

different risk factors for cardiovascular complications, both in the general population and in diabetes patients.

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**TYPE-2 DIABETES MODELS THAT DO NOT ACCOUNT FOR MICROVASCULAR DISEASE SCREENING RATES AND IMPORTANT CONCOMITANT MEDICATION USE MAY LEAD TO SUBSTANTIAL MISREPRESENTATION OF THE COST-EFFECTIVENESS OF NEW MEDICATIONS**

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**OBJECTIVES:** A number of diabetes models have recently been published. They are often used to assess the cost-effectiveness of new interventions and to generate health economic arguments for reimbursement submissions. The majority of these models do not account for rates of screening for important diabetes-related microvascular (eye, renal and foot) disease, nor do they consider the rates of use of important concomitant medications like ACE inhibitor/angiotensin-2-receptor inhibitors, statins, or aspirin. Our aim was to test the hypothesis that not accounting for these important factors may substantially influence projected long-term cost-effectiveness of new interventions. **METHODS:** A published and validated diabetes model was used to project the long-term cost-effectiveness of a hypothetical intervention that lowered HbA1c by 0.4%-points, and which cost an additional \$500/patient/year, versus no intervention. Quality-adjusted life years (QALY) and lifetime direct medical costs were calculated for each treatment arm, taking into consideration: A) no screening for- and appropriate treatment of diabetes-related complications, or B) screening rates and concomitant medication use as seen in a typical type-2 diabetes population in the US. **RESULTS:** If screening rates and concomitant medication use were not considered, the hypothetical intervention was dominant to no intervention, with 0.214 QALYs gained (discounted 3% annually), and discounted lifetime direct cost savings of \$165/patient. When screening rates and concomitant medication rates were accounted for, the intervention led to smaller improvements in QALYs, and increased costs, with incremental costs/QALY gained of \$34,024. **CONCLUSIONS:** Health economic models of diabetes must account for the costs and clinical effects of screening for- and appropriate treatment of important diabetic microvascular complications, and the costs and effects of important concomitant medications. Failure to account for these factors may lead to inaccurate assessment of the cost-effectiveness of new interventions in Type-2 diabetes patients.

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**INTERNAL VALIDATION OF THE ECONOMIC ASSESSMENT OF GLYCEMIC CONTROL AND LONG-TERM EFFECTS (EAGLE) DIABETES MODEL**

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**OBJECTIVES:** The Economic Assessment of Glycemic control and Long-term Effects (EAGLE) model version 2.0 simulates long-term diabetes-related complications and related costs for type-1 and Type-2 diabetes using equations derived from the published results of several large interventional studies (DCCT, WESDR, and UKPDS). To assess the model's validity, EAGLE was internally validated according to current guidelines. **METHODS:** Following in-house testing protocols, first-order validation identified inconsistencies in results and corrected programming errors. Second-order validation involved the fol-

lowing steps: 1) Simulation sets were created in EAGLE based on baseline data from the studies used to build the model; 2) Simulations were run. The results obtained with EAGLE were compared with the published event rates; and 3) Risk equations were refined if a deviation of >10% was observed between the model-derived and published results. Patient numbers and iterations were systematically changed until a final run was performed with 50,000 patients and 100 iterations. **RESULTS:** Fulfilling a criterion for validity, the cumulative incidence per 1000 patient-years and incidence rates for all events simulated with EAGLE fell within the range of  $\pm 10\%$ . The difference between published data and model results ranged from 0% to 9% for all patient populations after possible refinements. For example, in Type-2 diabetes, EAGLE successfully predicted the end-stage renal disease and fatal event rates reported in UKPDS (deviation = 0%). The rates of severe hypoglycemia differed by 1%. The EAGLE event rates for proliferative and non-proliferative retinopathy corresponded well with event rates derived from the WESDR publications (deviation = 3% and 4%, respectively). **CONCLUSIONS:** EAGLE consistently predicts event rates reported by UKPDS, WESDR, and DCCT, and is thus a valid and robust tool for the analysis of the long-term diabetes-related complications and related costs in type-1 and Type-2 diabetes.

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