Clinical Paper Summary Glucerna SR—Randolph

Economic analysis of a diabetes-specific nutritional meal replacement for patients with type 2 diabetes

Randolph S, Mustad VA, Lee J, Sun J. Asia Pac J Clin Nutr 2010;19:1-7.

Study Objective:

Many short-term studies show the benefits of diabetes-specific nutritional meal replacements (DSNMR) in comprehensive diabetes management programs. They have been shown to reduce hemoglobin A1c (HbA1c), however data on long-term effects are not yet available. Therefore, this economic analysis was designed to predict and evaluate the *long-term* clinical and financial effectiveness of DSNMR in different scenarios including: 1) as part of a structured lifestyle intervention program and 2) when DSNMR is the only difference between the intervention and usual care study groups.

Study Design:

The validated, computer-simulated model represented the 10-year costs and patient outcomes of 1,000 theoretical patients with type 2 diabetes based on data from the UK Prospective Diabetes Study (UKPDS).¹ The UKPDS, a landmark study, followed 5,000 patients with newly diagnosed type 2 diabetes to evaluate the role of intensive glycemic control versus standard of care on reducing diabetes-related complications. After following the subjects for 10 years, researchers found that the intensive control group had significantly fewer microvascular and macrosvascular complications.

Because patients can develop multiple diabetes complications, the model allowed the development and progression of multiple complications and was based on data from two large epidemiologic studies (Figure 1).^{1, 2}



Study Design (continued):

Figure 1. The model reflects the actuality that a patient can exhibit multiple complications



Legend: NPDR, Non-Proliferative Diabetic Retinopathy; PDR, Proliferative Diabetic Retinopathy; End-Stage RD, End-Stage Renal Disease; CHD, coronary heart disease; MI, myocardial infarction.

Annual costs and reductions in health status associated with each complication (utility value; a proxy for quality of life) used in the model are based on values reported in the medical literature.³⁻⁵

The cost and utility are computed for each patient at each of 10 years, then added together to get a total for the whole group. All costs are in U.S. dollars, inflated to the year 2008. Generally, costs and utilities are discounted at 3% per year to yield conservative values.

Three scenarios were run:

- 1. In the first scenario, the model extended the short-term results of a DSNMR structured intervention program.⁶ This scenario evaluates a 0.8% difference in mean HbA1c between the computer-modeled group (HbA1c 7.8%) and the intervention group (HbA1c 7.0%) reported by Sun and associates.⁶
- 2. In the second and third scenarios, the effects of smaller improvements in HbA1c were investigated. Improvement of HbA1c by 0.3% as reported by Tatti et al,7 and 0.5% as reported by Escalante et al,⁸ were evaluated.

Study Results:

Results are presented as incremental cost effectiveness ratios (ICER). This measure is the ratio between costs of care and number of quality life years gained (Table 1). Because ICER is closely tied to cost, lower ICERs are desirable.

Scenario Number	Scenario Condition	ICER (\$) with 3% discount rate*	ICER (\$) with 3% discount rate**	ICER (\$) with 0% discount rate**
1	Usual care (HbA1c 7.8%) compared to DSNMR + structured lifestyle intervention (HbA1c 7.0%)	34,979	47,917	45,942
2	Usual care (HbA1c 7.0%) compared to DSNMR + intervention (HbA1c 6.7%)	*	55,036	55,315
3	Usual care (HbA1c 7.8%) compared to DSNMR + intervention (HbA1c 7.3%)	*	50,414	44,935

*Scenarios where there is no additional cost for DSNMR. ** Scenarios where there is additional cost for DSNMR.

In scenario 1, the ICER of the DSNMR lifestyle intervention is \$34,979-\$47,917 per quality life year gained, depending on whether the DSNMR is at no additional cost or at additional cost. A 3% discount rate is given to provide a conservative evaluation of the ICER.

In scenarios 2 and 3, when the DSNMR is assumed to be an equal value to the meals replaced, the total costs are lower and the utility is greater compared with the standard of care. On the other hand, when the program costs are the same, the overall cost reduction is due to lower direct medical costs because of the lower incidence and later onset of complications. When the DSNMR is considered to be an additional cost, the ICER of the DSNMR intervention ranges from \$50,414 per guality life year gained to \$55,036, depending on the degree of improvement in HbA1c.

Study Conclusions:

Use of DSNMR is more cost effective when the reduction in HbA1c is greatest because it can help reduce the incidence and seriousness of complications, thus reducing cost of care per quality of life year gained.

This model is based on trial data from Europe, Asia and North America. The findings of benefit are conservative estimates because the researchers did not try to integrate the additional effects of weight loss and control of blood pressure and blood lipid levels on general well being or on complication risk.

References:

- 1. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk complications with type 2 diabetes (UKPDS 33). *Lancet* 1998;352:837-853.
- Klein R, Klien B, Moss S. Relation of glycemic control to diabetic microvascular complication in diabetes mellitus. *Ann Intern Med* 1966;124:90-96.
- O'Brien J, Patrick A, Caro J. Estimates of direct medical costs for microvascular and macrovascular complications resulting from type 2 diabetes mellitus in the United States in 2000. *Clin Ther* 2003;25: 1017-1038.
- 4. Herman W, Hoeger T, Brandle M, et al. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. *Ann Intern Med* 2005;132:323-332.
- 5. Coffey J, Brandle M, Zhou H, et al. Valuing health-related quality of life in diabetes. *Diabetes Care* 2002;25:2238-2243.
- Sun J, Wang Y, Chen X, et. Al. An integrated intervention program to control diabetes in overweight Chinese women and men with type 2 diabetes. Asia Pac J Clin Nutr 2008;17:514-524.
- Escalante-Pulido M, Milke-Najar M, Rodriguez-Lopez E, etl al. Clinical and metabolic effects of liquid nutrition meal replacement plan vs. individualized diet plan in obese childhood subjects with type 2 diabetes mellitus (Abstract). Presented at the International Diabetes Federation Congress, 2007.
- 8. Tatti P, Di Mauro P. Effect of a low calorie high nutritional value formula on weight loss in type 2 diabetes mellitus. *Mediterr J Nutr Metab*, in press.

