

(Nichols GA, Brown JB , 2002) (O'Brien JA, Patrick AR, Caro J ,2003) (Gilmer TP, O'Connor PJ, Rush WA, Crain AL, Whitebird RR, Hanson AM, Solberg LI, 2005) Large population-based studies have established that diabetes is associated with increased rates of cardiovascular morbidity and death (Kannel WB, D'Agostino RB, Wilson PW, Belanger AJ, Gagnon DR:1990) (Haffner SM, Lehto S, Rönnemaa T, Pyörälä K, Laakso M 1998) (Stamler J, Vaccaro O, Neaton JD, Wentworth D 1993) (Malmberg K, Yusuf S, Gerstein HC, Brown J, Zhao F, Hunt D, Piegas L, Calvin J, Keltai M, Budaj A 2000).

Clinical trials have shown the benefits of intensive glucose lowering therapies to reduce the risk of microvascular disease (UKPDS Group,1998), cardiovascular events and death (Gaede P, Lund-Andersen H, Parving HH, Pedersen O, 2008) (Holman RR, Paul SK, Bethel MA, Matthews DR, Neil HA2008), or the combined risk of micro- and macrovascular events (ADVANCE Collaborative Group, Patel A, MacMahon S, Chalmers J, Neal B, Billot L, Woodward M, et al , 2008), in diabetic patients. Diabetes-related complications greatly diminish patients' health-related quality of life (Clarke P, Gray A, Holman R, 2002) (Lloyd A, Sawyer W, Hopkinson P, 2001) (Huang ES, Brown SE, Ewigman BG, Foley EC, Meltzer DO ,2007). More recently, new evidence suggest that intensive treatment and extreme reductions in HbA1c below 6.5%, may have no effect, or (in one study) even increase the rate of cardiovascular events and death in high risk patients with diabetes (Duckworth W, Abraira C, Moritz T, Reda D, Emanuele N, Reaven PD, Zieve FJ,et al , 2009). Thus, until this new evidence can be completely understood and supported by large longitudinal studies, it seem plausible that an intervention targeting reduction in glycemia levels to current guidelines, as well as improving concomitant risk factors, such as blood pressure, lipid levels and bodyweight might prevent and reduce the risk of micro- and macro-vascular complications.

This intervention has recently been endorsed by a position statement of the American Diabetes Association and a scientific statement of the American College of Cardiology Foundation and