Title of the Study: CONTINUOS SUBCUTANEOUS INSULIN INFUSION IN ITALY (IMITA2)

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Study Design

In this multicentre cross-sectional study, data were collected using questionnaires sent by e-mail to adult and paediatric diabetes care centres that use CSII (continuous subcutaneous insulin infusion)for treatment. Centres were identified from previous surveys and through information from companies selling CSII devices. Incomplete data were obtained by phone or e-mail and integrated. Subjects treated with CSII for at least 1 year were consecutively enrolled among people who attended diabetes outpatient clinics between September 2015 and October 2016. Exclusion criteria were previous diagnosis of dementia or psychosis and pregnancy in progress. Before enrolment, informed consent was obtained from each participant. The study was approved by the ethical committee of each centre. Procedures complied with the ethical standards of the institutional and national committees on human experimentation and with the Helsinki Declaration of 1975.

Information on standard clinical variables (i.e. serum HbA1c, total cholesterol, high-density lipoprotein [HDL] cholesterol, triglycerides and creatinine), demographic data (i.e. age, gender, type of diabetes, duration of diabetes, duration of treatment with CSII and body mass index) and presence of hypertension and chronic diabetic complications (i.e. retinopathy, nephropathy and vasculopathy [cerebral, cardiac and peripheral]) was derived from local clinical management systems. The median HbA1c level of participants from the year before the study was calculated. Information on pump characteristics, use of advanced pump functions (i.e. different bolus types, bolus calculator and temporary basal rates), days of sensor use and frequency of self-monitoring of blood glucose was obtained from insulin pumps or glucometers or recovered from CGM receivers and was reported in the questionnaire.

Participants were asked to record the number of severe hypoglycemia episodes (SH) experienced during the year preceding enrolment in the study, and the frequency of episodes was expressed as the cumulative number of SH episodes per participant. For adult participants, an SH episode was defined as an event requiring assistance and the administration of carbohydrates (CHOs) or glucagon. For paediatric participants, the SH episode referred to an event associated with coma, seizures or neurological symptoms requiring parenteral treatment. The number of diabetic ketoacidosis (DKA), defined as acidosis and hyperglycaemia, and the number of visits to the emergency room for acute metabolic complications of diabetes were collected from medical records. Information about the organisation of each centre included the number of people with T1DM, start of CSII treatment, team composition (physicians, nurses, dieticians and psychologists) and around-the-clock availability.

Statistical analysis

Continuous data were expressed as median and interquartile range (IQR). Categorical data were compared

between groups using the chi-square test, whereas continuous data were compared between groups using the ManneWhitney or KruskaleWallis test. All tests were two sided, and a p value less than 0.05 was considered to be significant. A linear mixed-effect regression model was used to identify the predictors of HbA1c among clinically relevant variables (i.e. age, duration of diabetes, duration of CSII treatment, type of device, use of sensor-based treatment, CHO counting and use of advanced pump functions) that account for the centre's effects. The centre was included in the model as a random effect because participant outcomes were expected to differ from centre to centre, possibly owing to differences among centres instead of differences among participants who present at different centres. Statistical analysis was performed using R 3.3.2 (The R Foundation for Statistical Computing, Vienna, Austria)