High level control strategies for diabetes therapy*

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Abstract. The project we describe here is aimed at assisting out-patients affected by Insulin Dependent Diabetes Mellitus. Our approach exploits the usual scheme of diabetic patients management, based on (i) a periodic evaluation of the patients' metabolic control performed by the physician, and (ii) patient-tailored tables for self-adjustments of insulin dosages. Following this scheme we have defined a system built on a two-levels architecture, that can be conveniently implemented in a telemedicine context. The *High Level Module* exploits both medical knowledge and clinical information in order to assess an insulin protocol, defined in terms of insulin timing, type, and total amount. The High Level Module exchanges information with the *Low Level Module* in order to define the control actions to be taken at the low level, as well as to periodically evaluate protocol adequacy on the basis of patient data. The goal of the Low Level Module, whose characteristics can be chosen by the High-Level Module, is to suggest the next insulin dosage, depending on the actual blood glucose measurement and a certain pre-defined insulin delivery protocol. In this paper we outline the overall organization of the system and we describe in detail the methodology and the strategies exploited by the high-level module.

1 Introduction

The conventional therapy of *Insulin-dependent diabetes mellitus* (IDDM) tries to control the blood glucose levels (BGL) of the patients through subcutaneous insulin injections several times a day. The injections are usually planned according to an open loop strategy, decided by the physicians according to their experience. When possible, an effective strategy is to add closed loop control, managed by the patients themselves. To this aim the patient is taught how to select the insulin dosage using decision tables tailored by the physician. Blood glucose control is therefore obtained as the interaction of (at least) two basic control tasks, the first one being the definition of an insulin administration protocol and the second one being the closed-loop adjustment of the insulin doses.

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Many *decision support systems* (DSS) have been studied to assist patients and physicians in the design of a therapy. After some preliminary studies aimed at rationalizing the definition of the decision tables on the basis of mathematical models of glucose metabolism and of clinical experience [10, 9, 4], expert systems were developed in order to assist the management of IDDM [5, 3], as well as to provide an educational tool for patients and physicians [6]. These advisory systems may be broadly classified into two categories, that reflect the distinction between the two control tasks outlined above. The *day by day* advisory systems aim at assisting the patients during their every-day monitoring activity, by suggesting the next insulin dosage depending on the actual blood glucose levels; an example is the DIAS system proposed by Andreassen [1]. The *visit by visit* advisory systems aim at assisting the physicians in their periodic evaluation of the patients' glucose metabolism. One of the most complete realizations is represented by the AIDA system [7], that conjugates heuristic and model-based reasoning.

The system we propose integrates the above mentioned tasks in a comprehensive framework. It is meant to assist the patients in their routine self-monitoring activity as well as the physicians in assessing the basal insulin regimen and the diet plan. Note that since the goal of completely replacing the physicians' monitoring and control activity is unrealistic and probably undesirable, we prefer to limit the scope of our decision support system to the *routine* management of the patients. The contribution that we expect from our system is therefore the automatization of those decisions that are needed to handle normal situations, so that the physician may devote more resources to handling dangerous and exceptional episodes and the patients may achieve a better quality of life even without continuous assistance from an expert.

1.1 A Dual-Level Control Architecture

In order to precisely define the architecture of our system, it is essential to understand the structure of the decisions involved in IDDM management: *who* usually takes decisions, *what decisions* are to be taken, and *what control rules* are employed.

The two "natural" decision-makers in the IDDM management problem are the *physician* and the *patient*. The two control agents are hierarchically interrelated. The physician decides the insulin therapy, the diet and also what are the *decision rules* for insulin adjustment that the patient must follow during self-monitoring. Thus, the physician establishes a *policy* for the patient's self-management, that is summarized in a *protocol*. The tasks of the physician are very complex, and the knowledge that is used to accomplish them must be as deep as possible. On the contrary, the task of the patient usually reduces to consulting a set of predefined decision tables and the required medical knowledge could be limited to an understanding of the basic action-reaction processes related to diabetes control.

Although the definition of a policy is a complex reasoning process, the control strategies that the physician applies may be broadly classified into two cat-