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Health economics of nutrigenomics in weight management

Research Article

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Abbreviations: body mass index, (BMI); cost of illness, (COI); cost-benefit analysis, (CBA); cost-effectiveness analysis, (CEA); National Longitudinal Survey of Youth, (NLSY); World Health Organization, (WHO)

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Summary

The emerging field of nutritional genomics presents various clinical questions that require further investigations. One of those questions is whether nutrigenomic interventions reduce the cost of illness (COI). Prior to this study, there has been an absence of data evaluating the health economic implications of this new field of research. In this theoretical modeling study, we sought to evaluate the health economics implications of a nutrigenomic product for weight loss. We constructed a nutrigenomic economic model by linking 1) published study data related to the efficacy of a product and/or ingredients, 2) validated clinical assessments that have already been tied to health economics data, and 3) data involving condition prevalence and overall cost of illness. In this theoretical model, we demonstrate that LG839 variant positively reduces the cost of illness at the macroeconomic and microeconomic level based upon a cost-effectiveness and cost-benefit analysis. From this proposed model, we have forecasted the prognostic health economic implications of a nutrigenomic intervention to demonstrate a theoretical model of nutrigenomic economics. This study is hypothesis-generating and should be used in the definition of protocols to prospectively test the health economic benefits of nutrigenomics.

I. Introduction: Nutrigenomics an emerging new science

Nutrigenomics is the application of genomics in nutrition research, enabling associations to be made between specific nutrients and genetic factors. Nutrigenomics is facilitating a greater understanding of how nutrition affects metabolic pathways and how this process goes awry in diet-related diseases (Chadwick, 2004). The emerging field of nutrigenomics presents

various clinical questions that require further investigations. One of those questions is whether nutrigenomic interventions reduce the cost of illness (COI).

II. Pharmacoeconomics of pharmacogenomics applied to nutrigenomics

Cost of illness studies are a common type of economic study that aims to identify and measure all the costs of a particular disease, including the direct, indirect, and intangible dimensions. The output, expressed in monetary terms, is an estimate of the total burden of a particular disease to society (Rice, 1994). It is widely believed by many international organizations such as the World Health Organization (WHO) that estimating the total societal cost of an illness is a useful aid to policy decision making by telling us how much a society is spending on a particular disease and by implication the amount that would be saved if the disease were reduced or abolished (Murray and Lopez, 1994). Secondly, it identifies the different components of cost and the size of the contribution of each sector in society, suggesting areas for research and funding priorities where inefficiencies may exist[1] (Behrens and Henke, 1988; Ament and Evers, 1993).

In a previous publication, in a review of the pharmacoeconomics of pharmacogenetics a similar approach laid out various health economics cost analyses that could be employed to illustrate the economic benefits for pharmacogenetic testing (Dervieux et al, 2005). Those types of analyses included cost-minimization, cost-benefit, cost-effectiveness, and cost-utilization (Beltz and Yee, 1988; Greenberg et al, 1999; Leung et al, 1999) (**Table 1**).

Each form of analysis offers insights into the role of therapy-defining genetic testing to provide a positive economic result. In all of these analyses, the studies may involve comparing two treatment arms; one having its dosing and/or serving and patient selection guided by genetic testing or nutrient intake and another more representative of an empiric standard of care. In light of the incremental costs associated with genomic testing, it will likely be difficult to prove that such testing minimizes monetary units, but such studies may clearly show a net health outcomes benefit. In this study, we will evaluate these forms of analysis related to a nutrigenomic intervention for weight management called LG839 variant (LifeGen, Inc., San Diego, CA USA).

Table 1. Pharmacoeconomics of Pharmacogenomics Applied to Nutrigenomics.

Pharmacoeconomic Terms	Definition	Nutrigenomic Implication
Cost-Minimization Analysis (CMA)	Compares the effectiveness of two or more treatments in terms of clinical and quality-of-life (QOL) measures, with economic cost measured in monetary units being the only distinct factor	Evaluating an ingredient or serving size of an ingredient or combination of ingredients in terms of clinical and quality-of-life (QOL) measures, with economic cost measured in monetary units as the distinct factor.
Cost-Effectiveness Analysis (CEA)	Compares net monetary costs of a medical intervention with a measure of effectiveness (i.e. clinical or QOL) resulting from the intervention, and compares this ratio with those of other interventions	Compares the merit of preventing the net monetary costs of medical intervention with a measure of wellness effectiveness (i.e. clinical or QOL) resulting from the nutrient intake, and compares this ratio with those of other interventions.
Cost-Benefit Analysis (CBA)	Enumerates and compares the net costs of an intervention with the net benefits, or cost savings which arise from the intervention, to derive a ratio of total monetary cost divided by the benefits expressed as monetary savings in projected expenses	Enumerates and compares the net costs of the ingredient serving in the normal course of dietary intake or as a dietary supplement, or cost savings which arise from dietary adjustments to normal food consumption or consumption of supplementation, to derive a ratio of total monetary cost divided by the benefits expressed as monetary savings in projected expenses
Cost-Utility Analysis (CUA)	A type of CEA which incorporates the value of life in variables, by assigning values to various health outcomes to delineate the relative importance of the different kinds of health outcomes to people. These results are expressed in measurements such as cost per quality-adjusted life-year (QALY), which is the most commonly used unit	This would be applied in the same way for nutrigenomics.

III. The health economics in obesity

In a macroeconomic sense, obesity is the primary disease contributing to rising healthcare costs in the United States. Between 1987 and 2002, the proportion of private health spending attributable to obesity increased more than tenfold from $3.6 billion to $36.5 billion (Thorpe et al, 2005). In the year 2002, obesity-related medical care spending accounted for 11.6 percent of all private health care spending compared to just 2 percent in 1987. In 2001, obese adults with private health insurance spent $1 244 more per person per year on health care than normal-weight adults. Back in 1987, that number was just $272. In 2001, for example, 15.5 percent of obese adults were treated for six or more medical conditions, nearly double the 1987 percentage.

In a microeconomic sense, losing or gaining weight is directly proportional with losing or gaining wealth. A study published in the journal *Economics and Human Biology* in 2005, used data involving people who participated in the U.S. Bureau of Labor Statistics' National Longitudinal Survey of Youth (NLSY), a nationally representative survey conducted by Ohio State's Center for Human Resource Research. The study measured each participant's body mass index (BMI) scores by using their individual height and weight figures as part of a mathematical calculation. The study found that decreasing BMI by 5.8 points resulted in an increase in wealth by more than four thousand dollars ($4 085). In addition, when BMI was reduced by 10 points, which is considered a large weight change, a wealth increase as much as a $12 720 was observed. In general, a one-unit increase in a person's BMI was roughly associated with a $1 300 or 8 percent reduction in wealth (Zagorsky, 2005). In a newspaper story in the *Los Angeles Times*, the investigative reporter found a tremendous personal financial cost of obesity, including but not limited to 1) unreimbursed out-of-pocket medical expenses for the obese is higher than for those of normal weight; 2) the obese are likely to have lower incomes due in part to a reduced probability of holding managerial level job, more missed days from work, and a reduced likelihood of holding a college degree; 3) the obese are likely to have spouses with lower incomes - that is, when they are married at all, which is less likely than for those of normal weight; 4) the obese are likely to inherit less from their parents - who are likely to be obese themselves; and 5) plus-size clothing costs more on average than clothing for those of normal weight due to less selection, and use of more yardage of fabric and more inches of labor-intensive stitching (Costello, 2005).

Prior to this study, there has been an absence of data evaluating the health economic implications of this new field of research. In this theoretical modeling study, we evaluated the health economics implications of LG839 variant, a nutrigenomics product for weight management. By utilizing validated clinical assessments that have already been tied to health economics data, we have modeled the prognostic health economic implications of this intervention to demonstrate a theoretical model of nutrigenomic economics. This study is hypothesis-generating and should be used in the definition of protocols to prospectively test the health economic benefits of nutrigenomics.

IV. Methods

For the health economics of nutrigenomics therapies for obesity, we conducted a cost-effectiveness analysis (CEA) and cost-benefit analysis (CBA) of LG839 variant®, a DNA-customized nutritional program for weight management. For the CEA, we compared the average weight lost over 6 months versus the cost of treatment between LG839 variant® and prescription weight loss product, orlistat. For the CBA, considering that each 1-point reduction in BMI contributes to an 8 percent increase in wealth or an average of $1 300 in wealth (Zargorsky, 2005), we measured this monetary unit change proportional to published efficacy data versus the cost of treatment for both LG839 variant and prescription weight loss product, orlistat.

V. Results

For the health economics of nutrigenomics related to obesity, we evaluated two published studies on LG839 variant. In the T.R.I.M. Study, subjects lost an average of 17.15 pounds based upon an average weight of 164.3 pounds and an average height of 5 feet four inches. This weight loss occurred over an average period of six months. Based upon a calculation of Body Mass Index equaling 703 multiplied by weight divided by height squared, the average initial BMI score was 28.2 and the ending score was 25.3, or a difference of 2.9 (Blum et al, 2006). In the D.I.E.T. study, subjects lost an average of 3 kilos (Data on file, Salugen, Inc.). Based upon an average height of 165 cm (Ginkel et al, 1999), a starting weight of 106 kg and BMI of 38.9 and an ending weight of 103 kg and a BMI of 37.8, subjects in this study lost an average of 3 kg and reduced their BMI by 1.1 points (**Figure 1**).

Thus, considering that each one-point reduction in BMI results contributes to an 8% or average $1 300 increase in wealth (Zargovsky, 2005), in this theoretical model, LG839 variant can contribute to an 8 to 24 percent increase or $1 300 to $3 900 increase in individual wealth (**Figure 2**). Considering the data from the T.R.I.M. study is already published, we will use that data for the purposes of the health economics model.

From a Cost-Effectiveness standpoint, LG839 variant can be compared to orlistat (Xenical® Roche; alli® Glaxo SmithKline). According to its package insert, orlistat results in an average of 12.4 pounds lost in 6 months, which is a 5% reduction in BMI. For the purposes of this health economics model, we will compare orlistat using this data. The annual cost of LG839 variant, following the upfront DNA analysis, is about $1 200 per year, compared to $2 340 for orlistat. The first year cost of LG839 variant is close to $1 600 due to the upfront cost of the DNA testing.

VI. Cost-effectiveness analysis

From a cost-effectiveness analysis, orlistat results in an average of 12.4 lbs lost in 6 months at a cost of $1 170 or a CEA ratio of $94.35 per pound lost. LG839 variant results in an average of 17.15 lbs lost in 6 months at a cost of $1 000 or a CEA ratio of $58.30 per pound lost.

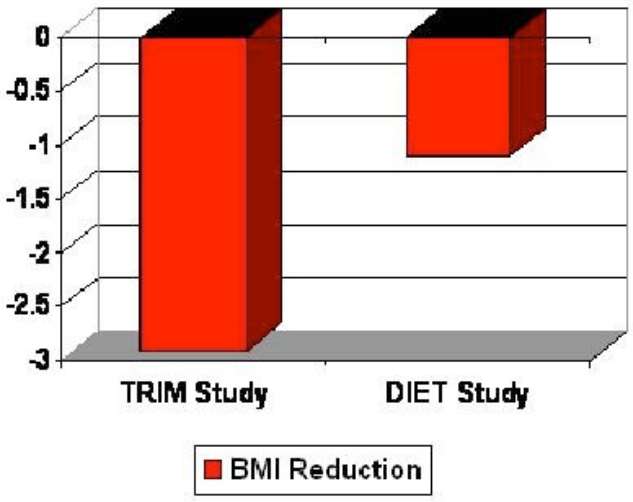

Figure 1. Change in BMI on LG839 variant.

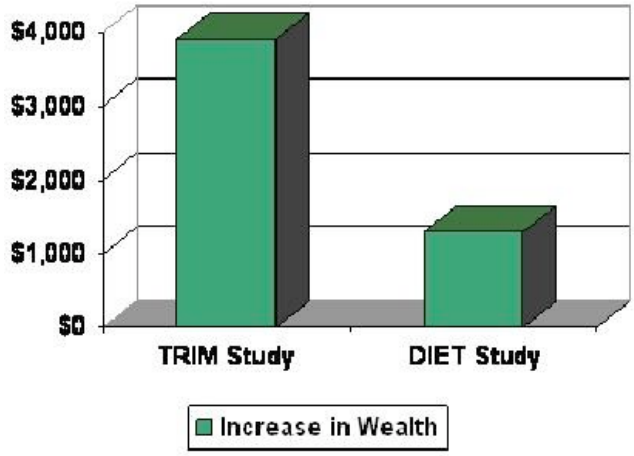

Figure 2. Change in wealth based upon proposed nutrigenomics health economics model.

VII. Cost-benefit analysis

Orlistat for six months cost $1 170 and should result in a 5% BMI reduction. The benefit would be a $2 600 increase in wealth. The cost-benefit analysis is 0.45. LG839 variant® has a six month cost of $1 000 and could result in a 10% BMI reduction. The benefit would be a $3 900 increase in wealth. The cost-benefit analysis is 0.26 (**Table 2**).

VIII. Discussion

In examining the data from this model in a macroeconomic perspective using the cost-effectiveness analysis technique, it is clear the model suggests that LG839 variant requires far less cost per pound lost (62% less) than orlistat. From this theoretical model, we can conclude that LG839 variant® may be a more cost-effective option to help support weight loss than orlistat, when combined with a diet. When considering that obesity is disproportionately contributing to the escalating healthcare costs, this theoretical model suggests that a DNA-customized nutritional program, like LG839 variant, may provide a viable option to reduce the overall cost of treatment. From a microeconomic perspective using the cost-benefit analysis technique, it is also apparent that LG839 variant may be superior to orlistat in that LG839 variant costs less and results in a greater reduction in body mass index.

It is important to note that LG839 variant is a DNA-customized nutritional supplement compared to orlistat which is offered as either a prescription pharmaceutical in the form of Xenical® (Roche) or as an over the counter pharmaceutical in the form of alli® (GlaxoSmithKline). Equally as important, it must be understood that there is significantly less data to support LG839 variant's efficacy compared to the clinical trials available to support orlistat. With these important concerns noted, this theoretical model definitely warrants further investigation as additional data on DNA-customized nutritional solutions is published.

IX. Conclusion

In this study, we established the first theoretical model to evaluate the health economics implications of nutrigenomics products. We chose to evaluate LG839 variant as a nutrigenomics product because it involves the nutrigenetic testing upfront and a nutrigenomic program involving DNA-customized nutritional supplements

Table 2. Health economics cost analyses

Intervention	Cost (6-months)	Weight Lost (6-months)	BMI Reduction (6-months)	Cost-Effectiveness Analysis (CEA) Ratio	Cost-Benefit Analysis (Ratio)
Orlistat	$1 170 ($195 per month)	12.4 lbs	5%	$94.35 per pound	0.45
LG839 variant	$1 000 ($99 per month plus $399 for DNA test)	17.15 lbs	10%	$58.30 per pound	0.26

designed to overcome genetic predispositions discovered through the upfront gene testing. In this model, we suggest that the health economics implications of nutrigenomics should consider both the macroeconomic and microeconomic cost of illness. We believe that this hypothesis-generating pilot study warrants further investigation and should be used in the design of prospective health economics studies evaluating nutrigenetic testing and nutrigenomic interventions.

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