T2DM patients on insulin-only regimens with at least one HbA1c value in the database and six months continuous eligibility pre-post HbA1c index. Data on HbA1c, insulin regimen, complications and demographic characteristics of all patients were analyzed using descriptive statistics. RESULTS: Of 689 patients, 29% had HbA1c 7% (mean age 52 years; female 40%; mean HbA1c 5.9%; basal-only 73%; basal-bolus 25%) while 71% had HbA1c 7% (mean age 51 years; female 41%; mean HbA1c 9.3%; basal-only insulin 63%; basal-bolus insulin 34%). The nature and incidence of microvascular complications in the two groups were: diabetic foot complications 2% and 6% (p < 0.05), neuropathy 13% and 9%, retinopathy 9% and 13%, kidney disease 5% and 7% for patients with HbA1c <7% and ≥7%, respectively. CONCLUSION: A sizable proportion of T2DM patients were uncontrolled on their current insulin regimen. This may reflect undue delay in insulin initiation and intensification by patients and providers. Moreover, a considerable proportion of patients at goal show signs of complications, signifying the urgency of earlier insulin initiation and more aggressive intensification to ameliorate current sub-optimal glycemc control.

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NON-INJECTABLE INSULIN—TO PAY OR NOT TO PAY?

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OBJECTIVE: To describe first and second-line use of antidiabetic drugs for management of type 2 diabetes in Italy, and to identify potential predictors associated with the use of antihyperglycemic drugs. METHODS: Primary care data were obtained from 400 Italian General Practitioners (GPs) providing information to the Health Search/Thales Database (HSD). All patients with a doctor-diagnosis of type 2 diabetes during the years 1996–2006 were selected. First and second-line drug therapy episodes were evaluated by assessing the sequential fulfillment of prescriptions of a particular antihyperglycemic drug class (or combination), which followed the diabetes diagnosis. A sub-sample of diabetic patients, with a registered diagnosis until the December 31, 2003 was also selected to evaluate the time-dependant clinical and demographic characteristics associated with the use of different antihyperglycemic drugs across the years 2004–2006. RESULTS: A total of 19,561 diabetic patients had diabetes drug therapy episodes between 1996 and 2006. Monotherapy with metformin increased (from 4.1% in 1996 to 44.8% in 2006), while monotherapy with sulfonylureas decreased over time (from 32.7% to 23.9%) as first line therapy. Thiazolidinedione (from 0.3% to 6.0%) and other oral antihyperglycemics (from 0.7% to 4.3%) also increased over the period. Second-line drug therapy episodes showed the same trend during study period with a substantial increased use of thiazolidinedione (from 2.5% to 3.8%). As regards prevalent patients characteristics, hypercholesteremia and obesity were significantly associated with the use of thiazolidinediones while coronary artery disease, chronic renal and hepatitis were associated with insulin use. CONCLUSION: Antihyperglycemic prescription patterns in Italy dramatically changed from 1996 to 2006 with increased use of metformin and decreased use of sulfonylures. The introduction of thiazolidinediones to the marketplace seems not change the management of diabetes mellitus as first line-treatment, although this drug class is preferred in chronic patients particularly affected by hypercholesteremia and obesity.

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WITHDRAWN

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PRESCRIBING PATTERN AND PREDICTORS ASSOCIATED WITH THE USE OF HYPOGLYCAEMIC DRUGS: A CROSS-SECTIONAL STUDY IN ITALIAN GENERAL PRACTICE

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OBJECTIVE: To systematically review the literature and published recommendations from four Health Technology Assessment Agencies (HTAAs) in order to report what may have contributed to the dearth of reimbursement of non-injectable insulins. METHODS: Two independent researchers systematically reviewed the published literature from 2003–2007 using the MEDLINE, EMBASE, and Cochrane databases. Publications of human trials involving non-injectable insulins reported in any language were included. Keywords such as Insulin, Oral OR Inhalation OR Aerosols OR Mist OR Spray OR Sublingual OR Nebulizers OR Vaporizers OR Intransal OR Dermal OR Buccal with the indication of Diabetes Mellitus Type 1 OR Diabetes Mellitus Type 2 were used. Clinical trials, with at least one intervention being a non-injectable insulin, were included. Exclusion criteria included inappropriate research design, outcomes not reported and/or not extractable. Listing decisions posted on the websites of the National Institute for Health and Clinical Excellence in the UK, the Scottish Medicines Consortium, the Institute for Quality and Efficiency in Health Care in Germany, and the Common Drug Review in Canada were reviewed. RESULTS: Of 233 identified citations, 20 articles were included for full text review. Reported outcomes included standard clinical efficacy measures (e.g., post-prandial glucose levels, Hba1c reduction) and tolerability. Few articles (N = 3) reported outcomes such as patient preference for treatment, general health-related quality of life, final health outcomes, and/or satisfaction. No studies were specifically designed for reimbursement purposes. There was a paucity of utility measures, the lack of which was the main criticism by the HTAAs leading to either “not to list” or very restricted listing recommendations. Other HTAA comments were the use of secondary versus primary clinical outcomes and the absence of adherence information. CONCLUSION: Clinical studies for non-injectable insulins do not include adequate information and/or outcomes that are required by decision makers for reimbursement recommendations.