the cost of dia-

betes is highly dependent on the level of HbA<sub>1C</sub>. Higher initial levels will increase the cost as will higher increments per year.<sup>32</sup> Improvement in glycemic control has proven to be cost-effective in delaying the onset and progression of T2DM, reducing the risk for complications associated with diabetes, and lowering utilization and cost of care.<sup>17,19,24,29,34,41</sup> A decrease of HbA<sub>1C</sub> levels of 1.0 percentage point could decrease significantly the cost of healthcare.<sup>36</sup>

#### *Economic analysis*

In a study by Gilmer et al,<sup>35</sup> medical care charges increase for every one percentage point increase in HbA<sub>1C</sub> above 7%. So, for an individual with an HbA<sub>1C</sub> value of 6%, successive increases of one percentage point in HbA<sub>1C</sub> will result in cumulative increases in charges of approximately 4%, 10%, 20%, and 30%, respectively. In another study, using general linear regression, Gilmer et al<sup>37</sup> estimated the relationship between 3-year health care costs and baseline HbA<sub>1C</sub> levels as well as other independent variables. The results demonstrated that a decrease in HbA<sub>1C</sub> from 10% to 9% could result in a direct cost savings of \$805 over a 3-year period for patients with diabetes without heart diseases or hypertension, \$1,130 for patients with diabetes and hypertension, \$2,078 for patients with diabetes and heart disease, and \$2675 for patients with diabetes, heart disease, and hypertension.

Ginsberg et al<sup>38</sup> examines the effect of a disease state management system that emphasizes a care system for diabetics, primary care providers, and a team approach. No control group is involved, and the approach is one of treatment goals and time lines being set for success with individual therapies. The study estimated that a reduction in HbA<sub>1C</sub> from 9.2% to 7.4% would result in a net direct lifetime cost savings of \$27,000 after payment for the disease management program. The cost of the diabetes management program was approximately \$800 annually.

In a retrospective study using regression analysis, Menzin et al<sup>39</sup> examined the potential short-term economic benefits of improved glycemic control on selected short-term complications of diabetes. Patients improving from fair

(8% to 10%) to good control (less than 8%) had a reduction in healthcare charges of \$410, poor (greater than 10%) to fair had a \$1,660 reduction, and poor to good had a \$2,070 reduction in health care charges over the same 3-year period. The adjusted admissions per 100 were 30, 38, and 74, and the mean adjusted charges were \$2,610, \$3,810, and \$8,320 over the 3-year period.

In comparing patients with different levels of HbA<sub>1C</sub>, Wagner<sup>40</sup> has shown that "a sustained reduction in HbA<sub>1C</sub> level among diabetic patients is associated with a significant cost savings within 1–2 years of improvement." Wagner used multiple linear regression analysis to estimate the relationship between glycemic control and cost of patients. In his study, he compared the health utilization and costs between one group of diabetic patients with a one percentage point lowering of HbA<sub>1C</sub> and another group with no HbA<sub>1C</sub> improvement. The total cost in the first year was lower but not significantly lower. In years 2–4, the cost savings for the improved cohort were significantly lower, and during the last 3 years of the study the average cost savings ranged between \$685 and \$950 per patient per year.

Another paper analyzes the cost savings from a medical perspective. Testa and Simonson<sup>41</sup> examined the gains from a societal perspective. Patients were randomized and given either a placebo or glipizide GITS. Both groups also were put on diet management. The study was for 12 weeks with the cohort receiving the treatment experiencing less absenteeism for a gain of \$91 per month, fewer days confined to bed for a gain of \$304 per 1000 person-days, and fewer restricted-activity days with a gain of \$2,615 per 1000 person-days. There was no mention of the cost of the program.

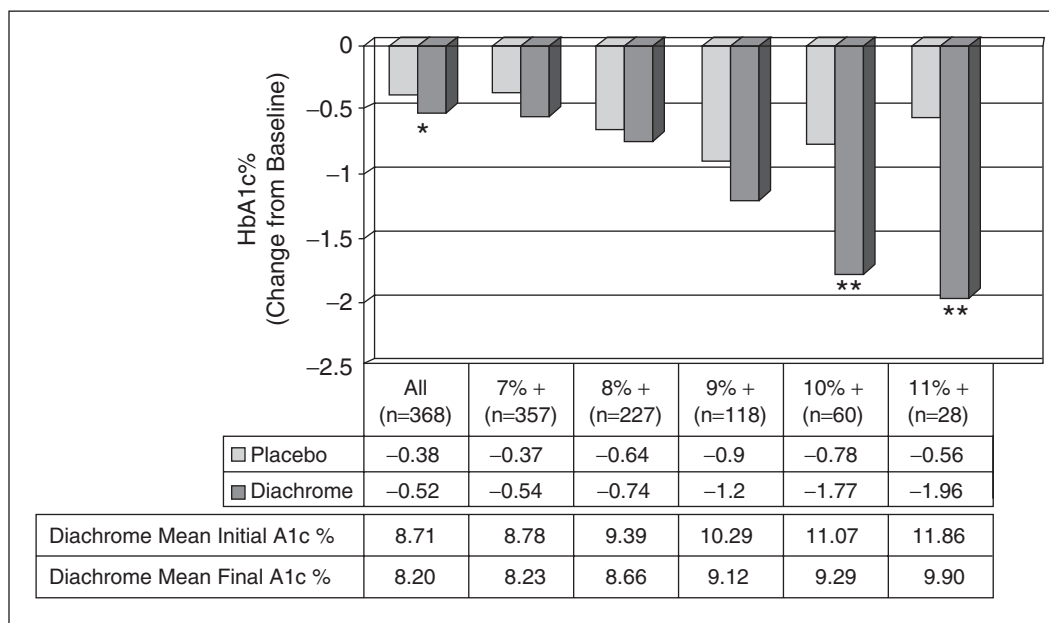
#### *Diachrome and its effects on glycemic control*

Chromium III, the most stable and nutritional form of chromium, is a safe trace element essential for normal carbohydrate and lipid metabolism and potentiates insulin.<sup>42–44</sup> Chromium III has long been shown to improve insulin sensitivity, enhance glucokinase activity, and lower blood glucose levels in people with insulin resistance and T2DM in both randomized<sup>48–57</sup> and open-label studies.<sup>44,45</sup> Chromium picolinate is

absorbable, safe, and the most widely tested form of Chromium III.<sup>42-68</sup> Biotin is a water-soluble B vitamin known to play a role in glucose metabolism by helping to break down glucose as well as enhance insulin sensitivity. Biotin stimulates the activity of glucokinase in the liver and improves pancreatic  $\beta$ -islet cell function.<sup>69</sup> Diachrome is the formulation of 600 mcg of chromium (as chromium picolinate) plus 2 mg of biotin. The supplementation effects of the combination of chromium picolinate plus biotin were first proposed in the mid-1990s by researchers at Nutrition 21, Inc.<sup>10</sup> Cell culture studies confirmed a synergistic effect of the combination on glucose uptake and glycogen synthesis in skeletal muscle cell cultures.<sup>67</sup> Animal models confirmed these results and further identified an improvement on lipid profiles, particularly reductions in total cholesterol and increases in HDL-cholesterol in obese, hyperinsulinemic rats.<sup>70</sup> Clinical research, including both open-label<sup>72</sup> and randomized, double-blind, placebo-controlled, multicenter trials,<sup>71</sup> verified the significant effect of chromium picolinate plus biotin (Diachrome) on both glycemic control and lipid profiles in patients with T2DM when used as adjunctive nutrition therapy to prescription oral antidiabetic agents. This combination appears to

combat insulin resistance, to improve beta cell function, to enhance postprandial glucose uptake, and to inhibit excessive hepatic glucose production through increasing glycogen syntheses levels in human skeletal muscle culture.<sup>73-77</sup> As a result, chromium picolinate plus biotin (Diachrome), when used with standard treatments, can significantly improve blood sugar control for people with and at high risk for T2DM.<sup>45,78</sup> In addition, in a 12-week randomized, double-blind, placebo-controlled, multicenter study of 453 patients with T2DM,<sup>79</sup> chromium picolinate plus biotin (Diachrome) decreased the mean HbA<sub>1C</sub> level by 0.51 (from 8.71 to 8.20) percentage points for patients with T2DM who had been taking oral antihyperglycemic drugs for at least the past 6 months. The more poorly controlled patients (based on baseline HbA<sub>1C</sub> levels) achieved the greatest improvements in their glycemic control by the end of the study. For patients who had baseline HbA<sub>1C</sub> levels of at least 10%, the mean HbA<sub>1C</sub> levels decreased by 1.78 (from 11.07 to 9.29) percentage points, whereas for those who had baseline levels of at least 11%, the mean HbA<sub>1C</sub> levels decreased by 1.96 (from 11.86 to 9.90) percentage points (Fig. 1).

The only difference pre- and post-study was the use of chromium picolinate plus biotin (Di-



**FIG. 1.** Diachrome study results. Effect on HbA<sub>1c</sub> levels. All, data from all subjects with baseline and final visits; n% +, data from subjects with baseline HbA<sub>1c</sub> levels  $\geq$  n%; \*, sig. diff. ( $p < 0.01$ ) using ANCOVA (treatment \* baseline HbA<sub>1c</sub>); \*\*, sig. diff. ( $p < 0.02$ ) compared to placebo.

achrome).<sup>80</sup> Two randomized, double-blind, placebo-controlled multicenter prospective studies further confirm the findings of improved glycemic control and lipid profiles in T2DM from this large prospective trial.<sup>79,81,82</sup> Chromium picolinate plus biotin (Diachrome) was studied as adjunctive nutritional therapy in patients with T2DM. The resulting improvement in glycemic control observed in each of these clinical trials was beyond that already achieved by use of the oral hypoglycemic medications. The purpose of this study is to estimate the potential cost savings that result from the decrease in HbA<sub>1C</sub> through the use of Diachrome. This paper addresses the potential economic benefits of chromium picolinate plus biotin (Diachrome<sup>®</sup>) use in people with T2DM.

## METHODS AND RESULTS

A 12-week clinical study showed that the use of Diachrome significantly decreased the average HbA<sub>1C</sub> at all levels of initial HbA<sub>1C</sub> ( $p < 0.05$ ). For example, for all patients in this study receiving Diachrome the mean HbA<sub>1C</sub> decreased by 0.51 from 8.71 to 8.20, and the 95% confidence interval for the group after the study was  $8.20 \pm 0.16$  (Fig. 1).

At all baseline levels Diachrome outperformed the placebo. However, only at levels of baseline HbA<sub>1C</sub> of at least 10% was the difference statistically significant ( $p < 0.02$ ). In patients with baseline levels of at least 10% HbA<sub>1C</sub>, the average HbA<sub>1C</sub> level decreased by 1.78 percentage points with Diachrome compared to 0.78 percentage points with the placebo (Fig. 1). The baseline average HbA<sub>1C</sub> in the Diachrome group was 11.07% whereas after the study the average HbA<sub>1C</sub> was 9.29 with a 95% confidence interval of  $9.29 \pm 0.53$ .

Chromium picolinate plus biotin (Diachrome) is a relatively low-cost adjunct method of controlling HbA<sub>1C</sub> for T2DM. The introductory cost of the recommended tablet per day is \$19.95 per 60-count bottle, and the annual cost would be less than \$120, which is considerably less than the cost of intensive and control therapies that have been examined in other studies. The potential clinical and economic benefits, therefore, could be considerable. Based on the literature re-

view and research findings, we constructed various estimates of the potential benefits of the use of chromium picolinate plus biotin (Diachrome) in T2DM.

The economic model employed to estimate the potential economic benefit from the use of chromium picolinate plus biotin (Diachrome) began with the establishment of a benchmark value for the direct cost savings reported in the literature for decreases in the level of HbA<sub>1C</sub>. The benchmark was then adjusted for inflation using the Medical Care Service Inflation Index which is a component of the Consumer Price Index. In some cases extrapolation was utilized so that the data found in the literature would conform to the study results. Statistical analysis was used to estimate a range of potential 3-year cost savings. Lifetime cost savings were estimated by adjusting a benchmark from the literature, and using the same price index to adjust for inflation.

Wagner et al<sup>14</sup> estimated an average annual cost savings per patient of \$685–\$950. These prices were adjusted to 2004 levels by using the January value of each year's Medical Care Services Inflation Index, a component of the Consumer Price Index. The result was an average annual cost savings of \$978–\$1,300.

The Gilmer<sup>37</sup> data was extrapolated to reflect the changes in average HbA<sub>1C</sub> from 10.62% to 9.18%. Using the data in Gilmer's study and adjusting the Medical Care Service Index to 2004 with 2002 as the base year, the average 3-year cost savings range from \$1,636 for patients with diabetes only, to \$5,435 for a patient with diabetes, heart disease, and hypertension (Table 2).

In addition, the retrospective study of Menzin et al<sup>39</sup> showed that depending on the change in health category (poor, fair, good), the

TABLE 2. CHANGES IN HbA<sub>1C</sub> LEVELS:  
THREE-YEAR COST SAVINGS

Patient classification	11.07%–9.29%
Diabetes with heart disease/ hypertension	\$5,435
Diabetes with heart disease	\$4,221
Diabetes with hypertension	\$2,296
Diabetes without heart diseases or hypertension	\$1,636
Overall	\$2,791

reduction in health care cost would range from \$410 to \$2,070 over a 3-year period. Adjusting for inflation to 2004 dollars the respective health care cost reduction over 3 years would be \$562–\$2,836.

*Existing T2DM patient savings estimate*

The medical cost savings from decreasing HbA<sub>1C</sub> levels varies among different studies depending on the assumptions made, such as severity of illness and initial level of HbA<sub>1C</sub>. As a result, the average medical cost savings per diabetic are difficult to ascertain. However, under all scenarios the annual medical cost savings is greater than the \$120 annual cost of chromium picolinate plus biotin (Diachrome). The Menzin study showed the average annual cost savings to be between \$978 and \$1300 for those whose HbA<sub>1C</sub> decreased by more than one percentage point. Using sensitivity analysis, three different estimates of annual medical cost savings of \$200, \$500, and \$1,000 are assumed. The annual potential cost savings of using chromium picolinate plus biotin (Diachrome) are \$80 (\$200 – \$120), \$380, and \$880, respectively. If the approximately 16.3 million type 2 diabetics (18.1M × 0.9) used chromium picolinate plus biotin (Diachrome), the estimated 3-year cost savings would be \$3.9 billion, \$18.6 billion, or \$52.9 billion, respectively (Table 3). Adding the pain and suffering associated with the additional medical complications, the time cost, and lost productivity, the savings from the use of chromium picolinate plus biotin (Diachrome) could be substantial.

*Newly diagnosed T2DM patient savings estimate*

About 1.3 million people are diagnosed each year with diabetes, approximately 90% of whom have T2DM. Using Ginsberg’s estimated

lifetime cost savings of \$27,000 (\$36,000 in 2004 dollars) per patient with good diabetes control, just for the newly diagnosed population with T2DM in 2004, the health care system could achieve lifetime cost savings of approximately \$42 billion. Adding chromium picolinate plus biotin (Diachrome) to this regimen appears to be economically judicious for both newly diagnosed patients as well as existing patients with T2DM, based upon the significant potential annual and lifetime cost savings.

**DISCUSSION**

Controlling diabetes in its early stages is necessary, and the progression of the disease is very expensive. A low-cost intervention could be beneficial to patients, third party payers, and society as a whole. Nutrition research is elucidating the important role that certain safe, inexpensive, essential nutrients may play in disease prevention and progression by reducing major risk factors in T2DM. Chromium and biotin are two such affordable essential nutrients that each have been clinically shown to be safe and effective in improving glycemic control in T2DM by enhancing insulin sensitivity and improving glucose metabolism. Research conducted at the United States Department of Agriculture (USDA) reported an improvement in glycemic control in T2DM subjects taking chromium picolinate as adjunct nutrition therapy to oral hypoglycemic medications.<sup>60</sup> Ravina et al<sup>45</sup> reported on the improvement in glycemic control in subjects with steroid-induced diabetes who took chromium picolinate. In another study, Ravina et al<sup>86</sup> reported on improved glycemic control in patients with type 1 diabetes who added chromium picolinate to their treatment regimen and reduced their in-

TABLE 3. TYPE 2 DIABETES POPULATION-WIDE THREE-YEAR COST SAVINGS

<i>Number of Type 2 diabetes</i>	<i>Annual cost savings per patient</i>	<i>Annual cost of diachrome per patient</i>	<i>Net benefit of use of diachrome per patient</i>	<i>Annual benefit of diachrome use</i>	<i>Three-year benefit of diachrome use</i>
16.3M	\$200	\$120	\$80	\$1.3B	\$3.9B
16.3M	\$500	\$120	\$380	\$6.2B	\$18.6B
16.3M	\$1000	\$120	\$880	\$14.3B	\$52.9B

sulin dosage by 50%. Researchers at Harvard School of Public Health reported an inverse relationship between tissue chromium status and the incidence of diabetes and cardiovascular disease.<sup>83</sup> Chromium's effect on glycemic control has been noted in research literature since the early 1950s.<sup>84,85</sup> Similarly, biotin has an impact on glucose metabolism and insulin sensitivity.<sup>87-89</sup> Diachrome, a new, low-cost nutritional therapy for T2DM, is a patented formulation of chromium picolinate and biotin.

Recent clinical trials suggest this composition improves insulin sensitivity and has a positive dual effect on both glycemic control and lipid profiles in T2DM. Furthermore, it is well tolerated with no significant adverse effects. A recent controlled study in T2DM demonstrated a significant decrease in average HbA<sub>1C</sub> levels of 1.78 percentage points in patients with initial levels of at least 9.5%, and 1.96 percentage points in patients with initial levels of at least 11% over a 12-week course of therapy, with an increased effect seen in subjects with higher baseline levels. At the final visit, FPG levels were lower in the active than in the placebo group (159 vs. 171 mg/dL). Furthermore, in subjects with baseline cholesterol >200 mg/dL, total cholesterol (-19.11 vs. -5.87 mg/dL) and LDL-cholesterol (-21.7 vs. -8.2 mg/dL) were significantly improved in actives compared to the placebo group.

The significant clinical impact of this non-prescription nutritional product on both glycemic control and lipid profiles, coupled with the absence of any product-related adverse events and its low cost, raise the question of the potential pharmacoeconomic value that this product could offer in the management of T2DM. Based on the clinical results, cost savings calculations indicate that its use could yield a \$36,000 inflation-adjusted lifetime health care cost savings per patient. An average 3-year cost savings was estimated to be between \$3.9 billion and \$52.9 billion for the 16.3 million existing patients with diabetes. Diachrome use among the 1.2 million newly diagnosed patients with T2DM each year could deliver lifetime cost savings of \$42 billion. Affordable, safe, and convenient, chromium picolinate plus biotin (Diachrome) could prove to be a cost-effective complement to existing pharmacological therapies for controlling T2DM.

This economic analysis is based on the reduction in HbA<sub>1C</sub> in the clinical trial and the data used for estimating cost savings are from the existing literature. Chromium picolinate plus biotin (Diachrome) also has shown significant positive clinical effect on lipid profiles. Additional cost savings can be expected based on this clinical improvement<sup>32</sup> and it is recommended that economic analyses be conducted to quantify these additional potential cost savings.

## CONCLUSION

Given the chronic nature of the disease and the devastating potential to develop costly complications, it is important to use the most cost-effective measure to help improve glycemic control in people afflicted with and at higher risk for T2DM. Medical nutrition therapy is one option.

Affordable, safe, convenient, and nutritional, chromium picolinate plus biotin (Diachrome) is considered by some "a definitive therapy" for people with T2DM.<sup>73</sup> It is being advocated as an effective complement to existing therapies for preventing and treating T2DM, with the potential of reducing the cost of care while maintaining quality of care and improving the quality of life for patients with T2DM. Chromium picolinate plus biotin's (Diachrome's) dual effect on both glycemic control and lipid profiles is unique among antidiabetes medications. It has few, if any, negative side effects compared to other therapies. Our study has shown that chromium picolinate plus biotin (Diachrome) is a cost-effective adjunctive therapy in the management of patients with T2DM and can substantially decrease the health care costs related to T2DM.

## ACKNOWLEDGMENTS

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Address reprint requests to:  
David B. Nash, M.D., M.B.A.  
Department of Health Policy  
Thomas Jefferson University  
1015 Walnut St., Ste 115  
Philadelphia, PA 19107

E-mail: david.nash@jefferson.edu